

From: Kelsey Eaton
Subject: Plan Commission Agenda Item #15
Date: March 23, 2015 at 11:20:39 AM CDT

Dear Members of the Plan Commission-

I am writing you regarding tonight's Plan Commission agenda and particularly item #15 (changes to tobacco zoning)

This ordinance has a number of significant issues for our small business. The 1000 and 500 foot requirements would cause both of our Madison locations along with nearly all other e-cigarette/vaping businesses to close. While allowing the majority of retailers selling traditional tobacco products the ability to operate with no zoning restrictions whatsoever. Last year when the city included Vaping products in the indoor air ban they specifically allowed for sampling to take place within businesses like ours that are catered towards adults seeking an alternative to traditional tobacco products.

By passing these new zoning changes the message that the city was supportive of efforts to get people to transition off of traditional tobacco products will be completely lost. These new ordinance changes will once again give big tobacco a significant advantage while hurting the many small businesses owners that have invested time and money in this community.

I am attaching a few documents that provide addition context as to some of the benefits of vaping products. It should be noted that each of the authors of these documents held, at one point, a position of leadership in internationally recognized organizations that sought to reduce tobacco consumption and limit it's harm. None of the authors receive any compensation from the tobacco or vaping industry.

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<http://www.wsj.com/articles/michael-b-siegel-the-misbegotten-crusade-against-e-cigarettes-1424821708>

OPINION

The Misbegotten Crusade Against E-Cigarettes

'Long term e-cigarette use can substantially decrease cigarette consumption in smokers not willing to quit.'

By **MICHAEL B. SIEGEL**

Feb. 24, 2015 6:48 p.m. ET

When electronic cigarettes came to the U.S. about 2007, I was skeptical. My assumption was they were a ploy by the tobacco industry to hook more people into smoking under the guise of being a safer product—the notorious low-tar cigarette scam all over again. But as I talked to many e-cigarette users, known as “vapers,” conducted research (*Journal of Public Health Policy*, 2011) and reviewed a growing body of scientific evidence, I became convinced that e-cigarettes have dramatic potential for reducing disease and death caused by smoking.

Yet many in the antismoking movement—in which I have been involved for decades—are conducting a misleading campaign against these products. And this campaign may be doing harm to public health.

The most common claim about e-cigarettes is that they are a “gateway” to smoking. In September 2013 Thomas Frieden, director of the Centers for Disease Control and Prevention, said “many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes.” He added that electronic cigarettes are “condemning many kids to struggling with a lifelong addiction to nicotine.”

These statements had no basis in fact when he made them, and the evidence is that they are bogus. One recent study in the *American Journal of Preventive Medicine* (January 2015) suggests that e-cigarettes are not acting as a gateway to smoking among youth. Another study in the journal *Drug and Alcohol Dependence* (February 2015) suggests the addictive potential of e-cigarettes is substantially lower than that of tobacco cigarettes.

Electronic cigarettes might even be a deterrent to tobacco addiction. Their use by high-school youth tripled between 2011 and 2013, rising from 1.5% to 4.5%, according to CDC data, and then, according to a University of Michigan study, skyrocketed in 2014, when 16% of 10th-graders and 17% of 12th-graders reported using them. That study reports a decline in youth smoking to a historically low level in these years, with smoking among 10th-graders dropping to 7.2% from 11.8% and among 12th-graders falling to 13.6% from 18.7%.



PHOTO: GETTY IMAGES

Other unfounded fears about e-cigarettes abound. There is no evidence that e-cigarettes entice ex-smokers to return to nicotine use and then back to cigarette smoking. There also is no evidence that e-cigarettes are hindering the quitting process for smokers who—if not for e-cigarettes—would have quit completely. What we do know suggests that e-cigarettes are indeed a gateway: a one-way gateway

away from combustible cigarettes and toward a much safer alternative product.

Are electronic cigarettes safe? Of course not. But e-cigarettes don't need to be absolutely safe. By definition, harm reduction involves an alternative product that is much safer. As electronic cigarettes contain no tobacco and do not involve combustion, they do not expose users to most of the more than 60 carcinogens in tobacco smoke, and they appear to be safer by orders of magnitude.

Still, to address legitimate safety concerns, the Food and Drug Administration should set uniform safety standards for e-cigarettes and “vaping” products. These standards

should include childproof packaging, battery safety, quality-control standards for nicotine labeling and for the production of e-liquids, and modest regulation of flavorings such as a ban on diacetyl, a flavoring which when inhaled can cause a rare form of obstructive lung disease. The temperature of the coils also needs to be regulated to prevent overheating of the e-liquid, which results in the production of formaldehyde, a recognized carcinogen.

These regulations would go far toward maximizing the benefits of e-cigarettes while minimizing the risks. But instead of working to get them, the products are being demonized by those who should know better.

Earlier this month the California Department of Public Health published a pamphlet, "Protect Your Family From E-Cigarettes," that claimed "E-cigarettes are just as addictive as regular cigarettes." This flies in the face of the research published in December by the journal *Drug and Alcohol Dependence*, which showed that e-cigarettes are much less addictive than tobacco cigarettes. That study found that the addictiveness of e-cigarettes is equivalent to that of nicotine gum, an FDA-approved smoking cessation product.

The same pamphlet asserted that "studies show that e-cigarettes do not help people quit smoking cigarettes." But a rigorous clinical trial in the *Lancet* showed e-cigarettes to be just as effective as the nicotine patch in getting smokers off cigarettes.

A January report by the California Department of Public Health on electronic cigarettes—"State Health Officer's Report on E-Cigarettes: A Community Health Threat"—concludes that "there is no scientific evidence that e-cigarettes help smokers successfully quit traditional cigarettes." But it does not cite the *Lancet* study, nor another, earlier clinical trial (*Internal and Emergency Medicine*, August 2014), which concluded that "long term e-Cigarette use can substantially decrease cigarette consumption in smokers not willing to quit and is well tolerated."

Last month a *New England Journal of Medicine* article reported extremely high levels of formaldehyde in the aerosol of an electronic cigarette and concluded that vaping may therefore be more harmful than smoking. But the study was carried out under unrealistic conditions in which the e-liquid was severely overheated. Under more realistic conditions the study failed to detect any formaldehyde. Unfortunately, the e-cigarette cancer scare had already been spread through the media.

In the U.K., the percentage of smokers quitting each year steadily declined until 2011,

but increased from 2011 to 2014, a period when the proportion of smokers using e-cigarettes increased from 2% to 14%. A U.S. study (Nicotine & Tobacco Research, October 2014) reported that during the same period smokers who used e-cigarettes daily were six times more likely to quit than those who did not. This was extremely good news, but more recently the news is not so good.

Bloomberg Business reported last summer that e-cigarette sales began to slip in the U.S., and their use by smokers may even be declining in the U.K. The percentage of the public that believes smoking is more hazardous than electronic cigarettes has fallen to 65% in 2013 from 85% in 2010, according to a 2014 study in the American Journal of Preventive Medicine.

This is a tremendous lost opportunity. Vaping technology—or something like it that may be developed—has the potential to be one of the greatest antismoking breakthroughs. I would hate to see its promise wasted because of misinformation by the very public-health authorities who should be in the vanguard of reducing the harm from cigarettes.

Dr. Siegel, a professor at the Boston University School of Public Health, has conducted tobacco research for 25 years and has been an advocate for antismoking policies.

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E-cigarettes, vaping and public health

A summary for policy-makers

Clive Bates

Counterfactual Consulting and Advocacy

February 2015

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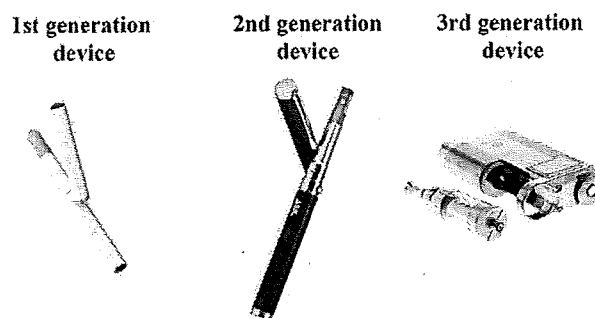
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1 Background

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 negligible¹. For the US, CDC gives frequent use at 1.9% of adults and any e-cigarette use at 4.2% of adults², equating to around 4.6 and 10.1 million users respectively. A synthesis of 10 country surveys³ 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-cigarettes in 2013. This is likely to be a significant contributor to declines in smoking in Australia.

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. [\[link\]](#)

2 The public health case – tobacco harm reduction

2.1 Challenging the burden of smoking

In 2013, 19% of British adults aged 16 and older, roughly 9.9 million people, smoked⁴. 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*⁵. The current annual premature death tolls attributed to smoking are 100,000 in the UK 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 century⁶. 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 any 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 important in poor families. Prior to the emergence of e-cigarettes, the alternatives were broadly

⁴ ONS, Opinions and Lifestyle Survey, Adult Smoking Habits in Great Britain, 2013, 25 November 2014 [\[link\]](#)

⁵ 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 [\[link\]](#)

⁶ WHO Factsheet *Tobacco*, May 2014 [\[link\]](#)

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, Professor 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 perspective⁷

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 Tobacco and Alcohol Studies, and his colleague Ilze Bogdanovica give a similar if unquantified message in an assessment for the government agency Public Health England⁸:

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 Practice⁹, 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, ignoring 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-Medical¹⁰

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 concludes¹¹

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.

The most comprehensive study so far of 'real world' use of e-cigarettes showed¹²

⁷ West R et al Briefing: Electronic cigarettes what we know so far. Presented to UK All-Party Parliamentary Group on Pharmacy: 10th June 2014 [\[link\]](#)

⁸ Britton J, Bogdanovica I. Electronic cigarettes: A report commissioned by Public Health England. May 2014 [\[link\]](#)

⁹ West R, Brown J. Electronic cigarettes: fact and fiction. Br J Gen Pract 2014; 64: 442-3. [\[link\]](#)

¹⁰ News-Medical, Electronic cigarettes and smoking cessation: an interview with Professor Peter Hajek, 5 Feb 2015 [\[link\]](#)

¹¹ 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. [\[link\]](#)

¹² Brown J, Beard E, Kotz D, Michie S, and West R (2014) Real-world effectiveness of e-cigarettes when used to aid

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 UK¹³ 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 concluded¹⁴.

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)¹⁵. 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 public health technologies of modern times.

smoking cessation: A cross-sectional population study. *Addiction*109: [\[link\]](#)

¹³ ASH (UK) Fact sheet: Use of electronic cigarettes in Britain, July 2014 [\[link\]](#)

¹⁴ Britton J, Bogdanovica I. Electronic cigarettes: A report commissioned by Public Health England. May 2014 [\[link\]](#)

¹⁵ Cited in *The Economist*, Kodak moment, 23 September 2013. [\[link\]](#)

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 concluded¹⁶:

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”¹⁷. Nicotine is not a cause of cancer, cardiovascular disease or the respiratory conditions that dominate the ill health from smoking¹⁸. Pure nicotine is not completely benign, but it is widely sold in medicinal form and does not cause any serious illness¹⁹. The US Surgeon General has made a detailed assessment of nicotine risks²⁰, 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,

¹⁶ 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 [\[Link\]](#)

¹⁷ Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976;**1**:1430–3. [\[link\]](#)

¹⁸ 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.

¹⁹ 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. [\[Link\]](#)

²⁰ 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 assumed²¹. 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^{22 23}. There is a simple protective measure available: to insist on child resistant packaging, for which there is an ISO standard²⁴.

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 exhaust²⁵. 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 baseless²⁶.

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 cigarettes²⁷. The mistake was repeated in a letter in the New England Journal of Medicine²⁸ 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 to²⁹. *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 said³⁰: *“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

²¹ 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. [\[link\]](#)

²² 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. [\[link\]](#)

²³ Full discussion of the evidence at Bates C. Keep calm it's only poison, The Counterfactual. 17 November 2014 [\[link\]](#)

²⁴ ISO 8317 Child resistant packaging [\[link\]](#)[\[guide\]](#)

²⁵ See for example, WHO paper for FCTC COP-6, Electronic nicotine Delivery Systems, 1 September 2014. Para 15-16 [\[link\]](#)

²⁶ Full discussion of the evidence at Bates C. Scientific sleight of hand: constructing concern about 'particulates' from e-cigarettes, The Counterfactual. 17 November 2014 [\[link\]](#)

²⁷ Farsalinos K. Electronic cigarette aerosol contains 6 times LESS formaldehyde than tobacco cigarette smoke. 27 November 2014. [\[link\]](#)

²⁸ Jensen RP, Luo W, Pankow JF, Strongin RM, Peyton DH. Hidden formaldehyde in e-cigarette aerosols. N Engl J Med 2015; 372: 392–4. [\[link\]](#)

²⁹ See full detailed critique at Counterfactual, Spreading fear and confusion with misleading formaldehyde studies, 21 January 2015, with links to detailed assessments [\[link\]](#).

³⁰ 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 biggest study on toxicants in vapour³¹ 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 medicines³²: *“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)³³. In fact, the study greatly over-interpreted the applicability of a mouse study to humans³⁴, 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 smoking³⁵.

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:

- By visible displays of smoking-like behaviour or marketing it might ‘renormalise’ smoking.
- It might 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

³¹ 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 [\[abstract\]](#)[\[paper from March 2015\]](#)

³² 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. [\[link\]](#)

³³ 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; [\[link\]](#)

³⁴ 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. [\[link\]](#)

³⁵ 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 concluded³⁶:

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 advertising³⁷. 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 less 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 Europe and most jurisdictions where tobacco advertising is banned – so the only visible brands are *rivals to cigarettes*. A recent code published in the UK controls e-cigarette advertising in much the same way as alcohol advertising is controlled – this is a proportionate approach³⁸ and contrasts favourably with the near complete ban to be imposed by the European Union.

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 one³⁹. The most thorough survey in the world, the Smoking Toolkit Survey for England⁴⁰, 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 states⁴¹:

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

³⁶ West R. Brown J, Beard E. *Trends in electronic cigarette use in England*. Smoking Tool Kit Study. 13 June 2014 [\[link\]](#)

³⁷ 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 [\[link\]](#)

³⁸ Committee on Advertising Practice, *Advertising Code: Electronic Cigarettes*, [\[non-broadcast\]](#)[\[broadcast\]](#)

³⁹ 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 [\[link\]](#)

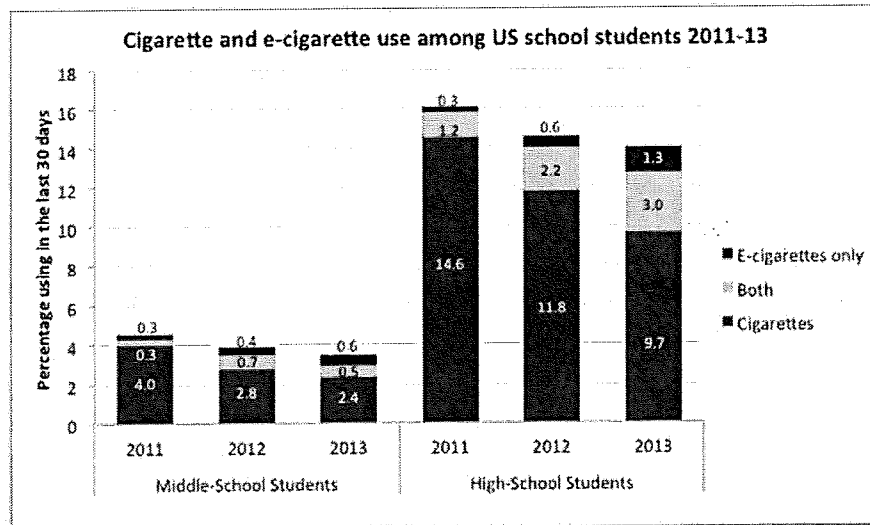
⁴⁰ West R. Brown J, Beard E. *Trends in electronic cigarette use in England*. Smoking Tool Kit Study. 15 January 2015 [\[link\]](#)

⁴¹ ONS, *Opinions and Lifestyle Survey, Adult Smoking Habits in Great Britain, 2013*, 25 November 2014 [\[link\]](#)

in e-cigarette use⁴². According to a top public health official:

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 smokers⁴³. 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 France⁴⁴ 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 2014⁴⁵. 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 smoking⁴⁶ –

⁴² CDC E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012, 5 September 2013 [\[link\]](#)

⁴³ CDC MMWR Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012, 15 November 2013. [\[link\]](#) Higher resolution graphic [\[link\]](#)

⁴⁴ Survey reported in English on *Le blog de Jacques LeHouezec*, 16 May 2014. [\[link\]](#)

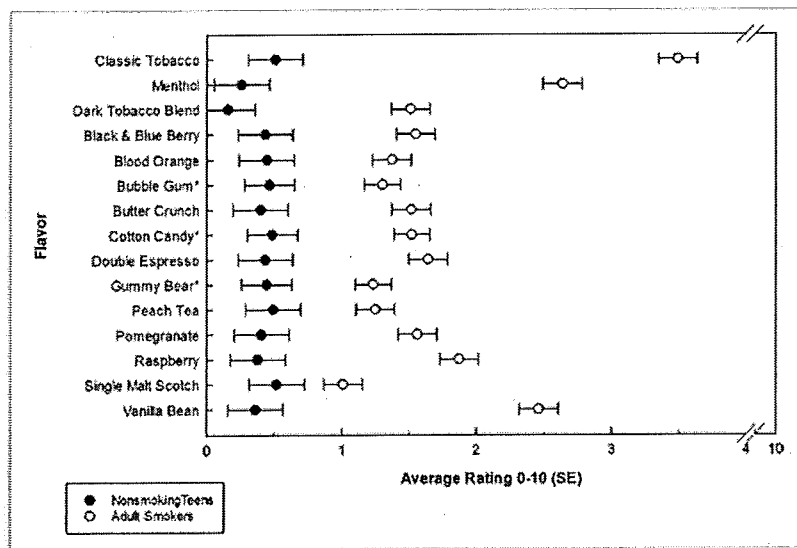
⁴⁵ L. D., O'Malley, P. M., Miech, R.A., Bachman, J. G., & Schulenberg, J. E. (2015). Monitoring the Future national results on adolescent drug use: Overview of key findings, 2014. Ann Arbor, Mich.: Institute for Social Research, the University of Michigan [\[link\]](#)

⁴⁶ 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. [\[link\]](#)

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 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 flavours⁴⁷. 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 category⁴⁸. 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% other⁴⁹. 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.

⁴⁷ 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 [\[link\]](#)[\[release\]](#).

⁴⁸ E-cigarette forum, Survey of users. *Big survey 2014 - initial findings eliquid*, 17 July 2014. [\[link\]](#)

⁴⁹ 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. [\[link\]](#)

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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 deliberate) in an editorial in the journal *Addiction*⁵⁰.

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 average⁵¹. 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 achieving 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

⁵⁰ West R, Electronic cigarettes: getting the science right and communicating it accurately, *Addiction*, virtual edition on e-cigarettes, December 2014. [\[link\]](#)

⁵¹ European Commission, [Special Eurobarometer 385](#), Attitudes of European Citizens to Tobacco, March 2012

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through the mechanism of market-based competition. The real danger from tobacco companies arises from excessively burdensome regulation, eliminating competition from more agile or innovative competitors, leaving them with an oligopoly protected by regulatory barriers to entry, and endorsed paradoxically by health organisations. Unfortunately many public health 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 aim⁵².

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 purity⁵³.
- **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 of 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.

⁵² 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 [\[link\]](#)

⁵³ 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 risks* through the unintended consequence of additional continuing smoking. All regulatory proposals advanced so far suffer from this weakness.

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 <i>worse</i> for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions; slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market 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' 2 nd and 3 rd generation products from the market. Many vapers report these are more effective alternatives to smoking. Note vaping may be a safer way to take other drugs than smoking – so there may be a harm reduction benefit to drug users.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. 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, suppress and control tobacco use. With e-cigarettes the public health imperative is best served by these products growing and innovating to capture market share from cigarettes – many of the tools of tobacco control applied to e-cigarettes are therefore harm-inducing and protective of cigarette sales.

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.⁵⁴ 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 innovation⁵⁵ and unlawfully forcing a non-medical consumer product into a medical definition and regulatory regime⁵⁶. 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

⁵⁴ 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 [\[link\]](#).

⁵⁵ Bates C, Stimson S, Costs and consequences of regulating e-cigarettes as medicines, 20 September 2013 [\[link\]](#)

⁵⁶ 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)⁵⁷ 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 2016⁵⁸. 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 2010⁵⁹, 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-cigarettes⁶⁰ (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 companies will meet approval⁶¹.

⁵⁷ Directive 2014/40/EU ‘Tobacco Products Directive’ [\[link\]](#)

⁵⁸ See more details at: *Totally Wicked legal challenge to the Tobacco Products Directive e-cigarette measures*, Counterfactual, November 2014 [\[link\]](#)

⁵⁹ U.S. Court of Appeals for the D.C. Circuit, in *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 2010 [\[link\]](#)

⁶⁰ 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

⁶¹ See CASAA assessment in: Fourth Call to Action for FDA Proposed Regulations Streamlined Version, 26 July 2014 [\[link\]](#)

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

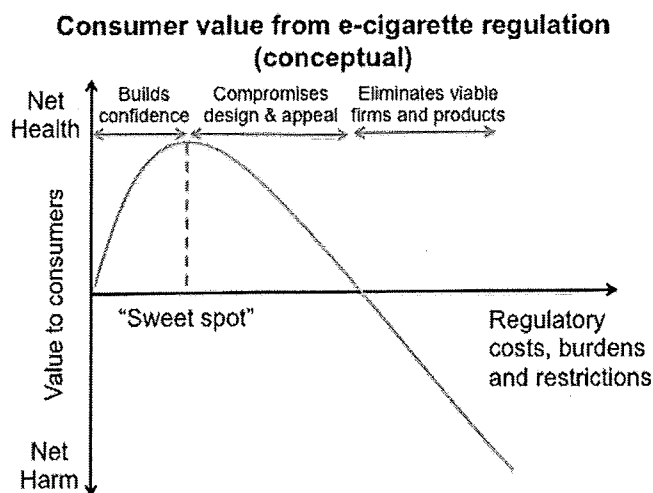
By defining these products as poisons or medicines, several jurisdictions have created an ostensible ban on e-cigarettes. As with all popular recreational drugs prohibition has led to a creative black market, which is likely to be reducing smoking and be beneficial to health. The force of the law has 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 issues⁶². 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)⁶³. The WHO would also like to include these products in UN targets to reduce tobacco consumption by 30% by 2025⁶⁴ – 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 approach⁶⁵.

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, bystanders and limiting the risks of harmful unintended consequences.

⁶² Bates C, WHO position on ENDS: A critique of the use of science and communication of risk, Oct 2014 [\[context\]](#)[\[report\]](#)

⁶³ 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 FCTC, October 2014. [\[link\]](#)

⁶⁴ See Clive Bates review of WHO documents: WHO plans e-cigarette offensive, 17 April 2014 [\[link\]](#)

⁶⁵ 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 [\[context\]](#)[\[letter\]](#)

4.5 Elements of an appropriate regulatory regime

A reasonable proportionate regulatory regime (the 'sweet spot') may cover many of the following elements, and it may develop over time. This list is not intended to be a full discussion:

Liquids

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

Devices

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

Testing

- A testing regime should support the regulatory objectives and regulatory decisions
- Focus on quality of liquids and devices, rather than vapour measurements

Marketing

- Claims must be true, not misleading and supported by evidence
- Proportionate warnings related to toxicity and addictiveness
- Restrictions on themes and media attractive to under-25s
- Restriction of sales to adults
- Age-verification for sales – on internet or in shops – as with any age-sensitive product

Companies

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

Vaping in public places

- 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
- There are many places, times, events, circumstances where vaping may be reasonable, desirable or commercially valuable and should not be ruled out by a blanket ban
- Owners and operators should decide their policy and make informed judgements [including the welfare value to vapers and smokers] and make clear whether vaping is permitted or not⁶⁶
- Vapers should approach vaping in public as a matter of etiquette with due regard for others

⁶⁶ See ASH structured questions: Will you permit or prohibit e-cigarette use on your premises? 2014 [\[link\]](#)

About the author

Clive Bates runs Counterfactual, a public interest consulting and advocacy organisation focussed on a broad approach to sustainability, policy-making for the long term and good governance. He was formerly a senior civil servant and Director of Action on Smoking and Health (London) as well as a founder of the NGO Framework Convention Alliance, set up to support the development of the WHO Framework Convention on Tobacco Control. He has been a long-term advocate of tobacco harm reduction^{67 68 69}, a critic of the public health establishment approach to harm reduction⁷⁰ and wrote about the policy challenge of products like e-cigarettes well before they were invented⁷¹.

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

⁶⁷ Bates C, Fagerström K, Jarvis MJ, *et al.* European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. *Tob Control* 2003;**12**:360–7. doi:[10.1136/tc.12.4.360](https://doi.org/10.1136/tc.12.4.360)

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

⁶⁹ Bates C. Taking the nicotine out of cigarettes—why it is a bad idea. *Bull World Health Organ* 2000;**78**:944. [[link](#)]

⁷⁰ Bates C. Flaw in WHO Framework Convention on Tobacco Control: letter identified wrong problem with the framework convention. *BMJ* 2004;**328**:1320. doi:[10.1136/bmj.328.7451.1320](https://doi.org/10.1136/bmj.328.7451.1320)

⁷¹ Bates C. What is the future for the tobacco industry? *Tob Control* 2000;**9**:237–8. doi:[10.1136/tc.9.2.237](https://doi.org/10.1136/tc.9.2.237)

THE SPECTATOR

E-cigarettes save lives

I understand why anti-smoking activists so distrust vaping. I'm one of them. But the evidence is clear

COVER FEATURE 84 Comments [Derek Yach](#) 21 February 2015

In the 1970s, a group of students in South Africa were planning a campaign against tobacco. I was one of them. We paid a visit to Rembrandt, the country's leading cigarette manufacturer, to hear their side of the story.

They showed us shiny floors, introduced us to well-paid employees of all races — a rarity in apartheid South Africa — and proudly described their extensive support for the arts, culture and the environment. We replied that this was great, but it failed to address the core issue: their products killed half their regular users and harmed many more.

So the campaign went ahead. For me, it was the start of decades of battles with tobacco companies that led to strong regulations in South Africa — and culminated in the World Health Organisation (WHO) Framework Convention on Tobacco Control, now in effect in almost 180 countries.

Along the way, I learnt to distrust every move by tobacco companies and felt fully justified when an inquiry, supported by WHO and the World Bank, declared: 'Evidence... reveals that tobacco companies have operated for many years with the deliberate purpose of subverting the efforts of WHO to control tobacco use. The attempted subversion has been elaborate, well financed, and usually invisible.'

It's not surprising that most people in public health strongly endorse the view of Dr Neil Schluger, a lung specialist and professor of medicine at Columbia University, that 'If there ever was an industry that does not deserve the benefit of the doubt when it comes to protecting or promoting the public's health, it is the tobacco industry.' The industry's deceptions have included the development of low-tar products and a crafty message

suggesting that they did less harm. Years after their launch, however, research showed that low-tar cigarettes had exactly the opposite effect.

Now we have electronic cigarettes. Is this the latest ruse, or is it really an innovation we should welcome?

Let's review the appalling statistics. There are about 1.3 billion smokers in the world and roughly six million smoking-related deaths every year. In the United Kingdom alone, smoking causes 80,000 deaths. That's 18 per cent of all deaths. What's more, for every death there are 20 smokers suffering from tobacco-related diseases, resulting in 450,000 hospital admissions each year. No other single cause of death and disease can so easily be prevented.

The WHO framework convention stresses the value of government-led measures: increasing excise taxes, banning all marketing and advertising, and promoting smoke-free workplaces. Early in its development, we invited tobacco company scientists to provide evidence that their harm-reduction measures were real and not merely marketing ploys. Their responses were unconvincing.

At the same time, the first public evidence emerged that, for decades, tobacco companies had a sophisticated understanding of the role of nicotine. But they had failed to act on this knowledge and separate the harm caused by combusted tobacco from the 'pleasure' some people obtain from nicotine.

Let's take a quick look at another tobacco product — one that's never caught on in the UK. Snus is smokeless tobacco in a little packet that Swedes tuck against their gum in order to get a nicotine buzz. For many years, the increased use of snus versus regular tobacco has been a major factor in Swedish men having the lowest death rate in the European Union.

Indeed, death rates from all causes among European men are about 2.5 times higher than among Swedish men — thanks, in part, to snus. Also, as snus use has increased, smoking has decreased. Snus was banned in all EU countries except Sweden (and Norway, which isn't in the EU). In Finland, the ban slowed down the drop in smoking. In Norway, by contrast, snus consumption by adults rose from 4 per cent in 1985 to 28 per cent in 2012 — and overall tobacco use fell by 20 per cent.

What drove these changes? Tobacco advertising (including for snus) has long been banned in all three countries. Public health authorities speak out against all forms of tobacco, including snus. Nonetheless, consumers, influenced by price and information from social networks, have increased their use of snus.

So what has this to do with the emerging e-cigarette debate?

We've seen that snus is banned in most of Europe despite overwhelming evidence that it is harm-reducing. And now e-cigs and other innovative ways of delivering nicotine without the dangers created by burning tobacco face the same challenge.

Traditionalists demand more of the same policies that have significantly reduced tobacco use: excise taxes, full implementation of smoke-free workplaces and more effective anti-smoking advertising. Long-term projections say this would reduce smoking in the United States from the current 20 per cent to 10 per cent by 2030. That's welcome — but it still leaves millions of smokers at risk.

The call for higher excise taxes ignores rising concerns about their regressive impact on poorer and more-addicted smokers. It also ignores advances in the genetics of nicotine use, suggesting that half of all smokers may not respond to tax increases because of their need for nicotine. In other words, our one-size-fits-all approach to tobacco control is doomed to fail.

Action on Smoking and Health estimates that 2.1 million British adults currently use e-cigs. About one third are former smokers, and two thirds are still smokers. Meanwhile, regular use of e-cigarettes by children and adolescents is confined almost entirely to current and former smokers. Users claim that e-cigs help them stop smoking entirely (38 per cent) or reduce the amount they smoke (25 per cent). Robert West, professor of health psychology at University College London, reports that e-cig use by never-smokers is negligible and similar to that of nicotine-replacement therapy (NRT).

In recent years, the increase in the popularity of e-cigs has more than offset a decrease in NRT use. Successful attempts to quit smoking, although escalating, are still low, at between 5 and 7 per cent. E-cigs could play a major role in helping those smokers most addicted to nicotine, who are shifting in increasing numbers from NRT products to 'vaping' as their means of quitting the tobacco habit.



Safety concerns were addressed recently. Two analyses reviewed toxicological, laboratory and clinical research on the potential risks. They concluded that e-cigs are by far less harmful than smoking, and that 'significant health benefits are expected in smokers who switch from tobacco to e-cigs'. Yet governments and the WHO remain unconvinced about the benefits of e-cigs. There is deep distrust of tobacco companies. This is borne out by article 5.3 of the framework convention, which requires that 'in setting and implementing their public health policies with respect to tobacco control, parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' — i.e., avoid any interaction with tobacco companies. But this policy is impossible to implement in countries where democratic law-making processes require interaction with all stakeholders, or where the government owns a tobacco company.

Moreover, it limits the potential to make use of scientific discoveries by tobacco companies. At a WHO tobacco control conference last October, governments stressed the need to protect tobacco-control activities from all commercial and other interests. That effectively means not talking to researchers developing new and safer products. They also wanted governments to consider prohibiting or regulating e-cigs as tobacco products — which would be a huge boost to the deadly status quo.

The US Food and Drug Administration (FDA) has already announced its intention to regulate e-cigs as tobacco products. About \$2.2 billion was spent on e-cigs in America last year, exceeding the amount spent on NRT but still representing a small part of the \$85 billion cigarette market.

At the same time, however, the FDA seems to favour a transition away from lethal combustible products. Mitch Zeller, director of its Centre for Tobacco Products, wants us to look at nicotine differently. People 'smoke for nicotine but die from tar', he says, and new products represent a public health opportunity.

The FDA's measured approach is in contrast to the continued unscientific approach of the US Centres for Disease Control and Prevention, whose director Dr Tom Frieden stated last year that 'many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes'. They have yet to produce evidence that this is the case. In November, Penny Woods from the British Lung Foundation said '[new] data should again alleviate the fears expressed by some over an e-cig gateway effect'. Let's spell this out. Unsupported statements are accepted as truth by policymakers and are used as the basis for stringent regulation of e-cigs in many jurisdictions.

This may well end up causing more public health harm than good. The benefits of e-cigs in helping smokers quit or cut down should be weighed against the danger of either recruiting new smokers or creating e-cig addicts. So far, there is no evidence that either of these things is happening. Studies in both Britain and America suggest that, as e-cig use increases, youth cigarette consumption declines.

Why are we in this position? One reason is that governments have become addicted to tobacco excise tax and may fear that, as e-cigs take off, they will lose a valuable source of revenue. Many leading NGOs and academics exert strong influence at WHO, within governments, in the media and among the general public. In the past, they helped bring tobacco control out of the shadows and into the mainstream of health policy. Now, alas, their intransigence threatens more profound progress.

We need clear, unambiguous messages to smokers about the safety and benefits of e-cigs. An example is the March 2014 statement on the Royal College of Physicians website that 'the main benefit of e-cigarettes is that they provide inhalable nicotine in a formulation that mimics the behavioural components of smoking but has relatively little risk... Switching

completely from tobacco to e-cigarettes achieves much the same in health terms as does quitting smoking and all nicotine use completely. Furthermore... risks associated with passive exposure to e-cigarette vapour are far less than those associated with passive exposure to tobacco smoke.'

If influential health officials were to make these points repeatedly, public sentiment towards e-cigs would shift quickly. And this could be done at the same time as strengthening anti-smoking measures.

We should praise 'good' e-cig companies who commit to safety, to avoiding youth marketing, and to making smoking obsolete. They need to be explicit about their long-term plans. Are they seriously committed to harm reduction, or introducing new products simply to delay progress and confuse policymakers, as many in public health believe?

From my meetings with major tobacco companies, it's clear that they are hedging their bets. Some of them have indicated, in private, a long-term goal of moving out of manufacturing harmful tobacco products — but these statements are not enough to inspire trust. Tobacco companies' intention to change must be stated publicly and backed by action.

Other market sectors need to adapt to the reality of e-cigs as a force for good. Retailers should voluntarily withdraw cigarettes from stores, or at least reduce their prominence, in favour of e-cigs and NRTs. CVS Health has yet to offer e-cigs, despite the fact that they work better than pharmaceutical products. Life insurers still treat e-cig users as regular smokers when they calculate premiums. This is short-sighted and misses a golden opportunity to spell out the benefits of quitting smoking and the positive impact of switching to e-cigs on people's longevity.

At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.

A toxic legacy

Evidence that the tobacco companies knew of the importance of nicotine to smokers 50 years ago:

— ‘Nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms.’ 17 July 1963, Brown & Williamson general counsel/vice president Addison Yeaman.

— ‘It is my conviction that nicotine ... both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect. ... under modern conditions of life people find that they cannot depend just on their subconscious reactions to meet the various environmental strains with which they are confronted. ... smoking has considerable psychological advantages and a built-in control against excessive absorption. It is almost impossible to take an overdose of nicotine in the way it is only too easy to do with sleeping pills.’ 29 May 1962, BAT memo ‘The Smoking and Health Problem’

Derek Yach is executive director of the Vitality Institute and previously headed tobacco control at the WHO.

This article first appeared in the print edition of The Spectator magazine, dated 21 February 2015

Tags: February 2015

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From: JIM AND VICTORIA TURNER

Subject: Please Oppose Ordinance that would force several vapor retail stores to close

Date: March 23, 2015 at 11:51:51 AM CDT

JIM AND VICTORIA TURNER
17TH AVE
MONROE, WI 53566

March 23, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

Because this ordinance will force several vapor shops to close, it will actually have the effect of protecting the sales of traditional cigarettes as they will still be allowed to be sold in hundreds of locations throughout the city. Moreover, including low-risk, smoke-free products like e-cigarettes in tobacco regulations sends a confusing message to existing smokers that these products are just as harmful as continuing to smoke. However, we know from a growing body of science that (a) these products are 99% less risky than traditional cigarettes, (b) they are helping more than several million people worldwide to eliminate or reduce their smoking habit, and (c) adult awareness of these low-risk, smoke-free alternatives is declining due to confusing laws and misinformation campaigns.

Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

Sincerely,
JIM AND VICTORIA TURNER

From: Nicole Paulus

Subject: Please Oppose Ordinance that would force several vapor retail stores to close

Date: March 23, 2015 at 9:57:10 AM CDT

Nicole Paulus
7th St.
Fennimore, WI 53809

March 23, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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Sincerely,
Nicole Paulus

From: Don Muehlbauer

Subject: Please Oppose Ordinance that would force several vapor retail stores to close

Date: March 23, 2015 at 9:47:00 AM CDT

Don Muehlbauer
W Innovation Dr
Wauwatosa, WI 53226

March 23, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

What this ordinance would actually do is

- Hurt children by keeping them exposed to the mass sale of cigarettes and cigarette advertising everywhere, including every local gas station and convenience store, while making it harder for the 20 - 25% of adults who smoke to find the alternative that really works to help them quit
- Hurt small businesses and help big tobacco. Small businesses created ecigarettes and as is now being proven more and more, are helping millions of adults to quit smoking. As opposed to Big Tobacco, who have been killing millions of their customers for years.
- If the concern is children, who do you think is more likely to do proper age verification, the small business, probably family owned vape shop who would be completely out of business if they sell to children, or the huge gas station chain manned by a part time worker.
- Discourages use of life saving products. No one want to see vape products used by minors, but they should be available, and in fact ENCOURAGED for use by committed smokers.

Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

Sincerely,
Don Muehlbauer

From: Dave Hohisel
Subject: Please Oppose Ordinance that would force several vapor retail stores to close
Date: March 22, 2015 at 8:28:30 PM CDT

Dave Hohisel
Adel St.
Janesville, WI 53546

March 22, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

Sincerely,
Dave Jon Hohisel
Dave Hohisel

From: Kallyon Matezevich

Subject: Please Oppose Ordinance that would force several vapor retail stores to close

Date: March 22, 2015 at 8:28:22 PM CDT

Kallyon Matezevich

Illinois Ave.
N. Fond du Lac, WI 54937

March 22, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

On a personal note, e-cigarettes are the only things that have worked for my husband and I, long time smokers, to quit tobacco. They have literally saved our lives and I beg you not to restrict access to them or close any stores.

Sincerely,
Kallyon Matezevich

From: janice scharpf
Subject: Please Oppose Ordinance that would force several vapor retail stores to close
Date: March 22, 2015 at 10:30:13 PM CDT

janice scharpf
S 75th Street
Milwaukee, WI 53219

March 22, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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Sincerely,
janice scharpf

From: steve hable
Subject: Please Oppose Ordinance that would force several vapor retail stores to close
Date: March 22, 2015 at 8:08:01 PM CDT

steve hable
Pizarro Cir
Madison, WI 53719

March 22, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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I would also urge this committee to strongly reconsider the classification of personal vaporizers and e-cigarettes. Being grouped in with traditional cigarettes is inaccurate. There is NO tobacco in any of the eliquid used. There is NO burning of tobacco (or no combustion). The only thing that these two items share in common is nicotine (and a lot of ecig users, actually use zero nicotine juice). Nicotine is a naturally occurring stimulant with effects similar to caffeine. I refer you to this well written article about the differences.

<https://medium.com/@CoffeeGeek/i-don-t-like-e-cigarettes-764ee8c96421>

Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

Sincerely,
steve hable

From: Mike Baratta
Subject: Please Oppose Ordinance that would force several vapor retail stores to close
Date: March 22, 2015 at 8:38:44 PM CDT

Mike Baratta
Eisner Ave
Sheboygan, WI 53083

March 22, 2015

Dear Tonya L. Hamilton-Nisbet,

I am writing to urge you to oppose an ordinance (file: 37398) that would amend sections of the City Zoning Code to include vapor retail shops in the city's definition of a "tobacco retailer". At the very least, dedicated vapor retail stores that sell vapor products exclusively should be exempt from this law. By subjecting vapor retailers to tobacco regulations, the city would be forcing at least nine dedicated vapor retail stores and several other retailers to shut down in the city of Madison. Aside from being a tremendous financial loss for the owners and employees of these locations, consumers would suffer an unjustifiable loss of access to low-risk products that help them live smoke-free.

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Again, I urge you to oppose or substantially amend this ordinance so that adult access to low-risk, smoke-free products like e-cigarettes is protected. I along with my fellow members of the Consumer Advocates for Smoke-free Alternatives Association (CASAA) thank you for considering my comments on this issue. I look forward to your response on this issue and I am available for any questions you might have.

I also work at a local vaping shop in Sheboygan, the number of customers that have cancer or copd I have that walk through the door and tell me the success stories since they have switched to e - cigarettes would make you change your view alone.

The number of medical studies done on the properties of the substances in the products should also have you rethink this bill. There is no harm in any part of this. Your taking away a healthy alternative to many people. This bill will drive people back to the big tobacco products. Passing this bill is like lighting the cigarettes for them, and saying "smoke up johnny".

Sincerely,
Mike Baratta

15

From: ROBERT LAUER

Subject: Amending tobacco zoning and licensing rules to include e-cigarette retailers

Date: March 22, 2015 at 7:57:26 PM CDT

Planning commission members;

I ask you to not support, or approve the ordinance proposed by Mayor Soglin to amend its tobacco zoning and licensing rules to include e-cigarette retailers.

As an adult former smoker, and current user of vaping products; these restrictions are not good business for Madison.

They will not convince people to stop smoking, or try prescription drugs to quit.

This type of legislation only serves to invite more attention to a habit you are attempting to get rid of.

You are going to eliminate jobs, and tax revenues in your city, and force the adults who want to use these products to shop outside of your boundaries.

It is a loss for business, government taxes, and personal freedom.

Robert Lauer

From: "Rick Gundermann, MHS"
Subject: Zoning Proposal
Date: April 1, 2015 at 11:18:23 AM CDT

Dear Ms. Hamilton-Nisbet,

I am emailing to encourage you to vote against Mayor Soglin's proposal to change zoning pertaining to what he refers to as "Tobacco Retailers".

The new zoning proposal seems directed mostly at electronic cigarette stores, and I think it has some serious (perhaps) unintended consequences.

The proposal unfairly lumps tobacco shops and e-cigarettes stores together, even if an e-cigarettes shop sells no tobacco whatsoever. Meanwhile a convenience store that sells both tobacco and e-cigs is given a pass.

Under the proposal tobacco shops or e-cigarette stores could not be located within 1,000 feet of any number of other establishments, including schools, parks, libraries, and other tobacco retailers.

Tobacco retailers could also not be sited within 500 feet of any store that sells tobacco. Effectively, 90% of the city would be off limits to a tobacco retailer. So, while current stores would be grandfathered in, this would make it difficult, if not impossible, for a tobacco retailer to open a new store or move their current store. One can see a case where landlords raise rents to tobacco shops, knowing they can't move (within Madison).

Meanwhile, convenience stores, gas stations, grocery stores, liquor stores and pharmacies would have no restrictions whatsoever. This seems especially unfair considering that there were no cases of tobacco stores selling to minors in 2014, while there were 61 cases of other stores selling to minors. (See attached.)

If the zoning change goes through, e-cigarette stores and tobacco shops, who card everyone who comes into their store (and who had zero cases of selling to minors) would be penalized severely. Other stores that sell tobacco, electronic cigarettes, and beer and don't card customers until they make a purchase (sometimes not checking ID's at all) would not only not be penalized, they would see their competition being forced out of their area.

Another unfair aspect of the proposal is that it defines stores by the square footage devoted to tobacco or e-cigarettes, and doesn't define stores by sales of tobacco products. So a convenience store that sells a larger dollar volume of tobacco/e-cigarettes than a vape shop is not restricted simply because it has a larger overall area.

I have emailed the Mayor to ask him to explain his thinking behind this proposal, but he has declined to answer.

I expect the Mayor will adjust his proposal to somewhat less draconian distance requirements, but I would suggest that the proposal simply makes no sense at its heart.

Thank you for your consideration.

Rick Gundermann, MHS



2014 Madison & Dane County Tobacco Vendor Compliance Report

Compliance Check Results:

330 tobacco retailers within Madison and Dane County were checked for sales of tobacco products to minors in 2014. A total of 51 underage sales were made resulting in an overall sales rate of 15.5% in both the City of Madison and Dane County (Table 1). 2014 saw the highest tobacco sales to minors' rate in over 6 years (Table 2). It is also important to point out that the highest sales rate among vendors was pharmacies—with all sales except one occurring at Walgreens stores.

The City of Madison had a sales rate of 17.9%, while the rest of Dane County had a sales rate of 13.2%. Even when separated out, these are the highest sales rates that have occurred in over 6 years in both jurisdictions (Table 3).

The majority of tobacco retailers in the City of Madison and Dane County that passed their inspections should be congratulated for consistently checking identification and refusing to sell tobacco to minors. Tobacco retailers are the first line of defense in limiting youth access to tobacco.

Table 1

2014 Madison & Dane County Compliance Checks				
Vendor Type	Number of Inspections	Number of Sales	Sales Rate (%)	Compliance Rate (%)
Gas/Convenience	189	30	15.9	84.1
Liquor	32	4	12.5	87.5
Grocery	34	5	14.7	85.3
Pharmacy	35	11	31.4	68.6
Department Store	9	0	0	100
Bar/Restaurant	19	0	0	100
Tobacco/Smoke Shop	10	0	0	100
Bowling Alley	0	0	n/a	n/a
Resort/Campground	0	0	n/a	n/a
Other	1	1	100	0
Total	329	51	15.5	84.5

Table 2

Historical Data—Madison & Dane County Combined				
	Number of Inspections	Number of Sales	Sales Rate (%)	Compliance Rate (%)
2008	788	58	7.4	92.6
2009	402	27	6.7	93.3
2010	280	17	6.0	94.0
2011	300	35	11.7	88.3
2012	232	30	12.9	87.1
2013	313	28	9.0	91.0
2014	329	51	15.5	84.5

Wisconsin WINS is a program of the Wisconsin Tobacco Prevention and Control Program and provides training, media and community outreach, and education to tobacco retailers. Funding for this program was provided by the state of Wisconsin. More information is available online at www.wiwins.org.

Table 3

Historical data—Madison and Dane County Separated								
City of Madison					Dane County (excluding Madison)			
	Number of Inspections	Number of Sales	Sales Rate (%)	Compliance Rate (%)	Number of Inspections	Number of Sales	Sales Rate (%)	Compliance Rate (%)
2008	354	29	8.2	91.8	434	29	6.7	93.3
2009	126	10	7.9	92.1	276	17	6.1	93.9
2010	128	10	7.8	92.2	152	7	4.6	95.4
2011	130	22	16.9	83.1	170	13	7.7	92.35
2012	117	18	15.4	84.6	115	12	10.5	89.5
2013	191	23	12.1	87.9	122	5	4.0	96.7
2014	162	29	17.9	82.1	167	22	13.2	86.8

This report was prepared by Nina Gregerson, TFCDC—January 2015

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From: William Holloway
Sent: Friday, March 27, 2015 9:59 AM
To: Zellers, Ledell
Subject: restrictions of tobacco, vaping businesses

Hi Ledell,

I just read about the proposed restrictions on where new tobacco and vaping businesses can be located (link below) and just thought I'd throw in my 2 cents.

I think preventing new businesses of these types from opening within 1000' of schools or daycare centers might make sense, since lots of kids will inevitably see them and may become interested in their products. However, I think restricting these businesses within 500' of health care facilities and residences is a bridge too far; it's hard to find locations that are not within 500' of someone's residence and I can't see how this is really a health or safety issue. Maybe the best course of action would be to treat these types of businesses in the same way that liquor stores are treated - both sell products we don't want kids using but neither gives off fumes/odors that would impact neighboring properties.

-Bill Holloway

From: Dave Hohisel
Date: 03/25/2015 10:41 PM (GMT-06:00)

Subject: Zoning Ordinance

It's imperative that these zoning laws be looked over and changed. While I agree tobacco and vaping products need to be away from certain areas and age groups. These laws will squeeze the life out of a community I and many other are part of. While vaping products contain nicotine they do not contain any tobacco. Big tobacco and the media shed a dark light on these products because it cuts into their profits. Tobacco companies have taken many lives and vapor products are saving them. Please reconsider your stance it will hurt many people. The below picture is not intended to insult but to inform. Thank you for your time.

David J Hohisel Jr.

From: Lisa Bell

Subject: The City's zoning code currently permits tobacco shops in the NMX, TSS, MXC, CC-T, and CC districts. Vaping Shops

Date: March 25, 2015 at 7:10:22 PM CDT

To: undisclosed-recipients;

To The Committee of Madison, Wisconsin (Zoning Ordinance):

"The Common Council of the City of Madison do hereby ordain as follows: 1. Section 28.211 entitled "Definitions" of the Madison General Ordinances is amended by creating therein the following: "Tobacco Paraphernalia. Tobacco paraphernalia means cigarette papers or wrappers, pipes, holders of smoking materials of all types, cigarette rolling machines, and any other item designed for the smoking or ingestion of tobacco products. Tobacco paraphernalia includes electronic cigarettes, personal vaporizers, electronic nicotine delivery systems, or any item designed to atomize liquid solutions that simulate smoking. Tobacco Retailer. A tobacco retailer is any establishment that either devotes twenty percent (20%) or more of floor area or display area to the sale or exchange of tobacco products or tobacco paraphernalia. Tobacco Products. Tobacco products means any substance containing any tobacco leaf, including but not limited to cigarettes, cigars, bidis, pipe tobacco, snuff, chewing tobacco, and smokeless tobacco. Tobacco products includes e-liquids such as propylene glycol, glycerin, nicotine, flavorings, or other products for use in electronic cigarettes, personal vaporizers, or electronic nicotine delivery systems."

I have relatives, acquaintances and friends in Madison, Wisconsin and have spent considerable amounts of time and money in beautiful Wisconsin.

I am opposed to "Definitions" in the Zoning Ordinance as it pertains to Electronic Cigarettes, Vaporizers, Nicotine Delivery devices (Nicotrol a pharmaceutical product, is also a nicotine delivery device), Ecigs are Adult consumer products that are correctly defined as "Alternatives to Tobacco". I am opposed because I read about this subject and there is no scientific basis for calling them "Tobacco Paraphernalia" what-so-ever.

I began replacing my smoking of Tobacco Cigarettes with Electronic Vaping in 2009. I have been SMOKE-FREE for almost 5 yrs., after smoking for 43 yrs. The availability, accessibility and affordability of these tobacco replacement alternative products are the reason that I am breathing better today. Not only should they not be classified incorrectly, but they shouldn't be zoned away from the public's easy access to them, that would be gravely harmful to public health. The more smokers can be made aware of these "Alternatives to Tobacco", the better the odds of many more smoker's smartly choosing to quit smoking. In fact, Electronic Cigarettes should be in all Hospital Pharmacies and commercial Drug Stores. There should be bill boards that tell smokers there is an alternative product that has been shown to improve people's health and quality of life that is AFFORDABLE & ENJOYABLE!

A wonderful Scientist and advocate for Electronic Vaping, who has spoke before the FDA a number of times has this to say:

Tobacco harm reduction, e-cigarettes, and e-cigarette use: an overview Handout to accompany 18 March 2015 [updated 19 Mar] presentation by: Carl V Phillips, MPP PhD Chief Scientific Officer The Consumer Advocates for Smoke-free Alternatives Association cphillips@casaa.org The Consumer Advocates for Smoke-free Alternatives Association (CASAA) is a nonprofit public health NGO dedicated to promoting tobacco harm reduction by preserving access to and providing education about low-risk alternatives to smoking. It is a U.S. membership organization with over forty thousand members, serving as the leading representative of the interests of consumers. CASAA is not affiliated with industry and does not represent their interests. (Material contained in this document may be attributed to either the individual or institutional author. Either is happy to engage in further communication.)

What is tobacco harm reduction (THR)? Tobacco harm reduction is the substitution of low-risk alternatives for smoking. Those low-risk alternatives include electronic cigarettes (e-cigarettes), smokeless tobacco (snus, snuff, chew), and for those who find them satisfying for long-term use, pharmaceutical nicotine products (a.k.a. NRT; nicotine gum, lozenges, etc.). All of these products are estimated to be about 99% less harmful than smoking. The harm reduction ethic is not just about reducing harm, but about respecting the liberty, dignity, and preferences of the individual. Rather than diminishing a person to the role of a patient to impose treatment upon – or worse, to a miscreant, sinner, or criminal to be punished and controlled – harm reduction involves empowering people to make their own best choices and protecting them from those who would punish them for those choices. Their options should include the lower-risk alternatives, and they are strongly encouraged to choose those, but ultimately the decision about what to do with their own bodies is their own. The term “harm reduction” is commonly used in the context of injection drug use (clean needles) or sexual behavior (condoms). But auto safety, because of the absence of moralizing, is perhaps a better way to think about it: We do not tell people to just avoid the dangerous behavior of automotive transport in spite of its benefits, but rather provide them with risk-reducing products (seat belts) and push for safer driving behavior. Indeed, the major contrast between THR and those other areas of harm reduction is the magnitude of the reduction: Available technologies and safer behavior reduce the risks from sex, drugs, and driving by half or a bit more. But THR comes so close to entirely eliminating the risk that there is almost no difference between low-risk product use and complete abstinence from tobacco/nicotine products. So why does there seem to be so much opposition to THR? Opposition to THR comes from a relatively small special-interest group of anti-tobacco activists, but they are high-profile, well funded, and hold key positions of power. When you present the case for promoting THR to the average person, they almost always agree it is a wise approach. Unfortunately, while anti-tobacco efforts started out based on a genuine concern for

people and their health, focusing on making sure people understood the risks of smoking, they have morphed into something altogether different. Many anti-tobacco activists have long-since stopped wanting to rid the world of the harms caused by tobacco use, and simply want to end all tobacco use regardless of how low the risk and how much people like using the products. Their goal is seriously threatened by THR: If people can use tobacco with very little or no health risk, those who derive benefits from it have little reason not to do so. For most of us, there is no apparent problem with people enjoying a low- or no-risk consumption choice. But for those who just want to eliminate all tobacco use – basically for “moral” reasons – it ends all hope. Additionally, many who have spent their careers trying to reduce smoking, to no great effect, resent the fact that the problem may be solved in spite of their efforts rather than because of them. It is just human nature to push back. Less forgivable is the financial motive. Anti-tobacco organizations, and indeed many major health charities, depend on smoking for their funding. Cigarette taxes are funneled to them, and their donations and public support depend on tobacco use being a costly scourge. If tobacco use becomes low-risk, they are out of business. Opponents of THR typically dress up their claims as concerns about health, because stating their real motivations would obviously not play very well, and they do manage to trick many others into repeating their inaccurate health claims. But keeping smokers smoking longer – which is what they are doing – is obviously bad for public health. Their health-based claims are easily and consistently debunked, but they simply keep repeating them, counting on their audiences never learning that they what they are saying has been scientifically shown to be false.

Thank you. I am proud to be an Ex-Smoker, an American Citizen, a voter and friend to many.
Lisa Bell