Bad science, poor insights and likely to do harm – rapid reaction to the Surgeon General's terrible e-cigarette report

Warning: The Surgeon General has crossed the boundary between science and propaganda

The Surgeon General's report on e-cigarettes is out. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. It is truly terrible – a heady mix of emotive propaganda and a completely warped and one-sided account of the science built on a lack of insight into youth behaviors and no knowledge of the tobacco and nicotine market or its consumers.

Previous posts: see Five questions for the Surgeon General about e-cigarette science and The critic's guide to bad vaping science (both 7 Dec 2016)

I've extracted the overall conclusions and main chapter conclusions from the report and provided a rapid reaction to each of these.

- Major Conclusions
- Chapter 1. Introduction, Conclusions, and Historical Background Relative to E-Cigarettes
- Chapter 2. Patterns of E-Cigarette Use Among U.S. Youth and Young Adults
- Chapter 3. Health Effects of E-Cigarette Use Among U.S. Youth and Young Adults
- Chapter 4. Activities of the E-Cigarette Companies
- Chapter 5. E-Cigarette Policy and Practice Implications

My overall view

Before comments on each section of the report, let me give my overall reaction.

- The report is a major failure on the part of the Surgeon General and his ghost-writers at CDC. Looking only at risks to teenagers without looking at benefits to adults has inevitably created a highly one-sided report. Even with a focus on youth, it fails recognise that for adolescents, vaping may be a positive route out of smoking – an exit gateway. Without considering how young people and adults transition between smoking and vaping the Surgeon General misses nearly everything that matters and presents a fundamentally flawed report.
- While the science is detailed in the body of the report, caution and caveat are abandoned in the headlines and marketing material. The report does not put vaping risks into context with smoking or other risks and plays fast and loose with anti-scientific risk communication.
- The Surgeon General proposes restrictive policies on e-cigarettes for the supposed benefits to youth, but without considering the likely harmful consequences for adult vapers or smokers – it is reckless and amateurish to propose policies from such a position without considering harmful unintended consequences to the largest class of users.
- The Surgeon General has completely missed the point of e-cigarettes, he makes alarmist theatre from negligible risks while denying the massive opportunities. The science is poor, the report is based on flawed assertions about youth behaviors, and, should it be taken seriously, it will do considerable harm.

Americans should expect better. Is there a better guide? As it happens , there is. If Americans want a more realistic take on the science of e-cigarettes from independent US experts, then the systematic review published by scientists at Truth Initiative and Schroeder Institute a few days before the Surgeon General's report is *far* better.

> *Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. Am J Prev Med. Elsevier; 2016 Nov;0(0):1469–71. [AJPM][PDF]*

Reactions by chapter conclusion

Major Conclusions

1. E-cigarettes are a rapidly emerging and diversified product class. These devices typically deliver nicotine, flavorings, and other additives to users via an inhaled aerosol. These devices are referred to by a variety of names, including "e-cigs," "e-hookahs," "mods," "vape pens," "vapes," and "tank systems."

2. E-cigarette use among youth and young adults has become a public health concern. In 2014, current use of e-cigarettes by young adults 18–24 years of age surpassed that of adults 25 years of age and older.

3. E-cigarettes are now the most commonly used tobacco product among youth, surpassing conventional cigarettes in 2014. E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products.

4. The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.

5. E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful constituents, including nicotine. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.

6. E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.

7. Action can be taken at the national, state, local, tribal, and territorial levels to address e-cigarette use among youth and young adults. Actions could include incorporating e-cigarettes into smokefree policies, preventing access to e-cigarettes by youth, price and tax policies, retail licensure, regulation of e-cigarette marketing likely to attract youth, and educational initiatives targeting youth and young adults.

Reaction. The report fails to explore the interactions between smoking and vaping behaviour and whether the widespread use of vaping is in whole or part responsible for the recent rapid declines in both youth and adult

smoking. It does not give an adequate comparison of the relative risk of smoking and vaping (including to young people) but lists risks that are minor, or based on speculation. Because it does not adequately assess whether vaping is displacing smoking, it has no basis for declaring the promotion of vaping to be harmful. Vaping *is beneficial* if it means young people who would otherwise smoke, switch to vaping instead – even if he would rather they did neither, the Surgeon General has limited control over youth risk behaviours.

Finally, the Surgeon General makes an extraordinary leap beyond the scope of the report by endorsing policy recommendations. How can he make policy proposals for e-cigarettes when the report does not even consider adult use and potential benefits for adults, and therefore potential harmful unintended consequences of policy intervention? A related point is whether the 'action' proposed will stop young people migrating away from smoking and onto vaping, and therefore cause harm – how does the Surgeon General know? He doesn't try.

Chapter 1. Introduction, Conclusions, and Historical Background Relative to E-Cigarettes

1. E-cigarettes are devices that typically deliver nicotine, flavorings, and other additives to users via an inhaled aerosol. These devices are referred to by a variety of names, including "e-cigs," "e-hookahs," "mods," "vape pens," "vapes," and "tank systems."

2. E-cigarettes represent an evolution in a long history of tobacco products in the United States, including conventional cigarettes.

3. In May 2016, the Food and Drug Administration issued the deeming rule, exercising its regulatory authority over e-cigarettes as a tobacco product.

Reaction. Even this fails to describe the most fundamental characteristic of e-cigarette and vapor products. That is that they deliver nicotine *without the combustion of tobacco leaves and subsequent smoke inhalation*. Given that products of combustion are overwhelmingly the source of harms arising from smoking (confirmed in multiple prio SG reports), the public health opportunity from having nicotine products with no products of combustion should be obvious, but is entirely overlooked in this report. This unwillingness to see

opportunity while obsessively searching for and exaggerating risk is at the heart of the report's failure.

The Surgeon General shows his penchant for propaganda over fact by describing e-cigarettes as 'tobacco products'. They have no tobacco in them. They are legalistically defined as 'tobacco products' in a piece of poorly drafted US legislation, but a scientist should recognise the difference between a nicotine product and a tobacco product and use accurate language that explains rather than obfuscates. The description of e-cigarettes as tobacco is usually an intent to smear by association or to justify policies by analogy (eg. by reference to smoking bans, cigarette taxes or warning labels).

Chapter 2. Patterns of E-Cigarette Use Among U.S. Youth and Young Adults

1. Among middle and high school students, both ever and past-30-day e-cigarette use have more than tripled since 2011. Among young adults 18–24 years of age, ever e-cigarette use more than doubled from 2013 to 2014 following a period of relative stability from 2011 to 2013.

2. The most recent data available show that the prevalence of past-30-day use of e-cigarettes is similar among high school students (16% in 2015, 13.4% in 2014) and young adults 18–24 years of age (13.6% in 2013–2014) compared to middle school students (5.3% in 2015, 3.9% in 2014) and adults 25 years of age and older (5.7% in 2013–2014).

3. Exclusive, past-30-day use of e-cigarettes among 8th-, 10th-, and 12th-grade students (6.8%, 10.4%, and 10.4%, respectively) exceeded exclusive, past-30-day use of conventional cigarettes in 2015 (1.4%, 2.2%, and 5.3%, respectively). In contrast— in 2013–2014 among young adults 18–24 years of age—exclusive, past-30-day use of conventional cigarettes (9.6%) exceeded exclusive, past-30-day use of e-cigarettes (6.1%). For both age groups, dual use of these products is common.

4. E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, particularly the use of combustible tobacco products. For example, in 2015, 58.8% of high school students who were

current users of combustible tobacco products were also current users of e-cigarettes.

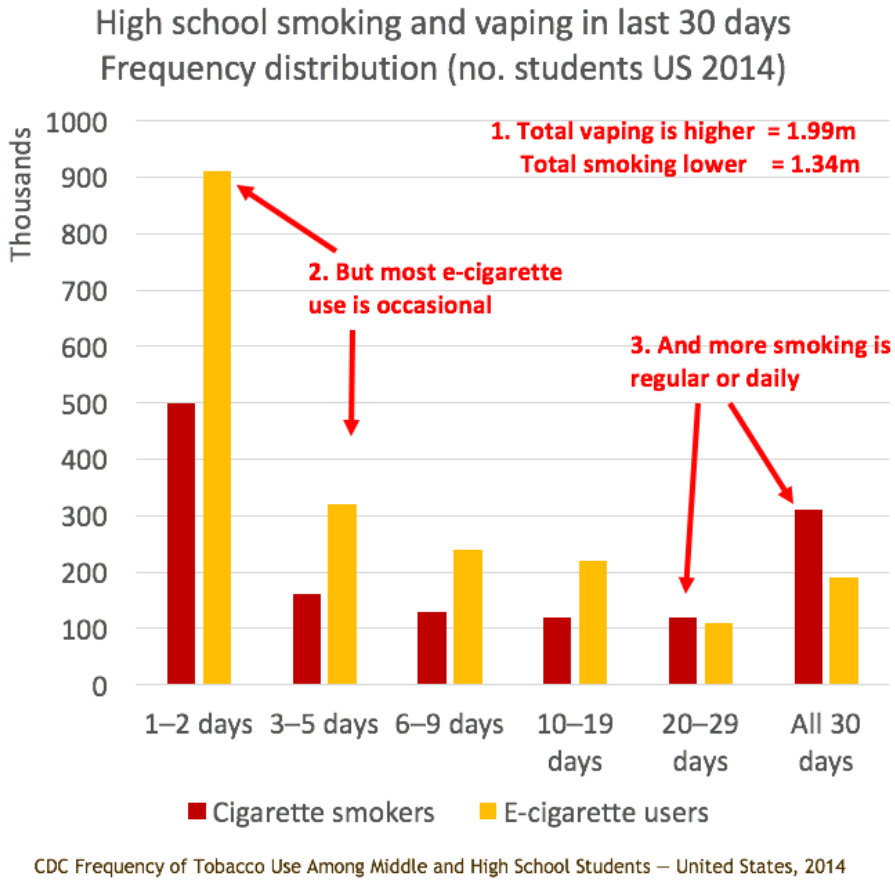
5. Among youth—older students, Hispanics, and Whites are more likely to use e-cigarettes than younger students and Blacks. Among young adults—males, Hispanics, Whites, and those with lower levels of education are more likely to use e-cigarettes than females, Blacks, and those with higher levels of education.

6. The most commonly cited reasons for using e-cigarettes among both youth and young adults are curiosity, flavoring/taste, and low perceived harm compared to other tobacco products. The use of e-cigarettes as an aid to quit conventional cigarettes is not reported as a primary reason for use among youth and young adults.

7. Flavored e-cigarette use among young adult current users (18–24 years of age) exceeds that of older adult current users (25 years of age and older). Moreover, among youth who have ever tried an e-cigarette, a majority used a flavored product the first time they tried an e-cigarette.

8. E-cigarette products can be used as a delivery system for cannabinoids and potentially for other illicit drugs. More specific surveillance measures are needed to assess the use of drugs other than nicotine in e-cigarettes.

Reaction. The data on usage patterns are correct but give an incomplete and highly misleading account of the picture. Most e-cigarette use among US high school students is occasional or experimental and does not involve nicotine (see Q2 of my Five questions for the Surgeon General) only around 1 percent of high school students vape daily. This is a more realistic view:



CDC Frequency of Tobacco Use Among Middle and High School Students – United States, 2014

Strong association between vaping and smoking. The Surgeon General should not be concerned by the strong association between vaping and smoking (4) because this means that vaping is concentrated primarily in those who smoke or would be likely to smoke – to the extent that they vape instead, there is a public health benefit that he appears to have overlooked. The way the statement is presented the unwary reader might come away with the idea that the vaping causes the smoking. Not so. It means the vaping is caused by the same independent factors that cause smoking – yet it offers a low risk alternative to smoking from which these adolescents susceptible to smoking would benefit.

Flavors. Much is made of flavors and shoring up U.S. activists obsession with flavors. An example of the reasons given for using e-cigarettes comes from Ambrose et al in JAMA, 2015

Leading Reasons for Non-cigarette Tobacco Product Use Among Past 30-Day Tobacco Users, by Product – Population Assessment of Tobacco and Health Study Youth Respondents Aged 12-17 Years, 2013-2014

Reasons for Use	% (95% CI) e-Cigarettes (n = 418)[c]
I use [product] because they come in flavors I like	81.5 (77.9-85.0)
I use [product] because they are affordable	47.8 (42.9-52.6)
I use [product] because I can smoke/use them at times when or in places where smoking cigarettes isn't allowed	58.9 (54.1-63.7)
I use [product] because I like socializing while using them	40.3 (34.9-45.8)
I use [product] because it doesn't bother non-tobacco users	53.9 (48.1-59.8)
I use [product] because they might be less harmful to me than cigarettes	79.1 (75.2-83.0)
I use [product] because they might be less harmful to people around me than cigarettes	78.1 (74.3-81.8)
I use [product] because they don't smell	58.7 (54.2-63.2)
I use [product] because they help people to quit smoking cigarettes	59.5 (54.6-64.5)
I use [product] because people who are important to me use them	34.9 (30.6-39.2)
I use [product] because people in the media or other public figures use them	36.1 (31.5-40.7)

This table illustrates the danger of overinterpreting surveys of what kids say they are doing to be the reasons why they are doing it. The subjects were presented with a yes/no choice for each of the reasons given. It is true that they answered 'yes' to the first question – they like the flavors. But isn't this an obvious answer if you have already decided to vape? Given you didn't have to choose only one answer, who would answer 'no' to that question: "*No, I don't use the products because they come in flavors I like*"? Also, note how many do give positive, pro-health reasons for vaping: less harmful than cigarettes (79.1%); less harmful to people around me (78.1%); help people to quit (59.5%); doesn't bother non-tobacco users (53.9%). Such virtuous reasons were overlooked by the Surgeon General.

A majority used a flavoured product first time. Given all vaping products are flavored, it must be assumed that he means a non-tobacco flavour. But what is the virtue of using a tobacco flavor? Surely, if more used tobacco flavors the SG would be consumed with anxiety about a gateway to tobacco use! You can see in this a pattern that can find pbad news in any observation – even in polar opposite findings.

Adults use tobacco. Of course tobacco flavors are more popular among older vapers – they are more likely to be habituated to tobacco, enjoy tobacco or need it as part of a transition.

The SG provides no evidence that vaping cannabinoids increases cannabis use. He does not consider that vaping cannabinoids might be safer than smoking cannabis and more controlled than eating it in cookie form. He has done little more than bring this in to add a whiff of reefer madness to the overall moral panic he is trying to develop.

Chapter 3. Health Effects of E-Cigarette Use Among U.S. Youth and Young Adults

1. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.

2. Nicotine can cross the placenta and has known effects on fetal and postnatal development. Therefore, nicotine delivered by e-cigarettes during pregnancy can result in multiple adverse consequences, including sudden infant death syndrome, and could result in altered corpus callosum, deficits in auditory processing, and obesity.

3. E-cigarettes can expose users to several chemicals, including nicotine, carbonyl compounds, and volatile organic compounds, known to have adverse health effects. The health effects and potentially harmful doses of heated and aerosolized constituents of e-cigarette liquids, including solvents, flavorants, and toxicants, are not completely understood.

4. E-cigarette aerosol is not harmless "water vapor," although it generally contains fewer toxicants than combustible tobacco products.

5. Ingestion of e-cigarette liquids containing nicotine can cause acute toxicity and possibly death if the contents of refill cartridges or bottles containing nicotine are consumed.

Reaction No-one in public health wishes young people to use nicotine in any form, but the Surgeon General fails to give any sense of the *magnitude* of

the risks he is describing or how they *compare* to the risks of smoking – or to other drugs like alcohol, caffeine or cannabis. Is this a big deal or not? We have no way to know. Some of these risks have a slender evidence base, for example the claim that nicotine harms the adolescent brain relies primarily on animal studies (see my Fourth question to the SG) and the Surgeon General does not present data that shows teenage nicotine exposure has led to material impairments in brain function in exposed human (eg. generations of smokers). Simply stating that there is an exposure to chemicals fails a basic tenet of toxicology – the magnitude of the dose matters, and "known to have health effects" ducks the issue of whether they have health effects at the exposures measured from e-cigarette use. Despite the prominence given to this argument the evidence relies almost exclusively on animal studies and smokers. It has no epidemiological support in human populations.

Pregnancy. Again, no-one would advise women who are pregnant to take up vaping, and almost no-one would. The question is whether vaping could help women who smoke radically to reduce risk to themselves and to their baby by vaping instead of smoking. The SG seems completely out of touch with the struggles people have with smoking. Professor Linda Bauld explains:

"This report mentions the issue of e-cigarette use in pregnancy, stating that nicotine delivered by e-cigarettes can affect fetal and post-natal development including causing sudden infant deaths (SIDS) and obesity in children.

"This is a fundamental misunderstanding of the evidence and leaps from studies in mice and rats to what might happen in humans. We know Nicotine Replacement Therapy is safe – a recent study from the University of Nottingham found no adverse impact on the children of mothers who used it in pregnancy and followed up these infants until they were two years old. The evidence on sudden infant deaths primarily relates to the tobacco smoking in pregnancy which is hugely harmful and is one of the main causes of SIDS. To conflate this with e-cigarettes is inaccurate.

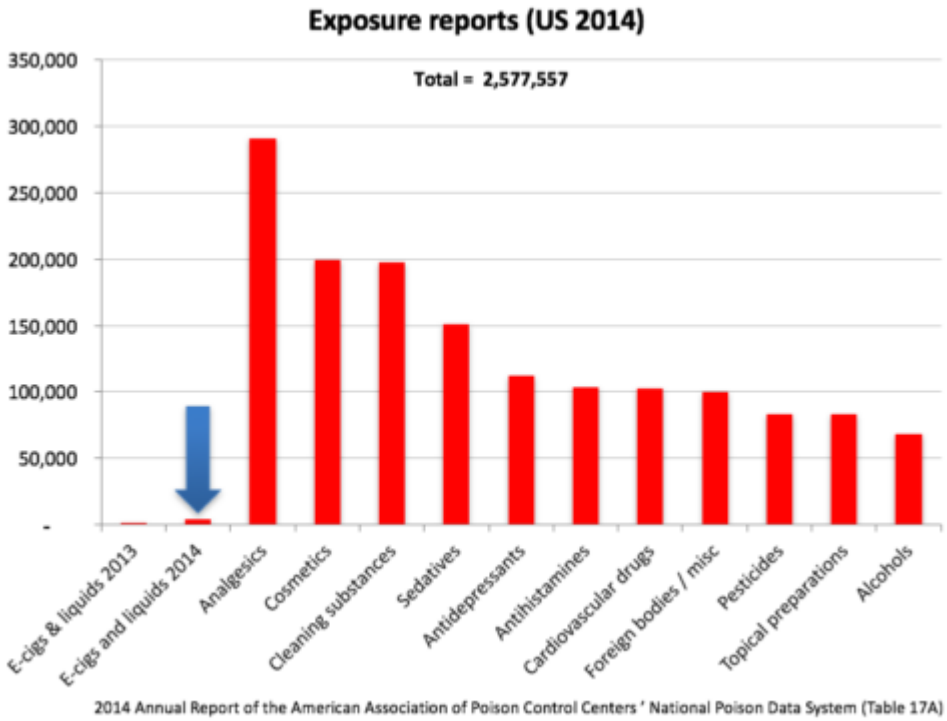
A more constructive approach is taken to smoking in pregnancy in the UK.

Youth behavior. The SG appears to have very little insight into young people. Here's the thing, they don't all do what you tell them. As with other youth risk behaviors extensively documented by CDC [CDC – Youth Risk Behavior

Surveillance — United States, 2015] for example teenage sex, alcohol use and illicit drugs, it is important to recognize that some will engage in risky behavior whatever advice they are given by Surgeon General or CDC and whatever measures are taken to stop them. The public health imperative should be to reduce any harm that is caused to the greatest extent possible. The changing patterns of nicotine use in recent years coinciding with the rise of e-cigarettes suggest a significant harm reduction effect to adolescent nicotine users. The Surgeon General does not say whether adolescents should no longer use NRT to quit smoking – or if he would rather have a lower probability of quitting smoking in return for a reduced exposure to nicotine. He takes the lazy doctor approach of wanting better people rather than helping people to get better.

Water vapor? Who claims this? It is actually a 'claimed claim', a straw man and a distraction.

Poisoning incidents are extremely rare and calls to poison centers are very low compared to other other substances commonly found in the household. We manage poison hzards in the home with child-resistant packaging, warnings, and advice on what to do if exposed.



Chapter 4. Activities of the E-Cigarette Companies

1. The e-cigarette market has grown and changed rapidly, with notable increases in total sales of e-cigarette products, types of products, consolidation of companies, marketing expenses, and sales channels.

2. Prices of e-cigarette products are inversely related to sales volume: as prices have declined, sales have sharply increased.

3. E-cigarette products are marketed in a wide variety of channels that have broad reach among youth and young adults, including television, point-of-sale, magazines, promotional activities, radio, and the Internet.

4. Themes in e-cigarette marketing, including sexual content and customer satisfaction, are parallel to themes and techniques that have been found to be appealing to youth and young adults in conventional cigarette advertising and promotion.

Reaction. Industry growth. The industry has grown and provided over 8 million Americans with low risk alternative to smoking, either to quit or to cut down – which is good news and should be welcomed by the Surgeon General. Because teenagers live in a world with shops and gas stations, televisions and magazines, and the internet, it is unsurprising that they see e-cigarettes and promotions aimed at adults. There is no excuse for targeting teenagers, but the Surgeon General should recognise that market that attracts adult smokers, of any age, to try vaping as an alternative to smoking is anti-smoking advertising and, if it is effective, it is beneficial to health. Again, the Surgeon General fails to place this marketing in context – a disruptive intervention in the dominant incumbent cigarette market.

Prices. E-cigarettes prices are inversely related to sales volume? Doctors never fail to embarrass themselves when then stray into commerce or economics. Prices can fall as volumes rise for several reasons: economics of scale, improving technology, greater competition, changing demand and so on. This is normal and beneficial.

Marketing. It is true that marketing imagery makes the product attractive –

that is the idea. It is what marks vaping products out from NRT (boring worthy) as consumer alternatives – this is the very essence of their success: they appeal to smokers as attractive alternatives to smoking – a marketing 'value proposition'

Chapter 5. E-Cigarette Policy and Practice Implications

1. The dynamic nature of the e-cigarette landscape calls for expansion and enhancement of tobacco-related surveillance to include (a) tracking patterns of use in priority populations; (b) monitoring the characteristics of the retail market; (c) examining policies at the national, state, local, tribal, and territorial levels; (d) examining the channels and messaging for marketing e-cigarettes in order to more fully understand the impact future regulations could have; and (e) searching for sentinel health events in youth and young adult e-cigarette users, while longer-term health consequences are tracked.

2. Strategic, comprehensive research is critical to identify and characterize the potential health risks from e-cigarette use, particularly among youth and young adults.

3. The adoption of public health strategies that are precautionary to protect youth and young adults from adverse effects related to e-cigarettes is justified.

4. A broad program of behavioral, communications, and educational research is crucial to assess how youth perceive e-cigarettes and associated marketing messages, and to determine what kinds of tobacco control communication strategies and channels are most effective.

5. Health professionals represent an important channel for education about e-cigarettes, particularly for youth and young adults.

6. Diverse actions, modeled after evidence-based tobacco control strategies, can be taken at the state, local, tribal, and territorial levels to address e-cigarette use among youth and young adults, including incorporating e-cigarettes into smokefree policies; preventing the access of youth to e-cigarettes; price and tax policies; retail licensure; regulation of e-cigarette marketing that is likely to attract youth and young adults, to the extent feasible

under the law; and educational initiatives targeting youth and young adults. Among others, research focused on policy, economics, and the e-cigarette industry will aid in the development and implementation of evidence-based strategies and best practices.

Rapid reaction. This section of the report is by far the worst and most damaging. How can the Surgeon General make policy proposals for e-cigarettes when the report does not even consider adult use and potential benefits for adults, and therefore potential harmful unintended consequences of policy intervention? A related point is whether the 'Action' proposed will stop young people migrating away from smoking and onto vaping. The Surgeon General recommends research to guide policy – it would be better to recommend policies *after the research is done.*

The Royal College of Physicians (2016) were seized by the risk of well-meaning policy intervention causing more harm than good by indirectly protecting the cigarette trade and causing more smoking.

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

The concept of 'unintended consequences does not even appear to have occurred to the Surgeon General, who has made multiple policy recommendations without even considering possible negative effects. His policy recommendations are baseless and irresponsible. It may be possible to justify these measures, but they are not justified here. Here's what could go wrong…

- Add vaping to smoke-free policies? This may drive vapers back to smoking and may reduce number who switch. It imposes legal override of property

owner's policy with no rationale and may have knock on effects to welfare.

- Prevent youth access to e-cigarettes? Increases relative ease of obtaining cigarettes, make it harder to switch to a lower risk product – encourages smoking. There is already evidence that youth e-cigarette access restrictions have increased smoking [PubMed][PubMed]
- Raise prices? Deter uptake of vaping and attenuate price motivation to switch.
- Regulating of marketing? If done to excess will make the marketing boring and sterile and make products unappealing to smokers. More smoking may result.
- Education initiatives? On the strength of the Surgeon General's advice to parents, such initiative will do more harm than good by frightening people (including adults indirectly) about vaping risks, so diminishing the appeal relative to smoking.