

# A response to the SCHEER preliminary opinion on electronic cigarettes

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In September 2020, the EU's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published a preliminary opinion (SCHEER 2020) on electronic cigarettes which assesses the risks associated with vaping products and is designed to alert the European Commission to the "potential need for legislative amendments" to the Tobacco Products Directive. This briefing responds to the committee's key claims and adds insights from the economics literature.

The authors of the SCHEER report appear to be biased against e-cigarettes and harm reduction. The report reheats several arguments, such as the 'gateway effect' and the 'renormalisation' hypothesis, which are now a decade old and have been contradicted by real world evidence. While it downplays strong evidence showing that e-cigarettes have been a gateway *from* smoking for millions of people, it amplifies speculation about hypothetical risks. When the authors are unable to find adequate evidence for anti-vaping claims, they quote from organisations which share the same prejudice. Much of the evidence is treated selectively and some of the conclusions made about the strength of evidence are baffling.

#### Introduction

On 23 September 2020, the EU's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published its preliminary opinion on electronic cigarettes (hereafter referred to as 'the report'). This briefing responds to the committee's key claims and adds insights from the economics literature.

The report identifies potential health risks from e-cigarettes, mostly due to nicotine consumption. Since the vast majority of vapers are former or current smokers, it would be more useful if the report had looked at the risks of vaping relative to the risks of smoking. Nevertheless, nothing in the report contradicts previous estimates that vaping carries less than five per cent of the risk of smoking tobacco.

The report can find very little evidence that secondhand exposure to e-cigarette vapour may be a health threat. Given the paucity of evidence showing substantial risk to active users, and the vastly lower doses non-users are exposed to, it is puzzling that the authors nevertheless conclude that the evidence of risk to non-users is "weak to moderate". It would be more accurate to say that it is negligible to non-existent.

The report finds no evidence that "specific flavourings used in the EU pose health risks for electronic cigarette users", but notes that "flavours attract both youth and adults to use electronic cigarettes". Flavoured (i.e. non-tobacco flavour) e-cigarettes are used by the majority of vapers of all ages. It is reasonable to assume that smokers would be less likely to switch to e-cigarettes if they did not like the flavour. A wide range of flavours is therefore essential to encourage this form of smoking cessation.

The report concludes that "there is strong evidence that electronic cigarettes are a gateway to smoking for young people". This mistakes quantity of evidence for quality. Studies showing a correlation between past use of e-cigarettes and tobacco all suffer from the same flaw: it is extremely difficult to control for personality traits which lead to experimentation and risky behaviours. It is impossible to categorically disprove the existence of a gateway effect, but the sharp decline in smoking prevalence in countries where vaping has become popular strongly suggests that if such an effect exists, it is trivial and heavily outweighed by the use of e-cigarettes as a gateway *from* smoking.

There is strong evidence from randomised control trials and observational studies that e-cigarettes are effective smoking cessation aids. SCHEER's conclusion that this evidence is "weak" is baffling, particularly when the committee interpret a weaker evidence base for the gateway effect as being "strong".

Evidence from the economics literature shows that cigarettes and e-cigarettes are substitute products. Taxes and policies aimed at suppressing demand for e-cigarettes, such as flavour bans, lead to higher smoking rates and greater consumption of the most hazardous nicotine product - the combustible cigarette. Evidence from economics, which is not included in the report, helps to resolve some of the questions faced by policy-makers.

## Health risks

Harm reduction is a well-established concept in public health. Reduced-risk substitutes for hazardous products are not expected to be totally safe (*nothing* is totally safe). They are only expected to be significantly safer. The UK's Royal College of Physicians (2016: 84) has concluded that the long-term health risks from vaping are "unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure". The evidence in the report is consistent with this.

The report would be more useful if it compared the risks of vaping with the risks of smoking, since the vast majority of e-cigarette users are current or former smokers. Instead, it speculates about possible risks from substances in e-cigarette vapour, particularly nicotine. Nicotine is known to have a modest effect on the cardiovascular system similar to caffeine and certain foods, but there is no evidence that this poses a significant health threat to vapers, nor to users of snus or nicotine replacement therapy (NRT). According to a review conducted by Stephens (2018), lifetime cancer risk associated with vaping is less than one per cent of that associated with smoking (this study is mentioned in the report, but that important finding is not.)

The report notes that the most common respiratory problem associated with vaping is mouth and throat irritation which dissipates over time. It classifies the evidence for this as "strong". Similarly, it classifies the evidence of systemic effects on the cardiovascular system as "strong". It is important to remember that the strength of evidence about specific risks does not necessarily imply that the risks are substantial. In this instance, the health risks are quite trivial, especially when compared to smoking.

The report notes rare instances of e-cigarette devices exploding or catching fire. This is an inherent danger with any electrical device and is dealt with through normal product standards regulation. All the incidents of product malfunction in the report involved products that did not comply with the Low Voltage Directive. The report also notes some rare instances of non-fatal poisonings due to people ingesting e-cigarette fluid. It correctly observes that none of the fluids consumed in incidents reported to Safety Gate were compliant with the Tobacco Products Directive (TPD).

## Secondhand exposure

The report can find very little evidence that secondhand exposure to e-cigarette vapour may be a health threat. It notes that "despite high levels of carbonyl emissions as reported in several studies above, limited impacts on cardiovascular and/or other health outcomes have been documented". It adds: "Surprisingly, particularly in relation to cardiovascular and other health effects of passive smoking secondary to electronic cigarettes, the authors found that the complete blood counts of otherwise naïve passive smokers are not affected by such exposures". Given the low risks associated with active e-cigarette use, it is not clear why the authors find this "surprising". The doses involved are orders of magnitude smaller, there is no equivalent of sidestream smoke (the smoke that emanates from the lit end of the cigarette), and the nicotine in e-cigarettes is mostly absorbed by the user.

The ability to detect the presence of substances at trace levels is not evidence of harm. Of the four relevant studies cited on pages 51 and 52, one is no more than a description of research yet to be conducted (Shearston et al.), one found no impact of passive (or active) vaping on lung function (Flouris et al.), another looked at carbonyl emissions as described above (Farsilinos and Gillman) and the last found trace levels of nicotine in e-cigarette users' homes. None of this implies harm to bystanders (Ballbe et al.)

Given the hypothetical nature of the threat and the committee's acknowledgement that" data on the long-term consequences of passive smoking of electronic cigarettes on human health are lacking", it is remarkable that the report assesses the evidence of risks to "second-hand exposed persons" as "weak to moderate". It would be more accurate to describe it as negligible to non-existent.

## Flavours

The report expresses concern about e-cigarette flavours possibly encouraging initiation by non-smokers and/or minors. Unflavoured e-cigarette fluid is rarely consumed by vapers. 'Tobacco' flavour is often classed as unflavoured by anti-vaping activists (and I will follow that convention below), but there is no logical reason for this. 'Tobacco' flavour only vaguely resembles

the taste of smoked tobacco and is an artificial flavour like any other. Some vapers like it, others do not. To encourage smokers to switch to vaping, it is important to have a wide range of flavours available.

When e-cigarettes first came on the market, they were only available in tobacco flavour. The higher prevalence of tobacco flavour use among older vapers is likely to reflect, in part, the earlier initiation of the first cohort of vapers. Goldensen et al. (2019) cite evidence from the US PATH survey showing that younger people are more likely to use flavoured juice than older people. However, it is important to recognise the majority of vapers of all ages use flavoured (i.e non-tobacco flavour) e-cigarettes.

The report does not mention another finding in Goldensen et al. (2019: 7):

'Data from observational and qualitative studies suggest that flavored e- cigarettes may aid adult smokers in smoking reduction and cessation efforts. Former smokers cite the wide variety of available flavorings and superior taste of e-cigarettes as factors that aid smoking cessation, and note that restricting the availability of flavorings would make the vaping less enjoyable and reduce the appeal of e-cigarettes.'

A recent study by Yang et al. (2020) found that a ban on e-cigarette flavours in San Francisco led to increased smoking prevalence among 18-24-year-olds. Cigarette sales in the USA have risen in 2020 as a result of federal restrictions on flavours in certain e-cigarette products (Maloney 2020).

The report refers to the Special Eurobarometer 458 survey, but does not mention that it found that "flavours of e-cigarettes were also relatively unimportant as a reason for starting to use them". This reason was cited by only 12 per cent of EU vapers when asked which factors were important in their decision to start using e-cigarettes. The most common response, mentioned by 61 per cent of vapers, was "to stop or reduce your tobacco consumption". The report correctly notes that the same survey found that 81 per cent of vapers opposed a ban on flavours, with only 9 per cent in favour.

The section on flavours concludes by repeating claims and recommendations from the European Heart Network, a pressure group that has always opposed tobacco harm reduction and wants e-cigarette flavours prohibited. It makes the unsubstantiated claim that young people who experiment with e-cigarettes are "at substantial risk of becoming regular cigarette smokers". However, the group admits that: "Whether these young people would have started smoking conventional cigarettes had e-cigarettes not existed is a question that we cannot answer" (European Heart Network 2019: 15). This issue is discussed below.

## **Gateway claims**

The 'gateway effect' is a term borrowed from War on Drugs rhetoric designed to encourage the prohibition of low-risk substances on the basis that their consumption inevitably leads to the use of high-risk substances. The concept remains highly controversial. Anti-vaping activists have been claiming that vaping acts as a stepping-stone to combustible tobacco consumption for at least a decade. A number of cross-sectional and longitudinal studies, mostly from the USA, have produced evidence that purports to supports this claim.

The report puts significant weight on a meta-analysis by Soneji et al. (2017) which looked at nine studies, one of which was a conference abstract. The lead author (Samir Soneji) was co-author of a third of the studies reviewed. All the studies found that people who had ever used an e-cigarette were more likely to have later smoked a cigarette. Several studies with similar results have since been published. From this, it is inferred that the individuals who began smoking would not have done so had they not first started vaping.

Since this is impossible to prove (or disprove), the report is wrong to claim that "there is strong evidence that electronic cigarettes are a gateway to smoking for young people". This mistakes quantity of evidence for quality. Regardless of how many studies find an association between ever-vaping and ever-smoking, they are all flawed in the same way. Meta-analyses then suffer from the problem of 'garbage in, garbage out'.

The crucial missing variable is personality. The kind of person who is more likely to try an e-cigarette is the kind of person who is more likely to try a cigarette. Conversely, the kind of person who has a strong aversion to cigarettes is more likely to abstain from vaping. These personality traits are extremely difficult to control for and no researcher has yet found an adequate way of doing so. In the absence of sound methodology, 'gateway' studies only show that adolescents who are not risk averse will try

different things and that the kind of people who would have experimented with cigarettes before e-cigarettes were on the market sometimes try vaping first (Phillips 2015).

Switching from e-cigarettes to cigarettes makes little sense in either financial or health terms, but we cannot rule out the possibility that it has ever happened. At the population level, the important question is whether the relative popularity of vaping among some adolescents has led to a surge in combustible tobacco use. A related question is whether the increased use of e-cigarettes has led to what the report calls the "renormalisation of cigarette smoking [that] could lead to a resurgence of cigarettes smoking" (p. 69). These concerns are now a decade old. The Soneji study suggests that non-smoking vapers are 3 or 4 times more likely to become smokers than abstainers. This would be a large effect, if true. If there was a gateway effect of any significance, it should be apparent in the data. Smoking rates should be rising, or at least falling more slowly, in countries where vaping has become popular.

In reality, e-cigarette use is associated with sharp declines in the smoking rate (including the youth smoking rate). After vaping became popular in 2012, England's smoking rate fell by 20 per cent in just five years, following five years in which the rate had been almost flat. In the same period, the smoking rate among children halved and is now at the lowest rate on record. Of the people in the UK who have used both cigarettes and e-cigarettes in their lives, 91.8 per cent used cigarettes first while only 0.1 per cent used e-cigarettes first (Office for National Statistics 2020).

The report acknowledges that the USA saw a decline in smoking prevalence between 2014-2017 "which coincides with the timeframe of electronic cigarette proliferation in the US" (p. 17). This understates the impact of vaping. Cigarette smoking by American middle school students nearly halved between 2011 and 2019, from 4.3 per cent to 2.3 per cent, and fell by more than half among high school students, from 15.8 per cent to 5.8 per cent. These are historic declines occurring at a time when 4.7 per cent of middle school students and 19.6 per cent of high school students are current (past 30-day) e-cigarette users. Vaping is far more common among US school students than it was in 2011, and whilst this is not a welcome development in itself, it is striking that it has coincided with large declines in the smoking rate. The same is true of American adults who now smoke at the lowest level on record: down from 18.1 per cent in 2012 to 13.7 per cent in 2018.

The US adult smoking rate fell by 4.4 percentage points between 2012 and 2018. England's adult smoking rate fell by 4.5 percentage points in the same period. By contrast, in Australia, which has a ban on nicotine vaping products and some of the world's strongest tobacco control policies, the adult smoking rate only fell by 1.8 percentage points between 2013 and 2019.<sup>1</sup>

None of this categorically disproves the existence of a gateway effect (which, as mentioned, would be impossible), but it strongly suggests that if such an effect exists, it is trivial and heavily outweighed by the use of e-cigarettes as a gateway *from* smoking. Amongst younger people, vaping may well act as a prophylactic against smoking.

The rapid decline of smoking in countries where e-cigarette use is common implies that there has been no 'renormalisation' of smoking. There is also empirical evidence from the UK showing that negative attitudes towards smoking among young people have remained strong despite the widespread acceptance of vaping (Brown et al. 2020; Hallingberg et al. 2020).

## **Smoking cessation**

It is now well established that vaping helps people quit smoking. The report does not agree. Why?

Unlike the issues of flavours and the gateway effect, smoking cessation can be studied through randomised control trials (RCTs), the gold standard of scientific evidence. The report acknowledges three RCTs included in the Hartmann-Boyce meta-analysis (Bullen et al. 2013, Carponnetto et al. 2013, Adriaens 2014). All of them showed that smokers were more likely to quit smoking if they used e-cigarettes than if they used a placebo or nicotine replacement therapy. This was particularly impressive since two of the RCTs involved smokers who had no desire to quit at the outset.

The report also mentions more recent RCTs by Hayek et al. (2019) and Walker et al. (2019). The former found smokers to be nearly twice as likely to quit using e-cigarettes than if they used nicotine replacement therapy. The latter found that smokers

<sup>&</sup>lt;sup>1</sup> The Australian government only collects smoking prevalence data every three years.

using nicotine patches plus a nicotine e-cigarette were more likely to quit than those using patches plus a zero-nicotine e-cigarette.

The evidence from RCTs is consistent with evidence from observational and ecological studies. For example, a study by Zhu et al. (2017), which is not cited in the report, found that the "substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level." A study of vape shop customers found that 41 per cent had quit smoking within a year of taking up e-cigarettes (Polosa et al. 2015). A clinical trial using second generation e-cigarettes saw 53 per cent of subjects quit smoking (Pacifici et al. 2015). A recent analysis of 13,057 current and former smokers in 28 EU countries, which is not cited in the report, found that current e-cigarette users were almost five times more likely to have quit smoking in the last two years than non-vapers and more than three times more likely to have quit in the last three to five years (Farsilinos and Barbouni 2020).

Given the large body of evidence showing that e-cigarettes are effective smoking cessation devices, it is strange that the report effectively dismisses the science and relies instead on quotes from the US Surgeon General and the European Heart Network, both of whom have a known prejudice against vaping. The report could easily have quoted eminent academics and health groups who believe that e-cigarettes are effective smoking cessation aids. Either way, it is not obvious what purpose such quotations serve in an independent evidence assessment other than to show whose side the authors are on.

The report's conclusion that "there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit" is an extraordinary interpretation given that at least five RCTs and numerous observational and ecological studies have provided strong evidence to the contrary. Elsewhere in the report a much weaker set of studies is cited to support the claim that there is "strong evidence" for a gateway effect. Even the almost non-existent evidence on secondhand vaping is described as "weak to moderate".

This is, at best, inconsistent. When evidence from observational epidemiology shows that some adolescents have as little as one puff on a cigarette having previously tried vaping, it is considered proof of a gateway effect, and yet when evidence from observational epidemiology, national surveys, personal testimonies and RCTs show that large numbers of smokers have switched exclusively to vaping, it is effectively ignored.

Since the SCHEER report was released, a Cochrane Review has concluded that there is "moderate-certainty evidence that ECs [electronic cigarettes] with nicotine increase quit rates compared to ECs without nicotine and compared to NRT" (Hartmann-Boyce et al. 2020).

## **Evidence from economics**

The report understandably focuses on evidence from the medical and scientific literature, but there are studies from the economics literature that help resolve some of the issues at stake. The observation that e-cigarettes are a substitute for, not a complement to, combustible cigarettes is an important one, not least because it suggests that efforts to suppress e-cigarette use will lead to greater use of traditional cigarettes. This is now well established. Several studies have shown that cigarettes and e-cigarettes are substitute products, both in the USA (Zheng et al. 2017) and in the EU (Stoklosa et al. 2016).

Unsurprisingly, therefore, it has been shown that policies designed to deter e-cigarette use have the unintended consequence of increasing both cigarette consumption and smoking prevalence. Pesko et al. (2020) found that "higher e-cigarette tax rates increase traditional cigarette use" and that an e-cigarette tax of US\$1.65 per ml would increase the number of daily smokers by one per cent. Cotti et al. (2020) studied e-cigarette taxes in eight US states and found that a decline in e-cigarette pod sales led to an increase in the sale of traditional cigarettes. Saffer et al. (2019) concluded that a large tax on e-cigarettes in Minnesota prevented 32,400 smokers from quitting. Abouk et al. (2019) found that e-cigarette taxes lead to more women smoking in pregnancy. Friedman (2015) found that banning the sale of e-cigarettes to minors increased the underage smoking rate by 0.9 percentage points.

Economic findings such as these provide indirect evidence that e-cigarettes are used by smokers to quit or cut down their cigarette consumption. And they give us direct evidence of the effects of policies designed to reduce e-cigarette consumption. Interventions that making vaping less attractive to consumers, such as taxes and flavours bans, have been repeatedly shown to increase cigarette consumption and smoking prevalence.

## Bias

The way in which the report places heavy emphasis on studies which imply negative consequences from vaping while downplaying or ignoring evidence showing benefits suggests a prejudice against tobacco harm reduction from at least some of the authors. There is evidence of bias throughout the document.

For example, the report refuses to use the word 'vaping' "because it may imply that the consumption of electronic cigarettes are a 'healthy' alternative to cigarette smoking and consumers may misperceive risks associated with the use of electronic cigarettes. The SCHEER prefers to use the neutral 'use (users) of electronic cigarette'" (p. 19). Aside from the fact that 'vaping' is a perfectly neutral and accurate term for inhaling e-cigarette vapour, the report elsewhere uses phrases such as "electronic cigarette smoking", "heavy smokers of electronic cigarettes" and "electronic cigarette smoking behaviour" which are neither neutral nor accurate and wrongly imply that vaping has similar health impacts as smoking.

On page 20 of the report, it says: "This Opinion is restricted to the terms of references given by the European Commission. It covers electronic cigarette products complying with the TPD". And yet the report makes frequent references to the US version of Juul which is illegal in the EU (although it refuses to refer to it by name), and its section on poisonings and injuries almost exclusively involves products that do not comply with EU regulations. Since illegal products are beyond the committee's purview, it is not clear what purpose this serves beyond spreading alarm.

On several occasions, the authors resort to quoting external organisations when they are unable to find scientific evidence to support anti-vaping claims. On page 46, for example, having admitted that the "health impacts of electronic cigarette's use are still difficult to be established due to the lack of long-term data from epidemiological studies or clinical trials", the report quotes the World Health Organisation saying, in 2016, that e-cigarettes "are harmful to health and are not safe". It then gratuitously lists some anti-vaping policies that the WHO would like to implement. Unless the WHO has some evidence that has been withheld from SCHEER, it is not clear what relevance its opinions have.

Similarly, on page 60, the report quotes another WHO document written by anonymous authors which claimed that "long-term use is expected to increase the risk of chronic obstructive pulmonary disease, lung cancer, and possibly cardiovascular disease as well as some other diseases also associated with smoking". None of this is supported by the evidence in the SCHEER report. The only reference for these claims in the WHO document is Britton et al. (2016) which, in turn, cites *Nicotine Without Smoke*, a report from the Royal College of Physicians (2016). The relevant section of the RCP report states that long-term e-cigarette use "would be expected, *from first principles*, to increase the risk of lung cancer, COPD, cardiovascular disease and other diseases caused by smoking, but at much lower levels of risk" (my emphasis). The RCP report further notes that "there is very little evidence that short-term use of e-cigarettes causes any appreciable harm to users or to others" and concludes: "The risks attributable to long-term inhalation of nicotine in isolation from tobacco smoke, and of the propylene glycol, glycerine and other components unique to e-cigarettes, are also uncertain but likely to be low. The health harm to long-term users of e-cigarettes is therefore likely to be marginally greater than for those who use conventional NRT." The SCHEER report, like the WHO document it quotes, ignores this important context.

## Conclusion

E-cigarettes have been on the market for over a decade. They have always split opinion, and they continue to face resistance from some activist-academics, particularly in California and Australia, but hard data from countries in which vaping has become mainstream has allayed the early concerns. By reviving concepts such as 'renormalisation' and the 'gateway effect', as well as by casting doubt on vaping's role in smoking cessation, the SCHEER report is a step backwards.

The authors appear to be biased against e-cigarettes and harm reduction. While the report downplays strong evidence showing that e-cigarettes have been a gateway *from* smoking for millions of people, it amplifies speculation about hypothetical risks. When the authors are unable to find adequate evidence for anti-vaping claims, they quote from organisations that share the same prejudice against e-cigarettes. Much of the evidence is treated selectively and some of the conclusions made about the strength of evidence are baffling. By misclassifying weak evidence as moderate or strong (and vice versa), the report sends a misleading message to the European Commission and to member states. Attention should be paid to evidence from the economics literature, which is not included in the report, but which helps resolve some of the questions faced by policy-makers.

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