Written evidence submitted by
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About the Authors
We write as a medically qualified professor of public health with considerable experience in researching tobacco policy, in particular the activities of the tobacco industry, and a health practitioner, involved in the management of patients with respiratory disease, who has undertaken an extensive review of the evidence on issues related to the use of electronic cigarettes. We welcome this opportunity to submit evidence regarding the Committee’s enquiry into e-cigarettes, and arrange the material in our submission sequentially, in order to address systematically the Committee’s stated requests for information regarding the health, regulatory and financial implications of e-cigarettes.

Executive Summary.

- It will be more than 30 years before epidemiological research can quantify risks from e-cigarette use (1)
- Claims that “. . . we must [now therefore] make judgements based on the toxicology of the vapour”. . . based on “measurable quantities” of carcinogens and toxins, concentrations that are “in fact “very low” (1) ignores expert toxicological opinion that carcinogens and toxins observed in e-cigarette aerosol can have significant deleterious health effects at repeated very low doses (2)
- We agree with those who warn of the risks of long term use of e-cigarettes “. . . including an increased risk of chronic obstructive pulmonary disease, lung cancer, possibly cardiovascular disease, and some other long term conditions associated with smoking.” John Britton, Deborah Arnott, Ann McNeill, Nicholas Hopkinson.
- We support an earlier critique of reports by Public Health England (3) and the Royal College of Physicians (4) describing e-cigarettes as “low risk” products as: “in the light of current knowledge, a reckless and irresponsible suggestion” (2)
- Data on efficacy of e-cigarettes as quitting aids are scant and inconclusive.
- Current safety and efficacy evidence do not justify any recommendation to “Promote e-cigarettes widely as substitutes for smoking.”
- Financial forecasting regarding the impacts of e-cigarettes on the NHS is, thus, very problematic
- The growing numbers of non-smokers that vape, and the potential for rising e-cigarette use in children to increase smoking initiation is a real concern.
- Current restrictive regulations on regarding media advertisements should thus be maintained.
The impact on human health of e-cigarettes—themselves and relative to ‘conventional’ smoking—and any gaps in the science knowledge-base in this area.

1.1 There are persisting concerns about the claim made by PHE (3) and the RCP (4) that: “...the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco” (RCP)

1.1.1 The study on which this estimate is based (5) had important limitations, acknowledged by its authors, who noted: “A limitation of this study [was] the lack of hard evidence for the harms of most products on most of the criteria” {our emphasis} Yet, inexplicably, the authors subsequently rejected this as a valid criticism (6). The authors also conceded: “Another weakness might be the kind of sample of experts. There was no formal criterion for the recruitment of the experts ...” Thus, it seems reasonable to conclude that a different selection of experts, sharing an alternate philosophical standpoint i.e. the Precautionary Principle, would likely have generated contrasting opinions.

1.1.2 Expert toxicologists state: “...in truth, ... there is no evidence for the 95% estimate . . .” ... “The quantification of risk in toxicology ... implies some greater confidence in a particular prediction than is conveyed by a mere qualitative statement ... in this case, the information was merely generated by an ad hoc group of experts, and was based on opinions, rather than being grounded in scientific observation” (2)

1.1.3 Despite a lack of hard evidence, the study’s results “provided Public Health England with the basis” ... for their estimate (6)

1.1.4 We, therefore, argue that the widespread promotion claim that e-cigarettes are 95% less harmful than conventional cigarettes cannot be substantiated. In this we fully agree with the view of the World Health Organisation (7), which has stated that: “...no specific figure about how much “safer” the use of these products is compared to smoking can be given any scientific credibility at this time”

1.2. The potential adverse health effects of e-cigarettes compared to conventional cigarettes can be considered in relation to cancer, circulatory and respiratory effects:

A) Cancer

1.2.1 Nicotine is not currently classified as a carcinogen. However, the International Agency for Research on Cancer has declared research into inhaled nicotine via e-cigarettes is a “High Priority” (8), stating that: “... recent evidence has indicated the potential for nicotine to cause DNA damage” ... “exposure to nicotine has [already] been shown to inhibit apoptosis, and stimulate cell proliferation and angiogenesis”

1.2.2 A potent lung carcinogen has been identified in studies involving e-cigarette-only users (9). E-cigarettes deliver the potent lung carcinogen, NNK (4-(N-Methyl-N-nitrosoamino)-1-(3-pyridyl)-1-butanone, also known as Nicotine-derived Nitrosamine Ketone) (9). The dose-effect curve for NNK is nonlinear, with substantial increases in incidence of tumour and DNA adducts at very low doses, at no clear threshold (2)

1.2.3 Other examples of cancer risk include known bladder carcinogens detected in the urine of e-cigarette users, but not non-users (10). It is, therefore, clearly premature for Cancer
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Research UK to publically claim that vaping does not cause cancer, especially considering that “The number of e-cigarette users who have never smoked is [approximately] 180,000 or 7.5% of current users.”

B) Circulatory/Cardiovascular

1.3 A recent review of the current evidence relating to potential cardiovascular health effects of e-cigarettes in humans suggested they are not benign, with some studies suggesting similar risks to smoking cigarettes (11). The major concern is the effect on endothelial function, with several studies showing evidence of oxidative damage even after short-term exposure (12, 13). Only one study has examined flow-mediated dilation of the brachial artery, known to correlate closely with coronary artery function and considered the best measure of the vascular effects of smoking, finding a significant reduction (14). It is noteworthy that the many studies funded by the manufacturers of e-cigarettes have not studied this parameter.

C) Respiratory

1.4 A recent study involving human subjects (15) suggested “the effects of e-cigarettes are overlapping with yet distinct from those observed in otherwise healthy cigarette smokers”, identifying “levels of innate defence proteins associated with Chronic obstructive pulmonary disease . . .”

1.4.1 A study (16) among human subjects reported that “Protein markers of cigarette smoke exposure and COPD pathogenesis were elevated in users of cigarettes and e-cigarettes . . .”

1.4.2 A recent independent review of the pulmonary toxicity of e-cigarettes (17) concluded that major gaps in understanding remained.

1.5 In summary, it is currently impossible to assess the full impact of e-cigarettes on human health due to the absence of appropriate longitudinal data. What evidence exists points to the distinct possibility that long term use of e-cigarettes could cause significant harm, with some effects, such as those on the cardiovascular system, potentially similar to those seen with tobacco cigarettes. However, the available data make it impossible to estimate such risks precisely (2).

1.6 Other important impacts of e-cigarettes to human health include:

1.7 Continued Dual Use of Conventional and E-Cigarettes.

1.7 The RCP highlighted that it is a “mistaken belief” that cutting consumption of cigarettes will elicit significant health benefits for individual smokers (4, p123); Professor Robert West has noted that: “there isn’t good evidence that [reduced consumption] has any benefit.”

1.7.1 This is problematic: a substantial proportion of e-cigarette users continue to smoke i.e. “dual use”, confirmed by ONS data, “Smoking in England: Electronic cigarettes in England” data and other UK research.

1.7.2 In England, there is an inconsistency between self-reported smoking cessation and biochemically validated cessation (18). Therefore, it is difficult to establish the true figure of sustained, fully quit smokers using e-cigarettes, and the extent of relapse over longer terms.
i) Secondhand E-Cigarette Aerosol Risks

1.8. The American Industrial Hygiene Association (19) and the American Society of Heating, Refrigeration and Air-Conditioning Engineers (20) incorporate emissions from e-cigarettes into the definition of “environmental tobacco smoke,” indicating that e-cigarette aerosol is incompatible with acceptable indoor air quality.

ii) Risks of Injuries from E-Cigarettes

1.9. A 2017 U.S. Fire Administration Report describe e-cigarettes as: “... a new and unique hazard” with “no analogy among consumer products to the risk of a severe, acute injury” . . . “One hundred and twenty-one (62 percent) of the incidents of explosion and fire involving an electronic cigarette or its battery occurred when the device was either in a pocket or actively in use” . . . “incidents resulted in 133 acute injuries” . . . “38 (29 percent) were severe.”

iii) The Health Effects of Nicotine on Children.

1.10. It has been clearly demonstrated that very minimal exposure to nicotine can cause, very rapidly, chronic addiction in children/adolescents (21). ASH England state: “Just a puff can lead to nicotine addiction. Children can get hooked at very low levels of exposure.”

1.10.1 One study (22) provided preliminary evidence that use of e-cigarettes with higher nicotine concentrations by youth may increase subsequent frequency and intensity of vaping, and smoking. The comprehensive U.S. Surgeon General Report described deleterious effects of nicotine on child/youth brain development. It has been confirmed that experimentation by children in the UK is increasing (23), including the group who have never smoked conventional cigarettes.

- “The benefits and risks of e-cigarettes as a ‘stop smoking’ tool, any gaps in the knowledge-base on this, and whether any approaches are needed to tackle e-cigarette addiction.

2.1 Only one randomised placebo controlled trial exists utilising biochemically validated smoking cessation, comparing an e-cigarette with NRT (24). It has significant weaknesses, the authors confirming “Achievement of abstinence was substantially lower than we anticipated for the power calculation . . .” “. . . thus we had insufficient statistical power to conclude superiority of nicotine e-cigarettes to patches or to placebo e-cigarettes.”

2.1.1 Allocation of treatment in the e-cigarette group was unrealistic: they were couriered to participants while subjects in the patches group had to take a voucher to a chemist to obtain treatment. It is entirely plausible that the results thus overestimated the efficacy of the e-cigarette. The rate of biochemically validated abstinence at six months was very “modest”: 7.3% in the nicotine e-cigarette group, only 21 of 289 subjects confirmed abstinent at 6 months, despite the idealistic, unrealistic allocation.

2.1.2 Another placebo controlled RCT (25), “overestimated expected abstinence rates and the subsequent sample size (n = 300) was insufficient to detect significant differences” between
placebo and two different strength nicotine e-cigarettes (26). Thus, the Cochrane Review merely notes:

“There is evidence from two trials that ECs help smokers to stop smoking in the long term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean our confidence in the result is rated 'low' by GRADE standards. (26)

2.1.3 An alternative meta-analysis (27) of the same data identified “substantial” loss to follow-up, and subsequently undertook a sensitivity analysis revealing “. . . . results . . . [that] fail to show a difference in the effects of ENDS in comparison with [placebo] ENNDS”.

2.1.4 The US Preventative Services Task Force concluded “the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation”

2.1.5 A meta-analysis of eight e-cigarette cessation cohort studies “failed to show a benefit in cessation”; a subsequent sensitivity analysis suggested “a reduction in cessation smoking rates” using e-cigarettes (27).

2.1.6 Major studies of e-cigarette and cessation (28), due to their cross sectional methodology, cannot establish causality. Promotion of e-cigarettes as scientifically proven, successful smoking cessation tools via such studies is scientifically misleading. A Eurobarometer cross-sectional study (29) cannot demonstrate causality, despite the author’s claims.

2.1.7 An influential “modelling” study (30), suggesting that 6.6 million Americans could be saved by switching to e-cigarettes, was based on major assumptions unsupported by empirical evidence: the authors stated that: “the aim was to examine a hypothetical endgame strategy of reducing cigarette use through switching to e-cigarettes.” [emphasis added]

2.1.8 Enthusiasm for e-cigarettes originated from their potential to deliver nicotine while also providing behavioural elements of smoking e.g. hand-mouth actions (24). However, scientific data demonstrates generally inefficient nicotine delivery compared to the cigarette (Figure 1) plus feedback from users regarding how unsatisfactory e-cigarettes are (31) helps explain key reasons why e-cigarettes have not proved to be a “disruptive technology”.
2.1.9 Claims that the failure to grow the e-cigarette market in the UK is due to misperception of risk ignores the inadequacies of the devices themselves, reported a majority of users (32), likely contributing to the weak data on efficacy in the literature.

2.1.10 The wisdom of adopting a policy of widely promoting e-cigarettes, with no substantiated scientific evidence as quitting aids remains to be seen, and, in our view, poses a risk to the Department of Health’s strategy to reduce smoking.

- The uptake of e-cigarettes among young people and evidence on whether e-cigarettes play a role in ‘re-normalising’ smoking.

3.1. Public Health England correctly stated: “Longitudinal research will be required . . .” to establish whether a “Gateway Effect” exists in youth: youth believed unlikely to ever smoke, to use e-cigarettes, and then, subsequently, transition to smoking. Such longitudinal data, which tracks the same young people over time, exists, coming from the UK, the US and elsewhere. The data suggests that the continued decline in smoking in young people could be faster, if e-cigarettes did not exist; that e-cigarettes are, likely, working to slow the observed decline.

3.1.1 There are two UK longitudinal studies that demonstrate a transition effect (33, 34). The findings suggest the effects of e-cigarettes on subsequent smoking are larger in youth at low risk of initiating smoking.
3.1.2 These data strongly support the findings of a meta-analysis of 9 US longitudinal studies (35). Other longitudinal data confirming a transition effect comes from Canada (36), Mexico (37) and Finland (38).

3.1.3 A study from prominent UK researchers (39) only involved surveys, and not the aforementioned longitudinal data. The authors use a criterion definition so stringent that the behaviour under investigation becomes virtually unidentifiable, decreasing the likelihood of identifying any systematic patterns that exist, and contrasts markedly with the methodology in the other published studies.

- “The effectiveness of regulation on the advertising and marketing of e-cigarettes.”

4.1 Reckless recommendations such as “Don’t discourage vaping” . . . “glorise” [it] (Viscount Ridley, Vice Chair, UK APPG for E-Cigarettes) highlight the importance of the ongoing CAP and BCAP consultation on the proposal to allow lawful ads to make health claims for e-cigarettes, and justifies the retention of the current, strict regulations regarding health claims.

4.1.2 There is inevitable concern about the 2017 Royal Society for Public Health undercover investigation demonstrating 9/10 e-cigarette selling products to non-smokers. The RSPH noted how this is in direct violation of the voluntary Code of Conduct set down by the “Independent British Vape Trade Association”, The Code should become mandatory.

4.1.3 A Trading Standards Institute undercover survey identified an “unacceptable” non-compliance rate of 25% of illegal sales to under 18s. The illegal sale rate of tobacco to under 18 years is 10% (FSI). A Trading Standards investigation in Knowsley, October 2016 identified multiple e-cigarette liquids packaged like children’s sweets, marketing strategies of vape products that mirror the previous irresponsible techniques utilised by the tobacco industry.

4.1.4 We note the close relationship between the UK APPG for E-Cigarettes and the UK Vaping Industry Association (UKVIA), which, as the British Medical Association and the Tobacco Control Research Group based at the University of Bath have shown, is part funded by tobacco companies: Philip Morris International; British American Tobacco and Japanese Tobacco International; and Fontem Ventures, which is the vaping subsidiary of Imperial Products.

4.1.5 It is inconceivable that the tobacco industry has any genuine interest in the promotion of “Tobacco Harm Reduction” policies. As the RCP (4) state:

“Tobacco companies make their money by selling tobacco,” . . . There is little likelihood that the industry sees e-cigarettes as a route out of the tobacco business,” . . . “There is no firewall between a ‘good’ tobacco industry . . . marketing harm-reduction products in the UK and a ‘bad’ one that promotes smoking, or undermines tobacco control activities, in low- and middle-income countries”
4.1.6 The UK Government recently experienced tobacco industry attempts to undermine evidence-based policies with the industry’s legal challenge to standardised tobacco packaging. Mr Justice Green’s ruling described, in detail, tobacco industry misrepresentation, and concealment of evidence.

4.1.7 It is clear that the fundamentally anti-public health behaviours of the tobacco industry have not changed in the time period between Judge Gladys Kessler’s findings, “brought against the major US cigarette manufacturers under the Racketeer Influenced and Corrupt Organizations (RICO) Act for creating an illegal “enterprise” to defraud the public about a wide range of issues related to smoking and health”, and today. The collaboration of the APPG for E-Cigarettes with a tobacco industry front group is inappropriate, and profoundly concerning.

4.1.8 The RCP (4) highlight issues relating to not just politicians, but academics and scientists collaborating with the tobacco industry on “tobacco harm reduction”:

“Tobacco companies’ interest in the concept of harm reduction increased markedly following a 2001 Institute of Medicine report, driven by recognition of a dual opportunity to both ‘(re-) establish dialogue with and access to policymakers, scientists and public health groups and to secure reputational benefits via an emerging corporate social responsibility agenda’” . . .

4.1.9 Although not an e-cigarette, the PMI “Heat-not-Burn” IQOS device is being similarly touted as an alternative tobacco harm reduction device. PMI claim that IQOS is evidence of their $1bn commitment to a “smoke-free world”. Initial, independent evaluations of the “harm reduction” potential for IQOS demonstrate limited benefits, here and here. A recent analysis of the PMI claim (40) elucidates substantial evidence to the contrary. PMI 2017 Third-Quarter Results here demonstrate, at a time when they are claiming to desire a smoke-free future, they are incongruously proud of their expanding share of the international cigarette market.

4.1.10 A study (41) professing to compare the real-world effectiveness of e-cigarettes for adult smokers in two countries with restrictive policies towards e-cigarettes (Canada and Australia) with two countries with less restrictive policies (USA and UK) merely produced a non-representative study. A compelling critique highlighted: “... [that] there are only 50 respondents from either Canada or Australia who reported using an e-cigarette over the entire 11-year period” (42).

- The public finances implications of e-cigarettes, including how the rise in e-cigarette consumption could affect NHS costs.

5.1 APPG for E-cigarettes has argued that:

“*The value of the health gains associated with a single successful quit attempt is £74,000 according to the MHRA. Even applying simple arithmetic shows that the smokers who have switched to vaping, and no longer smoke, already represent savings to the UK of more than £111 billion.*”

This “simple arithmetic” presumes that:

1) Long term vaping will carry zero health costs, which is inconceivable
2) The ASH estimate that 1.5 million smokers have actually switched exclusively to vaping is correct.

5.1.1 In the UK, it has been estimated that e-cigarettes had led to an additional 16,000 – 22,000 smokers successfully quitting in 2014 (43). These estimates on the impact of e-cigarettes on population trends of smoking in England are based on the aforementioned, fundamentally fragile efficacy data (24, 25, 26, 27) and, therefore, cannot be claimed with any certainty, and should not be seen as trustworthy.

5.1.2 It is clear that estimating the financial implications of e-cigarettes is challenging, given severe gaps in evidence on the long term health effects of vaping to smokers, and non-smokers; efficacy of e-cigarettes in maintaining sustained smoking cessation; effects of any increasing transitional effect in youth from e-cigarettes to conventional cigarettes.

All views are of the authors alone, and do not necessarily reflect those of their employers.

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Reference List:


4) Royal College of Physicians. 2016. Nicotine without smoke: Tobacco harm reduction, London, UK.-


