Comment and Context

Please note that the authors, Professor McKee and David Bareham, have previously submitted representations to the Committee regarding their enquiry into E-cigarettes here, however, subsequent to the publication of a very important and comprehensive scientific review of the public health consequences of the devices, and after contacting the House of Commons Science and Technology Committee, it was confirmed that we could “indeed submit another piece of evidence outlining [our] analysis and opinion of this report.” The 613 page report states that:

“Although the use of these products is relatively new, the committee identified more than 800 peer-reviewed scientific studies in this report. Based on this review, the committee has provided a summary of the current state of knowledge about the health risks and benefits of e-cigarette use, and has provided a series of research recommendations.”

It, thus, appeared entirely appropriate to bring the report to the attention of the Committee, and we welcome the opportunity to comment upon it.

Executive Summary.

- The United States National Academies of Sciences, Engineering and Medicine (NASEM) published on 23.01.18. a Report entitled “Public Health Consequences of E-Cigarettes”

- The context for the this report was thus:

  “In 2016 youth e-cigarette use was substantially higher than cigarette smoking or use of any other tobacco product. The Center for Tobacco Products of the Food and Drug Administration requested that the National Academies of Sciences, Engineering, and Medicine convene a committee of experts to conduct a review of the available evidence of the health effects related to the use of e-cigarettes and identify future federally funded research needs. The resulting report is a comprehensive and systematic review of the literature that evaluates the evidence about e-cigarettes and
health, highlights gaps that are a priority for future research, and makes recommendations to improve the quality of this research.”

Key findings of the report include:

1. Relating to the transition of youth from e-cigarettes to conventional cigarettes:
   - “There is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”
   - “Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *moderate evidence* that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.”

2. Relating to the efficacy of e-cigarettes as aids to quit smoking:
   - “Overall, there is *limited evidence* that e-cigarettes may be effective aids to promote smoking cessation.”
   - “There is *moderate evidence* from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation.”
   - “There is *insufficient evidence* from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration–approved smoking cessation treatments.”

3. Relating to “Second-Hand” Exposure to E-Cigarette Aerosol:
   - “There is *conclusive evidence* that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels.”

4. The Report presents a “modelling” analysis that attempts to predict the potential range of population effects that e-cigarettes may have in the future. This is discussed below

The report, therefore, provides answers to some important questions, however, leaves many other vital ones unanswered, and hanging in the balance.
1. Analysis of the Evidence Substantiating a “Gateway Effect” in Children from E-Cigarettes to Conventional Cigarettes.

1.1 The NASEM report concludes that there is “substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults” (their emphasis). This, importantly, runs entirely contrary to the currently stated positions of leading UK organisations on this key issue e.g. Public Health England (PHE), the Royal College of Physicians (RCP) and ASH (UK). The opinion of these organisations comes, as described in our previous submission, from survey data only (1), and not the longitudinal data required to appropriately investigate this issue with optimal scientific methodology (i.e. data generated from the same individuals from at least two time points). As the NASEM authors state: “longitudinal studies were considered stronger evidence compared with cross-sectional studies.”

1.2 The NASEM analysis states that:

“Associations between e-cigarette use and subsequent ever use of combustible tobacco products were observed in regional U.S. samples from California, Hawaii, Texas, Virginia, in nationally representative U.S. samples; and in Canadian, Scottish, and British samples. The overwhelming consistency of results across studies from different locations and across studies that differed in other ways (e.g., wording of survey questions; paper versus internet survey; with versus without biochemical verification of self reported smoking; length of follow-up) strengthened the committee’s confidence in the robustness, validity, and causality of the association of e-cigarette use with transition from never to ever-smoker status.”

Some have questioned the importance, and significance of, “only ever use” of a single cigarette (2), arguing that “One puff on a cigarette, or even more experimentation, provides little evidence of progression to significant smoking.” However, this optimistic presumption ignores other very recently published data (3), indicating that at least 3 in 5 people who ever try a single cigarette continue subsequently to be daily smokers. As the lead author, Professor Peter Hajek of Queen Mary University London, explained:

1.3 “This is the first time that the remarkable hold that cigarettes can establish after a single experience has been documented from such a large set of data. In the development of any addictive behaviour, the move from experimentation to daily practice is an important landmark, as it implies that a recreational activity is turning into a compulsive need. We’ve found that the conversion rate from ‘first time smoker’ to ‘daily smoker’ is surprisingly high, which helps confirm the importance of preventing cigarette experimentation in the first place.”

1.4 As previously highlighted in our initial submission, there are two relevant longitudinal studies from the UK that contributed to the NASEM analysis (4, 5). Other recent data, published outside of the time period searched by the report authors (6), as well as contributing further data supporting the increased risk of transition of low-risk, non-smoking youth from e-cigarettes to cigarettes, provides evidence that counters the claim made by some in the UK that that e-cigarettes are not a “gateway from smoking” for youth. As the authors concluded:

“E-cigarette use was associated with future cigarette use across 3 longitudinal waves, yet cigarette use was not associated with future e-cigarette use.”
1.5 We, therefore, urge the Committee to acknowledge the growing international evidence that there is a real “gateway” from e-cigarettes to conventional cigarettes in youth. We do not argue that the impact of youth transitioning from e-cigarettes to cigarettes will, currently at least, produce sufficient “upward force” on youth smoking rates that will outweigh all the other, multiple forces created by the UK’s comprehensive tobacco control policy. The issue is, however, that a policy of widely promoting e-cigarette use in adult smokers, especially in the clear absence of sound efficacy data for the devices as quitting aids, has the unintended consequence of causing harm to others. Encouraging non-smoking, low-risk youth to smoke, has to be viewed with profound concern.

2. The NASEM Report in relation to the efficacy of e-cigarettes as aids to quit smoking:

2.1 The report confirms the unavoidable conclusion that, currently at least, “Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”

2.2 The NASEM report states that “There is moderate evidence from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation” (their emphasis). The fact that we are not even sure if a nicotine e-cigarette is more effective than a placebo is, as we argued previously, concerning. Proposed UK public health policy and/or stop smoking campaigns that advocate the widespread use and promotion of e-cigarettes as effective quitting aids cannot, we contend, be substantiated by the available efficacy data. Moreover, NHS adverts appearing to claim that e-cigarettes offer, indeed, a “proven” method to quit smoking cannot, clearly, be scientifically substantiated via the current evidence base.

3. Relating to “Second-Hand” Exposure to E-Cigarette Aerosol:

3.1 The NASEM analysis concludes that “There is conclusive evidence that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels.” This substantiates our previous concerns. They explain this important issue thus:

3.2 “The levels of both particulate matter and nicotine were higher in experiments with more than one vaper, and they were extremely high in studies of vaping conventions, where levels of particulate matter and nicotine concentrations were comparable to those founds in bars and nightclubs. Among the other constituents, two studies have detected airborne toluene and other VOCs in the air following vaping experiments. Total VOCs were markedly high and increased with increasing levels of vaping, during a vaping cloud competition, supporting that VOCs are released from the e-cigarettes into the environment during the exhalation of the e-cigarette aerosol. Overall, these exposure studies indicate that e-cigarette vaping contributes to some level of indoor air pollution, which, although lower than what has been observed from second hand combustible tobacco cigarettes, is above the smoke-free level recommended by the U.S. Surgeon General and the WHO FCTC.”

3.3 Thus, the NASEM report states that: “As with second hand smoke, children, pregnant women, the elderly, and patients with cardiorespiratory diseases may be at special risk. The e-cigarette convention studies also suggest that e-cigarette aerosol exposure could be
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substantial for workers in these venues, especially those who are exposed during multiple events.”

3.4 This analysis is, therefore, similar to the conclusions of the American Indoor Hygiene Association here, the American Society of Heating, Refrigerating and Air-Conditioning Engineers here, and now, further we note, subsequent to their submission to the Committee’s enquiry, the UK Committee on Toxicity of Chemicals, Consumer Products and the Environment here, who state:

3.5 “The scoping literature provided in July 2016 on bystander or secondary exposure was sufficient to indicate a possible concern for health, but not conclusive enough to fully evaluate the risk and the Committee will carefully consider exposure to vulnerable populations.”


4.1 The NASEM report presents a model-based prediction of the effects, short-term and long-term, of e-cigarettes. It states that:

4.2 “Under the assumption that the use of e-cigarettes increases the net cessation rate of combustible tobacco cigarette smoking among adults (i.e., the increase in permanent quitting offsets the potential relapsing of former smokers because of e-cigarettes), the modeling projects that use of these products will generate a net public health benefit, at least in the short run. The harms from increased initiation by youth will take time to manifest, occurring decades after the benefits of increased cessation are seen. However, for long-range projections (e.g., 50 years out), the net public health benefit is substantially less, and is negative under some scenarios. With the range of assumptions used, the model projects that there would be net public health harm in the short and long term if the products do not increase net combustible tobacco cessation in adults.”

4.3 This conclusion draws on the evidence summarised in the report on the efficacy of e-cigarettes as an aid to quitting smoking, and the transition effect of youth to smoking via e-cigarettes. There are few data on relapse rates but one newly published study (8) provides some preliminary information, with, among former smokers, e-cigarette use being associated with greater odds of smoking relapse. The new data analysis further provides evidence of initiation of cigarettes by formally non-smokers. In the US, new data published by the CDC (9) reveals, despite the acknowledged rapid increase in use of e-cigarettes over the last few years by adult smokers, and in contrast to the trend from 2005, that in “2016, the prevalence of current cigarette smoking among adults was 15.5%”, and that “no significant change has occurred since 2015 (15.1%) . . .” Thus, the CDC rightly argues elsewhere that: “Proven population-based interventions are critical to reducing the health and economic burden of smoking-related diseases” (9): currently, clearly, e-cigarettes have not been proven to be such. It seems plausible that mass use of e-cigarettes is locking very many smokers into continued dual use with conventional cigarettes, for, as the CDC say elsewhere, “most adult e-cigarette users do not stop smoking cigarettes and are instead continuing to use both products” (10): even one cigarette per day carries with it significant risks (11).

4.4 We note that the concept of “Tobacco Harm Reduction” considers that the “main concern is to reduce tobacco-related diseases . . . provided it is not physically,
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psychologically or socially harmful to the user or to others” (7) {our emphasis}. However, as elucidated by the NASEM report, and other new data, that there is already a significant volume of scientific data confirming that e-cigarettes are, or are likely to, cause unintended harm to various populations i.e. non-smoking youth, bystanders, relapsing smokers, if a policy of advocating their currently uncertain benefits is promoted. We advocate policies incorporating the well-evidenced Precautionary Principle, therefore, when considering the already on-going effects of e-cigarettes.

5. No doubt, the Committee will wish to inquire why the NASEM report and the most recent evidence review from Public Health England (PHE) come to such different conclusions. Having read both, we believe that the former takes a much more critical approach to the evidence, examining the methods in much more detail and, in our view, objectively. In contrast, we suggest that the PHE report places much more evidence on criticising studies that conflict with its conclusions. Thus, we are very surprised that it can be so enthusiastic about the value of e-cigarettes as cessation aids when it notes that “We identified 14 systematic reviews of e-cigarettes for smoking cessation and/or reduction published since our last report, seven of which included a meta-analysis. The authors of the systematic reviews arrived at the same conclusion that further randomised controlled trials of e-cigarettes are needed. However, the reviews that included a meta-analysis produced different results; two found a positive effect on cessation for e-cigarette use, four found an inconclusive effect for cessation and one found a negative effect.” (P16). It then, puzzlingly, fails to give prominence to how the two positive ones were looking at the same limited set of trials. Moreover, given the lack of evidence from high quality trials that these products are effective, it then argues for the need to use observational, non-randomised data, while criticising those meta-analyses that use such sources. It also pays strikingly little attention to conflicts of interest among the authors of the studies it cites, something that we have found separately to be very strongly associated with the study’s conclusions.

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

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Reference List.


10) Centre for Disease Control and Prevention. Electronic Cigarettes. Available at: [https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm)