



5 October 2018

Hon Aaron Stonehouse MLC
Chairperson
Select Committee on Personal Choice and Community Safety
Parliament House, 4 Harvest Terrace
West Perth, WA, 6005

Dear Mr Stonehouse,

Thank you for the opportunity to make a submission to the *Select Committee on Personal Choice and Community Safety*.

The rapid growth of electronic nicotine delivery devices ((ENDS) or more commonly knowns as electronic cigarettes or e-cigarettes) has been heralded by some, including multi-national tobacco companies ('Big Tobacco'), as a potentially important public health measure that could ultimately replace tobacco cigarettes.¹⁻³ However, other authoritative groups, including the Office of the Surgeon General of the United States of America (USA), The World Health Organization, and most Australian medical and public health organisations recommend a cautionary approach until there is clear evidence that they will not become the 'new tobacco' bringing with it a possible myriad of other problems.⁴⁻⁶

In mid-2015 in our commentary published in the Australian Health Promotion Journal of Australia,⁷ we concluded, "From the limited evidence available to date on ECs [e-cigarettes], it is apparent that a cautious approach is warranted with a case that supports strict regulation until rigorous research is conducted." Despite new international publications over the last three years, the conclusions and recommendations documented in our most recent publication⁸ in 2018 on e-cigarettes remain largely unchanged for Australia, as Australia is a unique environment due to its very low smoking rate (12% of adults; and only 2% of 12-17 year olds).⁹

The international debate continues in the public media and scientific literature as to whether ENDS should be readily available to the general public. For example the recent Royal College of Physicians report *Nicotine without Smoke*¹ created substantial conversation amongst the scientific community and was quickly picked up and cited by Big Tobacco, and the vaping industry and community. There were numerous critical reviews of the report and of particular note was the concern relating to the claim of ENDS being 95% less harmful than regular cigarettes. Eminent toxicologist Robert Combes and colleague explained that this finding was simply based on a multi-criteria decision analysis (MCDA) study, whereby a group of "so called" experts considered the harm of a wide range of tobacco products.¹⁰ The products were ranked on a scale where cigarette smoking was ranked at 100% and ENDS at 4%.^{10, 11} This ranking was then uncritically cited by Public Health England (a UK executive agency sponsored by the Department of Health)¹². Combes and Balls¹⁰ stated "If e-cigarettes are really 'safer', then their use should be recommended, but only after an intelligent analysis of their risk to human health, based on integrated in silico, in vitro and clinical studies for both scientific and logistical reasons". Unfortunately, this figure of 95% has been restated and used to support arguments in favour of ENDS.

Fundamental to public health practice is the requirement to do no harm. In their book *Law and the Technologies of the Twenty-First Century*, the authors explored the legal frameworks and principles through which risk from new technologies can be mitigated.¹³ The use of ENDS or vaping is an example of new technology with an impact upon health. Central to the risk mitigation process is the precautionary principle, which is a principle of decision making that requires decision makers in cases where there are threats of

environmental or health harm not to use “lack of full scientific certainty” as a reason for not taking measures to prevent such harm.¹⁴ The trigger to invoke a precautionary principle is based upon the desire to protect a population from a level of risk, and the acknowledgement that there may be a gap in the evaluation of the level of risk due to insufficient data. This insufficiency may include; absence of cause and effect relationship (which for smoking took a long time to demonstrate); quantifiable dose-response relationship; and quantitative evaluation of probability of the emergence of adverse effects following exposure. There should be a reversed burden of proof by requiring that the substances be deemed hazardous until proven otherwise. Until this is done the legislator is not legally entitled to authorise use of the substance unless exceptionally for test purposes. The decision to act is a political decision with decision makers having to determine the level of risk that is acceptable to the society on which the risk will be imposed.

Evidence from the European Union concludes that the ready availability of ENDS in community outlets accompanied along with promotions makes these products attractive to children.¹⁵ Dr Scott Gottlieb, US Food and Drug Administration (FDA) Commissioner, recently singled out vaping giant [JUUL Labs](#) (who now dominates almost 73% of the US vaping market) for what he calls an “epidemic of high school students using e-cigarettes.” In response to the increase in youth vaping in the US, the FDA is investigating JUUL Labs marketing practices, and very recently seized thousands of pages of documents in a surprise inspection.¹⁶ The inspection comes weeks after the FDA announced a crackdown that requires ENDS manufacturers, including JUUL, to submit plans to address youth use of their products within 60 days.¹⁷ The agency has also threatened to ban some flavoured nicotine liquids,¹⁸ which have been found to attract children.^{19, 20}

Tobacco companies are ramping up their advocacy for ENDS as they claim they plan to eventually replace their tobacco products with the much safer ENDS alternative.^{2, 3} Tobacco control experts however are concerned about the dubious tactics of the tobacco industry. They claim that promotional activities to date smack of luring non-smokers especially young people to the new product, rather than just encouraging current smokers to switch to ENDS as a quit aid.⁶ Daube and Moodie²¹ are very clear that Phillip Morris and associated global tobacco companies cannot be trusted as they continue to pour millions of dollars into undermining the global ‘tobacco control’ movement. It is very unlikely they are serious about designing a ‘[Smoke-Free Future](#)’. Evidence from leaked documents offers no indication that the tobacco industry has become less cynical and dishonest over time. Their hypocrisy is epitomised in Phillip Morris’s youth oriented marketing of their ‘[Be Marlboro](#)’ cigarette campaign targeting low and middle income countries.²¹

A critical question is posed for the future. *If the target of ENDS sales is current tobacco smokers, who will be the target once the numbers of smokers continues to fall to very low levels? Can we trust that the ENDS manufacturers will not make their main target young people as the tobacco industry did so successfully over many decades? Now that Big Tobacco is a major player, such a scenario is very likely considering their atrocious and unethical marketing record. Indeed, there is evidence this is already happening worldwide.*^{6, 21}

From the inconclusive evidence we have to date on ENDS, it is apparent that a cautious approach is warranted with a case that supports strict regulation until rigorous research results are published. More randomised controlled trials are needed to compare ENDS to other nicotine replacement therapies and research studies should be designed to assess long-term health outcomes of ENDS use. The same rigor that is applied to new therapeutic products should to be applied to ENDS.⁷ We should remember that nicotine replacement and cessation programs played only a minor role in the decline in regular smoking prevalence in Australia, as the main influences were due to a comprehensive health promotion approach that restricted access and opportunities to smoke. However, above all we must support the precautionary principle, which is a principle of decision making that requires decision makers in cases where there are threats of environmental or health harm not to use “lack of full scientific certainty” as a reason for not taking measures to prevent such harm.¹⁴ The trigger to invoke a precautionary principle is based upon the desire to protect a population from a level of risk, and the acknowledgement that there may be a gap in the evaluation of the level of risk due to insufficient data on the health impact of ENDS.

On behalf of all authors, thank you for your time and the opportunity to make this brief submission.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Kahlia McCausland". The signature is written in a cursive style with a small dot at the end.

Ms Kahlia McCausland, BSc Hlth Prom

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