



14 March 2019

Hon Aaron Stonehouse MLC
Chair, Select Committee on Personal Choice & Community Safety
Legislative Council Committee Office
Parliament House,
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Dear Mr Stonehouse,

RE: Inquiry into Personal Choice and Community Safety

Thank you for your request, dated 27 February 2019, for further details in relation to our recent submission to the Select Committee on Personal Choice & Community Safety. The answers to your questions are provided below.

The Committee understands that Telethon Kids Institute recently published research that found that 6 out of 10 nicotine-free e-liquids contained nicotine as well as a toxic chemical typically found in pesticides. Can you please elaborate on your findings in this research?

This manuscript is freely available at the Medical Journal of Australia website (<https://www.mja.com.au/journal/2019/210/3/nicotine-and-other-potentially-harmful-compounds-nicotine-free-e-cigarette>). In summary, we arranged for ten e-liquids to be tested for nicotine and other ingredients by an independent commercial laboratory. All of the e-liquids tested were labelled as "nicotine-free" and were purchased from Australian suppliers. We found that six of the ten liquids contained nicotine (0.05 to 0.29% abundance). All e-liquids tested also contained 2-chlorophenol, which is used in disinfectants and pesticides, and a range of other contaminants. The percentage of liquids containing nicotine was very similar to that found by the NSW Dept of Health in a similar, but larger, study (<https://www.abc.net.au/news/2018-06-12/not-all-e-juices-are-as-nicotine-free-as-they-claim/9857540>).

Can you please elaborate on the potential for the liquids used in e-cigarettes to poison children?

There have been numerous incidents of children ingesting e-liquids and being poisoned. There has been at least one fatality in Australia (<https://www.kidspot.com.au/news/victorian-baby-dies-after-being-poisoned-by-nicotine-from-ecigarette/news-story/5ebe0240ebb1fb8ee2383c15f65e8678>) and multiple fatalities overseas. A number of recently published studies also show that a significant proportion of total e-liquid/nicotine poisonings occur in children, both in Australia (e.g. <https://www.mja.com.au/journal/2019/210/3/exposures-e-cigarettes-and-their-refills-calls-australian-poisons-information>) and overseas (e.g. the National Poisons Information Service Report 2015/2016: <http://www.npis.org/NPISAnnualReport2015-16.pdf>; and Kamboj et al 2016, *Pediatrics* e20160041: <https://pediatrics.aappublications.org/content/137/6/e20160041>).

Nicotine is highly toxic and recent estimates suggest that that the LD₅₀ of nicotine in humans (the dose required to cause death in 50% of individuals) is between 6.5 and 13mg/kg (Mayer 2014, *Archives of Toxicology* 88(1): <https://link.springer.com/article/10.1007/s00204-013-1127-0>). Thus, for an average 3-year-old, weighing around 14kg, doses of nicotine between 91 and 182mg could be

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fatal. Indeed, one case report shows that ingestion of only 50mg of nicotine (10mL of a 5mg/mL e-liquid) resulted in the fatality of a 15-month-old child (Seo et al 2016, *Korean Journal of Pediatrics* 494; 59(12): 490-3: <https://europepmc.org/abstract/pmc/pmc5300914>). As a result, many jurisdictions (including the EU and certain states in the US) are limiting the size of e-liquid refill containers and the concentration of the nicotine contained therein.

Can you please comment on the unregulated nature of e-cigarettes and what your opinion is on the effects of legalising e-cigarettes?

The unregulated nature of ENDS (electronic nicotine delivery systems) in Australia obviously forces users to obtain these devices and, more importantly, the e-liquids from potentially less-than-reputable (online) sources. This is particularly important with respect to the liquids as many/most are made overseas and there is little-to-no information in regard to their ingredients or the conditions under which they were made. Whilst regulation may increase ENDS usage in Australia, it could potentially therefore make their use safer for the individual.

If regulation is contemplated, however, it should be consistent with all other tobacco products and should extend protections for children and young people. It is clear that marketing approaches that in the past have been used by industry to target young people are also being employed around the world to make vaping attractive to youth (see photograph below). The reality is that e-cigarettes and related devices are just as likely to promote nicotine addiction as combustible cigarettes because they are designed to be efficient delivery devices.



Typical European vaping outlet display, with marketing clearly targeted to children (Italy, 2019).

Can you please comment on the widely-quoted data from Public Health England that e-cigarettes are 95% less harmful than combustible cigarettes?

The PHE report, that stated that e-cigarettes are 95% less harmful than combustible cigarettes, has been widely criticised due to the way the estimate was obtained. Briefly, the “95% less harmful” figure was not based on a review of the available evidence, but rather it comes from a single meeting of 12 people convened to develop “a multicriteria decision analysis (MCDA) model to synthesise their opinions on the harms associated with different nicotine containing products”. Some of the 12 people attending the meeting declared conflicts of interest and/or had received

money from e-cigarette / cigarette companies (Nutt et al. (2014) *European Addiction Research* 20:218-25). Even the PHE report itself admitted that there is a “lack of hard evidence for the harms of most products on most of the criteria.”

Unfortunately, there is simply not enough data at present to accurately estimate how more or less harmful e-cigarettes are than either smoking or breathing clean air. However, as devices that have been designed for the efficient delivery of nicotine to the lungs, they can be considered just as likely to promote nicotine addiction as conventional cigarettes.

What is your view about claims that e-cigarettes and similar products assist smokers to quit smoking tobacco and should therefore be regulated as a therapeutic good?

There is potentially an argument for certain ENDS devices / liquids to be of benefit in assisting smokers to quit smoking tobacco. However, for this to even be considered, such devices would have to go through the process of being registered as a therapeutic good, and to the best of our knowledge, this has not been done for any ENDS device, in any country (there have been attempts in the UK, but they have failed).

In terms of whether e-cigarettes and similar devices actually help smokers to quit, the evidence is slightly in favour of nicotine-containing e-cigarettes helping adult smokers to quit. The 2018 NASEM (National Academies of Sciences, Engineering, and Medicine) report on the Public Health Consequences of E-Cigarettes delivered four main conclusions with respect to e-cigarettes and smoking cessation:

- Conclusion 17-1. Overall, there is **limited evidence** that e-cigarettes may be effective aids to promote smoking cessation.
- Conclusion 17-2. There is **moderate evidence** from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation.
- Conclusion 17-3. 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.
- Conclusion 17-4. While the overall evidence from observational trials is mixed, there is **moderate evidence** from observational studies that more frequent use of e-cigarettes is associated with an increased likelihood of cessation.

Should e-cigarette products that make no therapeutic claims be regulated as consumer goods?

Regulating e-cigarette products that make no therapeutic claims as consumer products could have significant implications on e-cigarette usage rates, particularly amongst non-smokers. It potentially sends the signal that e-cigarettes are completely safe, which is clearly not the case. E-cigarette proponents including Big Tobacco and the Australian Retailers Association have been lobbying for some time to have e-cigarettes regulated as consumer goods in Australia. This lobbying is clearly based on commercial interests, rather than on any data which show that e-cigarette products are beneficial. Conversely, the Thoracic Society of Australia and New Zealand, and Lung Foundation Australia caution against a consumer regulation approach, emphasising that unless e-cigarettes can be proven to be therapeutic (and hence be approved by the TGA), they should be prohibited. This is a complex area, where the current regulatory framework for e-cigarettes largely draws on existing regulations that apply to tobacco products, therapeutic goods, poisons and consumer goods. Nicotine for use in e-cigarettes is currently illegal in Australia (it is classified as a Schedule 7 poison), and therefore selling nicotine containing e-cigarettes, or e-liquids would require changes to the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard).

Do e-cigarettes etc have a proven role to play in harm reduction in relation to tobacco smoking?

According to the NASEM 2018 report on the Public Health Consequences of E-Cigarettes, there is a role for e-cigarettes in harm reduction. The evidence suggests that e-cigarettes pose less risk to an individual than combustible tobacco cigarettes. There is also conclusive evidence that completely substituting tobacco cigarettes with e-cigarettes reduces users' exposure to numerous toxicants and carcinogens present in tobacco cigarettes. That said, completely replacing tobacco cigarettes with almost anything else is likely to reduce users' exposure to toxicants and carcinogens. Additionally, there are no long-term studies investigating the potential for e-cigarette use, or dual use of e-cigarettes and tobacco cigarettes to impact health in humans.

Finally, while the individual risk of harm may potentially be less from the use of e-cigarettes versus regular tobacco products on a unit comparison basis, it is likely that electronic devices increase both the uptake of tobacco smoking and the frequency of tobacco smoking, and hence the level of harm from such products on a population level is likely to be increased. The evidence around this point is discussed in greater detail in the section below. In addition, due to reasons of lower cost and perceived non-toxicity, e-cigarette users may potentially use such devices with much greater frequency than they would smoke tobacco cigarettes, resulting in a greater exposure to harm. We know that tobacco use is highly price sensitive (i.e. there is high price elasticity), and regulation of this industry should thus include tax disincentives to discourage young people taking up vaping, becoming addicted to nicotine, and moving to combustibles.

What is your view about claims that e-cigarettes are not a route into smoking tobacco for children and young people?

There is empirical evidence that teenagers who use e-cigarettes are more likely to start smoking tobacco cigarettes (e.g. Chapman S. *The Conversation*, 2015: <https://theconversation.com/are-e-cigarettes-a-gateway-to-smoking-in-14-year-olds-new-us-data-46468>; and Leventhal et al. *JAMA* 2015;314:700-7: <https://jamanetwork.com/journals/jama/fullarticle/2428954>), and in response to such concerns, the U.S. Food and Drug Administration (FDA) introduced comprehensive measures in 2016 to regulate the sale and marketing of these products. At the end of last year, the FDA extended these regulations to restrict the sale of flavoured e-cigarette products, having identified that these encourage the uptake of smoking in young people (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>). Further to this, in December 2018, the U.S Surgeon General released an advisory on e-cigarette use in young people, describing it as a problem of 'epidemic' proportions, and stressing the importance of protecting children from a lifetime of nicotine addiction and associated health risks (<https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html>).

Finally, the NASEM 2018 report into the Public Health Consequences of E-Cigarettes, perhaps the most comprehensive assessment of the evidence in relation to this question, found that "e-cigarettes might cause youth who use them to transition to use of combustible tobacco products". More specifically, they concluded that:

- Conclusion 16-1. There is **substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.
- Conclusion 16-2. 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.
- Conclusion 16-3. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is **limited evidence** that e-cigarette use increases, in the near term, the duration of subsequent combustible tobacco cigarette smoking.

Your submission (at page 2) briefly touches on several issues which the Committee is considering as part of this inquiry, such as e-cigarettes – can you please elaborate on your position on these issues? Can you please provide the Committee with the research that you have relied upon to reach this position?

As a research organisation, the Institute has advocated on issues only where there is evidence to support that position. As the committee would understand, there is a significant body of evidence underlying each of the issues we outlined. Therefore, it would be particularly helpful if specific questions were identified (as above regarding e-cigarettes) that would assist the committee in its deliberations. I can then direct our resources in answering those questions in the most effective way.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Jonathan Carapetis', with a stylized flourish at the end.

Professor Jonathan Carapetis
Executive Director