

5 October 2017

Dear Professor Robinson,

By email: [bruce.robinson@sydney.edu.au](mailto:bruce.robinson@sydney.edu.au) (cc Council members and Executive)

We write to you as the chair of the NHMRC Council. The latest NHMRC CEO Statement on E-cigarettes<sup>1</sup> was published on 3 April 2017. As a result of subsequent research and overseas experience, in our opinion it is not consistent with the totality of evidence, particularly important studies that have been published since it was completed.

We believe the development of NHMRC Guidelines (as opposed to a CEO Statement) is now appropriate and would be of greater value to consumers, clinicians and policy makers.

We are Australian academics, researchers and clinicians with a special interest in public health, tobacco control and drug and alcohol treatment. We call on the NHMRC to commission an open and comprehensive review of the science. Given the controversial nature of this topic, we believe this process should be conducted by independent scientists with expertise in the area, ones who do not reflect only one of the shades of opinion. Input from international experts would also be desirable.

We recommend that the review takes a harm reduction perspective. E-cigarettes are being used by smokers and ex-smokers as a safer alternative to an existing consumer product, combustible tobacco that prematurely kills around two thirds of its long-term users. Use by non-smokers is rare. **The key safety question is not whether these products are safe, but whether they are sufficiently less harmful than smoking for there to be a potential public health benefit.**

The review would ideally include consideration of how these products can be regulated to minimise risks and maximise potential benefits if that is not beyond the NHMRC's remit. Given the reality that they are commonly used as consumer products, any review of how to regulate them should not be restricted to consideration of regulation as therapeutic goods, but should include options for regulation as consumer products.

According to the National Drug Strategy Household Surveys (AIHW), Australia's smoking rate did not decline significantly over the last 3 years (2013-2016) for the first time in decades. However, smoking rates continue to fall in countries where e-cigarettes are freely available, in some cases, such as the US, faster than ever. It is likely that e-cigarettes are contributing to this rapid decline.

## New evidence

Since the completion of the literature search for the CEO Statement on 4 January 2017 there have been many important scientific studies and reviews on e-cigarettes. Some of the more important recent publications are listed in the Appendix. Along with previous research they support the following statements:

- **Amongst adults, e-cigarettes are being used almost exclusively by smokers and ex-smokers**  
Use by adults who have never smoked is rare in the US<sup>2</sup> and UK<sup>3</sup> (both 0.3%) and even lower in the EU<sup>4</sup>.
- **There is overwhelming scientific agreement that e-cigarettes are much less harmful than smoking**  
The cancer risk from vaping has been estimated as <1% that of smoking<sup>5</sup>, vapers have substantially lower toxin levels (biomarkers) than smokers<sup>6</sup> and the concern about high formaldehyde levels has been debunked<sup>7</sup>.
- **There is growing evidence that e-cigarettes are helping smokers quit, reducing population smoking rates and deaths from smoking**  
A modelling study from the US found that replacing most cigarette smoking with vaping would

prevent 6.6 million smoking-related deaths and 86.7 million fewer life years lost over 10 years. The equivalent effect in Australia would be the prevention of about 500,000 deaths.<sup>8</sup> Smokers who used e-cigarettes in the US were 75% more likely to succeed<sup>2</sup> and daily e-cigarette users were three times more likely to quit than non-users<sup>9</sup>. E-cigarettes are the most popular quitting aid in the US<sup>10</sup>, UK<sup>3</sup> and many other countries.

- **There is no good evidence that e-cigarette use increases adolescent smoking rates**  
In comparable countries, most notably in the USA, as rates of experimental use of e-cigarettes has risen, it has been accompanied by declines in smoking. This scenario is impossible if there is any meaningful gateway effect, meaning some other explanation is required for the positive prospective association between prior e-cigarettes use and subsequent smoking in youth. Further, e-cigarette use by adolescent non-smokers is almost entirely experimental and short-lived. Regular use (at least weekly) by young people who never smoked is rare, <0.5% in the UK<sup>11</sup> and <0.7% in two major national surveys in the US<sup>12</sup>.
- **Secondhand vapour presents minimal risk if any to bystanders**<sup>13, 14</sup>

We note that the NHMRC CEO Statement was heavily referenced to the WHO report, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS).<sup>15</sup> This report was harshly critiqued by the United Kingdom Centre for Tobacco and Alcohol Studies.<sup>16</sup> For balance we would respectfully suggest consideration of the more recent comprehensive review by the University of Victoria Centre for Addictions Research of BC, Canada 2017.<sup>13</sup>

## International policy

Based on the evidence, international policy is shifting in favour of legalising and regulating nicotine for vaping. Australia is increasingly out-of-step with similar western countries.

- New Zealand<sup>17</sup> and Canada<sup>18</sup> are currently legalising nicotine for use in e-cigarettes.
- The US FDA has recently announced a shift in policy with strong support for e-cigarettes for tobacco harm reduction.<sup>19, 20</sup>
- The UK Department of Health has recently strongly endorsed the use of e-cigarettes in a new report, 'Towards a Smokefree Generation. A Tobacco Control Plan for England'.<sup>21</sup> These devices are available as consumer products and through a therapeutic goods pathway. However, even though products have been approved, none have come to market.
- The European Union has adopted a dual system where there is both an ordinary consumer market and potential for a therapeutic market.<sup>22</sup>
- NHS Health Scotland and twenty health organisations issued a consensus statement stating that 'vaping e-cigarettes is **definitely less harmful** than smoking tobacco. ... Thus, it would be a good thing if smokers used them instead of tobacco'.<sup>23</sup>

## Australian medical organisations

Two leading Australian medical and nursing professional organisations have recently reviewed the evidence and endorsed the use of e-cigarettes for tobacco harm reduction

- The Royal Australian and New Zealand College of Psychiatrists [\[link\]](#)
- Drug and Alcohol Nurses of Australasia [\[link\]](#)

Thank you for considering these important issues.

Yours sincerely

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On behalf of the following signatories...

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# Appendix

Key research studies since 4 January 2017

## Harm to health from of e-cigarettes compared to smoking

### 1. Levy DT. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. *Tobacco Control* 2017 [\[link\]](#)

Modelling the health effects of replacing most cigarette smoking with vaping over a 10-year period in the US

- 'Our projections show that a strategy of replacing cigarette smoking with vaping would yield substantial life year gains, even under pessimistic assumptions regarding cessation, initiation and relative harm'.
- 'Compared with the Status Quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost'

### 2. Chen J, Bullen C, Dirks K. A Comparative Health Risk Assessment of Electronic Cigarettes and conventional cigarettes. *IJEUPH* 2017 [\[link\]](#)

A risk assessment model to evaluate the health risks of ECs evaluating the toxicants most strongly associated with adverse health effects from smoking

- Concluding statement: 'The health effects of using ECs (e-cigarettes) are still not well understood, but current evidence points to ECs being less harmful than CCs. Using ECs to replace CCs as nicotine delivery products could lead to millions of lives saved and significant reductions in the burden of many smoking-related diseases.'

### 3. Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products with those of tobacco smoke. *Tob Control* 2017 [\[link\]](#)

- The modelling study assessed the level of chemicals found in studies of vapour, the cancer risk from each substance and calculated lifetime cancer risk for vaping compared to smoking tobacco.
- The vast majority of carcinogens are at much lower levels than cigarette smoke, and the risk from most chemicals is <1% compared to tobacco smoke.
- The two most dangerous carcinogens in tobacco smoke are not present in vapour. 'Acrylonitrile and 1,2-butadiene account for more than three-quarters of the cancer risk from tobacco smoke and are not found in vapour at all'.
- Conclusion 'Optimal combinations of device settings, liquid formulation and vaping behaviour normally result in e-cigarette emissions with much less carcinogenic potency than tobacco smoke'.

### 4. Shahab L. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. *Annals Int Med* 2017 [\[link\]](#)

Biomarker study after >6m use

- Long-term NRT-only and e-cigarette-only use is associated with substantially reduced levels of 26 measured carcinogens and toxins relative to smoking only combustible cigarettes
- 'Our results suggest that complete substitution of combustible cigarettes with e-cigarettes may reduce disease risk and support the assertion that e-cigarette use may be less harmful than smoking'

### 5. Clearing the Air: a systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, Centre for Addictions Research BC, Canada. January 2017 [\[link\]](#)

Comprehensive review of 1,622 journal articles concluding that

- Second hand exposure has been shown to create measurable but small exposure to nicotine and no significant exposure to carcinogens such as found in tobacco smoke.
- Vapour from e-cigarettes contains substantially fewer toxicants than does smoke from regular tobacco cigarettes.



**6. Glasser AM. Overview of Electronic Nicotine Delivery Systems. Am J Prev Med 2017. [\[link\]](#)**

Systematic review of 687 articles by The Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative

- ENDS (e-cigarettes) 'pose substantially less harm to smokers than cigarettes'
- 'Studies on the health effects of vaping indicate no or minimal impact on physiologic biomarkers and some possible acute positive effects on cognition and mood regulation. Adverse events reported by vapers are generally mild and resolve, though there have been serious adverse events reported in some cases.'
- Secondhand vapor studies: 'the level of exposure is low, and exposure to other compounds also appears very low, or at trace or non-detectable levels when compared with secondhand smoke.'

**7. Benowitz NL. Cardiovascular effects of electronic cigarettes. Nature Reviews Cardiology 2017 [\[link\]](#)**

- 'With the exception of nicotine and particulates, potentially toxic constituents are generally present in much lower levels in EC aerosol compared with cigarette smoke.'
- 'Although ECs might pose some cardiovascular risk, particularly in people with pre-existing CVD, the risk is less than that of cigarette smoking.'
- 'we support the statement from the AHA: "if a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medications, and wishes to use [ECs] to aid quitting, it is reasonable to support the attempt".'

**8. Farsalinos K. E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users. Food Chem Tox. 2017 [\[link\]](#)**

Replication of a previous flawed study that claimed vapers were exposed to high formaldehyde levels

- 'The high levels of formaldehyde emissions that were reported in a previous study were caused by unrealistic use conditions that create the unpleasant taste of dry puffs to e-cigarette users and are thus avoided'.

## Effectiveness for smoking cessation

**1. Zhu S. E-cigarette use and associated changes in population smoking cessation. BMJ 2017 [\[link\]](#)**

- 'This study, based on the largest representative sample of e-cigarette users to date, provides a strong case that e-cigarette use was associated with an increase in smoking cessation at the population level.'
- Smokers who used e-cigarettes were more likely to make a quit attempt than those who didn't and were 73% more likely to succeed, 8.5% vs 4.8% respectively.

**2. Glasser AM. Overview of Electronic Nicotine Delivery Systems. Am J Prev Med 2017. [\[link\]](#)**

Systematic review of 687 articles by The Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative

- 'RCTs and population-based studies with more-precise exposure measures show that ENDS are at least as effective as NRT in helping some smokers to quit or reduce their smoking and may reach more smokers at scale than NRT'

**3. Clearing the Air: a systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, Centre for Addictions Research BC, Canada. January 2017 [\[link\]](#)**

Comprehensive review of 1,622 journal articles concluding that

- Overall, there is encouraging evidence that vapour devices can be at least as effective as other nicotine replacements as aids to help tobacco smokers quit.

**4. Levy DT. The Relationship of E-Cigarette Use to Cigarette Quit Attempts and Cessation: Insights From a Large, Nationally Representative U.S. Survey. Nicotine Tob Res 2017 [\[link\]](#)**

Data from the 2014/15 Tobacco Use Supplement-Current Population Survey (TUS-CPS)

- E-cigarette users were more likely to make a quit attempt than non-users. 'Quit attempts and quit success were positively associated with increased frequency of e-cigarette use'.

#### **5. ASH. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017 [\[link\]](#)**

Annual national survey, n=12,696 adults age 18+ (ASH UK and Kings College London)

- 1.5 million UK ex-smokers are now vapers (in addition to ex-smokers who have quit vaping as well)
- Use of the devices is confined almost exclusively to current and ex-smokers
- Use amongst never smokers remains very low

#### **6. Giovenco DP. Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers. Addict Behav 2017 [\[link\]](#)**

- In a study of 15,532 recent smokers 'Daily e-cig users were 3 times more likely to be quit than never e-cig users. Some smokers may have quit or are preventing relapse with frequent e-cig use'.

#### **7. Caraballo RS. Quit Methods Used by US Adult Cigarette Smokers, 2014–2016. Prev Chronic Dis 2017 [\[link\]](#)**

Online survey of US adult cigarette smokers (n=15,943)

- E-cigarettes are more commonly used for quit attempts than FDA-approved medications

## Gateway to smoking for young people

#### **1. Bauld L. Young People's Use of E-Cigarettes across the United Kingdom Findings from Five Surveys 2015–2017. IJERPH 2017 [\[link\]](#)**

- Of 11-16 year olds in the UK (n>60,000) 'only 3% or less report using them at least weekly, most of whom are regular smokers, with less than 0.5% of never smokers reporting weekly e-cigarette use'
- Professor Linda Bauld: 'Our analysis of the latest surveys from all parts of the United Kingdom, involving thousands of teenagers shows clearly that for those teens who don't smoke, **e-cig experimentation is simply not translating into regular use**'

#### **2. Polosa R. A critique of the U.S. SG's conclusions regarding e-cig use among youth and young adults in US. Harm Red J 2017 [\[link\]](#)**

- 'Multiple years of nationally representative surveys indicate the majority of e-cigarette use among US youth is either infrequent or experimental, and negligible among never-smoking youth'
- In the two large national studies, regular e-cigarette use by never smokers was <0.1% (NYTS 2015) and 0.7% (MTF 2014)

#### **3. Kozlowski L, Warner K. Adolescents and e-cigarettes. Objects of concern may appear larger than they are. Drug Alc Depend 2017**

- The data from large national cross-sectional studies provide no evidence that kids' use of e-cigarettes is increasing smoking. If anything, those data suggest the opposite.
- 'We conclude, currently, that youth use of e-cigarettes is unlikely to increase the ranks of future cigarette smokers.'

#### **4. Clearing the Air: a systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, Centre for Addictions Research BC, Canada. January 2017 [\[link\]](#)**

Comprehensive review of 1,622 journal articles concluding that

- There is no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use.

#### **5. Etter JF. Gateway effects and electronic cigarettes. Addiction 2017 [\[link\]](#)**

- The gateway hypothesis cannot currently be either accepted or confidently refuted because the evidence for it is scarce and inconclusive.

- In fact, it is more plausible that vaping uptake is largely explained because smoking causes people who are already dependent upon nicotine to look for less dangerous, more socially acceptable and cheaper ways to obtain nicotine

#### **6. ASH Youth Survey 2017 GB (prepublication)**

- Regular use of e-cigarettes (at least weekly) was reported by **0.1% of never-smokers**
- Ever use of e-cigarettes was reported by 4% of never-smokers

#### **7. Glasser AM Overview of Electronic Nicotine Delivery Systems. Am J Prev Med 2017. [\[link\]](#)**

Systematic review of 687 articles by The Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative

- 'ENDS uptake trends have coincided with significant reductions in smoking prevalence to record lows among youth and adults.'

#### **8. Selya AS. Evaluating the mutual pathways among electronic cigarette use, conventional smoking and nicotine dependence. Addiction 2017 [\[link\]](#)**

Longitudinal study over 4 years of young adults 19-23y (n=1,007)

- 'E-cigarettes did not predict later smoking or later nicotine dependence'
- 'the current study calls into question the concerns that e-cigarettes pose a risk for later conventional smoking'
- 'Increased initiation with e-cigarettes may be replacing, rather than adding to, initiation with conventional cigarettes'

## Uptake by adult non-smokers

#### **1. Farsalinos K. Prevalence and correlates of current daily use of electronic cigarettes in the European Union. Intern Emerg Med 2017 [\[link\]](#)**

Survey of 27,801 EU residents aged ≥15y

- Current daily EC use was mainly observed in current and former smokers but is very rare among never smokers.
- Minimal current daily nicotine-containing EC use (0.04%) was observed among never smokers

#### **2. Zhu S. E-cigarette use and associated changes in population smoking cessation. BMJ 2017 [\[link\]](#)**

- Only 0.3% of never smokers currently used e-cigarettes at the time of survey (US)

#### **3. ASH. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017 [\[link\]](#)**

- 0.3% of never smokers are current users in 2016

#### **4. Smoking Toolkit Study. Trends in e-cigarette use in England, July 2017 [\[link\]](#)**

- 0.3% of never smokers were e-cigarette users

## International policy

### **1. New Zealand**

- Nicotine e-cigarettes to be made legal with appropriate controls, March 2017 [\[link\]](#)
- New pathway for risk-reduced products eg heat-not-burn, snus, moist snuff, inhaled nicotine etc, July 2017 [\[link\]](#)

### **2. United States**

- FDA announces strong support for e-cigarettes for tobacco harm reduction, July 2017 [\[link\]](#)
- "Envisioning a world where ... adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts'.

- **Gottlieb S. A Nicotine-Focused Framework for Public Health. NEJM Aug 2017** [\[link\]](#)
  - 'the availability of potentially less harmful tobacco products could reduce risk while delivering satisfying levels of nicotine for adults who still need or want it'.

### 3. England

'Towards a Smokefree Generation. A Tobacco Control Plan for England', July 2017 [\[link\]](#)

- Stopping smoking is hard and many smokers are turning to e-cigarettes to help them in their
- attempts. In 2016, it was estimated **that 2 million consumers in England had used these products and completely stopped smoking and a further 470,000 were using them as an aid to stop smoking.**
- The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco.

### 4. Canada

Bill S-5. An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts [\[link\]](#)

- Passed by the Senate 1/6/17
- First reading in the House 1/6/17

### 5. Scotland

NHS Health Scotland. Consensus statement on e-cigarettes, September 2017 [\[link\]](#)

- 'There is now agreement based on the current evidence that vaping e-cigarettes is **definitely less harmful** than smoking tobacco. ... Thus, it would be a good thing if smokers used them **instead** of tobacco'. (original emphasis)

## Critique of 2016 Surgeon-General's report on e-cigarettes

### 1. Polosa R. A critique of the U.S. SG's conclusions regarding e-cig use among youth and young adults in US. Harm Red J 2017 [\[link\]](#)

- 'The U.S. Surgeon General's claim that e-cigarette use among U.S. youth and young adults is an emerging public health concern does not appear to be supported by the best available evidence on the health risks of nicotine use and population survey data on prevalence of frequent e-cigarette use'