Public Submission to the Senate Select Committee on Tobacco Harm Reduction.

Emeritus Professor Simon Chapman AO PhD, Emeritus Professor Mike Daube AO, Professor Matthew Peters AM MD

3 Nov 2020

About the authors

Professor Simon Chapman AO PhD FASSA Hon FFPH (UK) is an Emeritus Professor in Public Health at the University of Sydney. In 1997 he won the World Health Organisation's World No Tobacco Day Medal and in 2003 he was awarded the American Cancer Society's Luther Terry Award for outstanding individual leadership in tobacco control. In 2008 he won the NSW Premier's Cancer Researcher of the Year award and the Public Health Association of Australia's Sidney Sax medal. He was inaugural deputy editor (1992-1997) then editor (1998-2008) of the BMJ's specialist journal *Tobacco Control* and is now editor emeritus. In 2013, he was made an Officer in the Order of Australia for his contributions to public health.

Emeritus Professor Mike Daube AO was Professor of Health Policy at Curtin University from 2015 - 2018. Before this he was Director General of Health for Western Australia. His roles have included President of the Public Health Association of Australia and the Australian Council on Smoking and Health, Deputy Chair of the National Preventative Health Taskforce (and chair of the tobacco committee), Vice-Chair of the WHO FCTC Review Group, and chair, member and patron of many further government and non-government committees in Australia and elsewhere. He has worked on tobacco issues nationally and internationally for 47 years, and has published widely on this and related issues. He is an Officer in the Order of Australia, was the 2018 Western Australian of the Year, and has received further awards from the World Health Organization, the American Cancer Society, the Australian Medical Association, the National Heart Foundation of Australia, the Public Health Association of Australia, the Thoracic Society of Australia and New Zealand, Environmental Health Australia, the World Federation of Public Health Associations and many other organisations.

Professor Matthew Peters AM MD FRACP FThorSoc is a Respiratory Physician and Head of Respiratory Medicine at Concord Hospital. He has academic appointments at Macquarie University and Sydney University. For more than a decade he was Chair of Action on Smoking and Health, Australia. In 2017 his work in preventing and improving the

treatment and care of patients with lung cancer was acknowledged when he received a lifetime achievement award from Lung Foundation Australia. In 2019 he was made a Member of the Order of Australia for his work in respiratory medicine and tobacco control.

****

We write as three of Australia's most experienced tobacco control experts who have been actively involved in action and research on tobacco issues at state, national and international levels over many years. Given our long involvement in this area, and the importance and complexity of the issues to be addressed by the Committee, we have felt it appropriate to present our views in some detail, not least because we believe that a thorough discussion is critical to any serious consideration of these issues.

We note that while the Committee is entitled the "Select Committee on Tobacco Harm Reduction", its focus, and in particular the "tobacco reduction strategies" in its terms of reference essentially address only issues related to e-cigarettes. It is important to be clear that reducing harm from tobacco has been a major focus for governments and health organisations over many decades. The measures implemented over this period have dramatically reduced smoking, and the harms it causes in the community. The measures recommended by the World Health Organization and health and medical organisations will similarly reduce tobacco use and its harms. We are aware that the tobacco industry and some of those who support e-cigarettes and other novel tobacco products use terms such as "harm reduction" or "tobacco harm reduction" as though they should only apply to these products. We believe that "tobacco harm reduction" should be defined much more broadly, and should not be used as a descriptive or promotional term for products whose purported benefits are unproven, and where there is growing evidence of current and future harm.

We address action necessary and appropriate for genuine tobacco harm reduction at the end of this submission.

In the following sections of this submission we address the Committee's terms of reference.

ToR-A: the treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks

Australia has long been recognised as a global pioneer in tobacco control. It has among the world's highest priced cigarettes, and was the first nation to run well-funded national quit campaigns, to implement plain packaging, and to require tobacco products to be stored

out-of-sight, and one of the first to ban tobacco advertising and introduce smokefree regulations. Many countries have looked to Australia for leadership.

This progressively implemented suite of policies and programs, has driven smoking down almost continuously over the past 40 years and Australia today is in the very front row of low national smoking prevalence (see ToR B below). Both adult and teenage smoking prevalence are at the lowest levels ever recorded. The incidence of lung cancer in men has been continually falling in Australia since 1982, while the rise in women (from a much lower base), reflects the historical later uptake of smoking by women.

New Zealand, the United Kingdom, Canada and the United States are commonly referred to by promoters of e-cigarettes as countries that Australia should follow by having liberal and successful regulatory environments and ubiquitous retail availability. These countries all have seen dramatic increases in youth vaping and easy e-cigarette access has expanded the number of young people regularly using nicotine. In these countries, easy, widespread corner-store and vape shop access has clearly been a disaster that we must never replicate.

In Australia 96.6% of those aged 14-17 have never smoked, a proportion that has steadily increased. This is an extraordinary public health achievement that must be very carefully protected.

With so-called harm reduced products, Australia has been purposefully cautious, a position advocated by all state and federal governments and nearly all major health and medical NGOs and medical colleges (see table below). This reflects concerns that policy should be evidence-based and carefully implemented, and with special caution following a history over many decades of products for which misleading claims were made in relation to their being “safer” and bringing purported health benefits, as well as similar claims for various cessation products and approaches.

E-cigarette regulation in Australia

Want strong e-cigarette regulation	Want weak e-cigarette regulation
Therapeutic Goods Administration	Philip Morris International
National Health & Medical Research Council	British American Tobacco (Australia)
Public Health Association of Australia	Fontem Ventures (Imperial Tobacco subsidiary)
Thoracic Society of Australia and New Zealand	Japan Tobacco International
Australian Lung Foundation	Australasian Association of Convenience Store
Australian Council on Smoking and Health	Numerous e-cigarette manufacturers and retailers
Cancer Councils (national and in all states)	Australian Tobacco Harm Reduction Association
National Heart Foundation of Australia	Royal Australian College of Psychiatrists
Royal Australasian College of Physicians	Legalise Vaping Australia (run by the Australian Taxpayers Alliance)
Royal Australian College of General Practitioners	Australian Lotteries and Newsagents Association
Australian Medical Association	Master Grocers Association
Telethon Kids Institute	Progressive Public Health Alliance
Quit Victoria	Tasmanian Small Business Council
VicHealth	
CSIRO	
Australian Dental Association	
Cancer Australia	
Minderoo Foundation Collaborate Against Cancer	
Australian Association of Smoking Cessation Professionals	
Australian Competition & Consumer Commission	
All state and federal health departments	

As summarised below, the evidence on the effectiveness of e-cigarettes in real world cessation and reduction is weak; the evidence on the long term health consequences of use is unknown (with many early warning signs of likely cardiovascular and respiratory problems); and their attractiveness to nicotine-naive young people is high.

Together, these concerns threaten that any weak system of regulation in Australia would release a Trojan horse which could attract new cohorts of young people into nicotine dependency; popularise a highly addictive and potentially unhealthy fad in young people with all the promises of owning the latest and most prestigious vaping apparatus and peer-kudos from vape clouding displays; lure some long-term quitters back into nicotine dependency; hold many smokers in smoking, in the erroneous belief that smoking *reduction* (not quitting) confers risk reduction; renormalise smoking behaviour; and distract attention and focus from proven evidence-based action to reduce smoking.

Australia is not some colonial outpost of UK health policy nor a slavish imitator of all public health policy in the USA. In 2020, both those nations and others in the European Union are experiencing devastating numbers of cases and deaths from COVID19. Their public health policy

templates are therefore hardly obvious role models for Australia. Australian public health policy has been internationally lauded in many areas (e.g. road safety, HIV/AIDS, SIDS, COVID19 containment, immunisation and tobacco control). Australian governments should not in any way feel that our tobacco control policies need to mirror what happens in nations that have let e-cigarettes off the regulatory leash and are now struggling to contain negative consequences..

ToR-B. the impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption

Vaping advocates often claim that nations where e-cigarette use is widespread have lower smoking prevalence than Australia, where e-cigarette use is far less prevalent. The latest available data on smoking prevalence from 5 nations which are often compared (Australia, Canada, New Zealand, UK, USA) show Australia has 14% of its ≥14 population who smoke; the UK has 14.1% of its ≥18 population who smoke; Canada (14%) and New Zealand (14.2%) report their data for those aged ≥15years.

Very importantly, the way these nations count "smoking" differs. Of these 5 nations, only Australia, Canada and the USA include *all* combustible tobacco products (cigarettes, cigars, pipes, shisha) in their data on "smoking" prevalence figures. Canada also includes chewing tobacco use, but unlike the other four nations, only counts recent (past 30-day) smoking. The inclusion of chewing tobacco would inflate Canada's "smoking" prevalence figure, while its "within-30-day" limit would reduce it, compared with the other nations which *also* count less-than-monthly smoking in their current smoking figures.

By not including all combustible tobacco product use , the "smoking" prevalence figures from the UK and New Zealand will thus *underestimate* the true prevalence of "smoking" in both nations. This point has previously been made about an earlier (2015) "headline" smoking prevalence figure of 15.1% for the USA where a true "smoking" prevalence in the US was estimated at the time as being significantly higher at 18.4%.

Taking these factors into account, and noting the confidence intervals and margins of error noted in the data below, it is likely that Canada, Australia and New Zealand have almost the same smoking prevalence; that England may have slightly higher prevalence because it does not count combustible tobacco other than cigarettes and roll-your-own tobacco in its "smoking" data (and it has a significant immigrant population where shisha smoking is prevalent); and that the USA has the highest smoking prevalence of the five nations.

- Australia:(2019 AIHW ages ≥14 and ≥18): (all combustible tobacco users, at any smoking frequency –people who reported smoking cigarettes daily, weekly, monthly or less than monthly) ≥14yrs: 14.0% (margin of error 0.6); ≥18 yrs: 14.7% (margin of error 0.7%) Daily smoking by 11%.
- Canada:(2019 Canadian Tobacco and Nicotine Survey ≥15yrs 14% (Only past 30-day use of any tobacco product — including chewing tobacco)
- New Zealand:2018 Current smoking (smoke at least monthly, and have smoked more than 100 cigarettes in their whole life time) among persons aged ≥15): 14.2% (CIs: 13.4-15.0) (Māori adults 34% (31.1-37.1) (cigarettes & RYO only at any smoking frequency)
- UK:(2019 Office of National Statistics; ages ≥ 18): 14.1% "who smoke cigarettes nowadays")
- USA: (2018 NHIS ages ≥ 18): 16.5% (CIs 15.9-17.2) (all combustible tobacco users at any smoking frequency "every day or some days"

Is vaping the primary cause of falls in smoking prevalence in nations where vaping is prevalent?

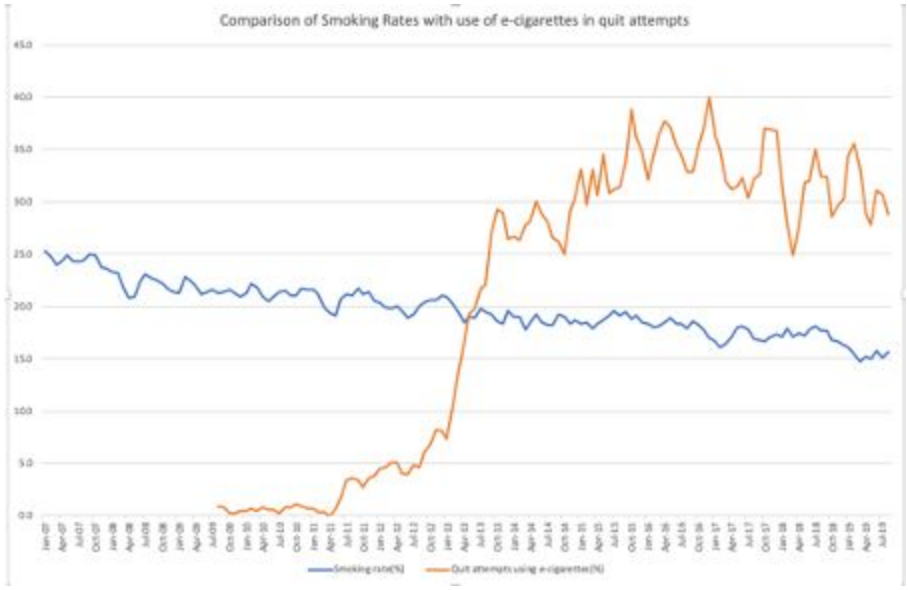
There are many factors which can combine to cause changes in smoking prevalence over time. Vaping advocates argue that nations with widespread vaping are seeing their falls in smoking prevalence accelerate *because of* vaping.

Here OECD data for change in daily smoking prevalence between 2010 and 2016 are illuminating. The falls between 2010 and 2016 as a percentage of 2010 daily smoking rates were:

Australia	19.5%
Canada	23.3%
New Zealand	19.6% (period from 2012-18)
UK	19.5%
US	21.9%

It is clear that countries with widely different e-cigarette regulatory approaches and patterns of community use have achieved similar declines in smoking rates.

Data from the Smoking in England project in the graph below show that the role of e-cigarettes in accelerating the downward trend in England is trivial or non-existent. The dramatic upsurge in smokers using e-cigarettes in quit attempts commenced in late 2012 and has more-or-less plateaued since mid 2013, and does not appear to have had any marked impact on the downward slope of the historically declining smoking prevalence rate.



Does vaping reduce smoking frequency (number of cigarettes smoked)?

An important report from late 2017 considered the surge in e-cigarette use in England and whether this was reducing the *number of cigarettes* being smoked at the population level across the country. The authors concluded:

> "No statistically significant associations were found between changes in use of e-cigarettes while smoking and daily cigarette consumption. Neither did we find clear evidence for an association between e-cigarette use specifically for smoking reduction and temporary abstinence, respectively, and changes in daily cigarette consumption. If use of e-cigarettes and licensed NRT while smoking acted to reduce cigarette consumption in England between 2006 and 2016, the effect was likely very small at a population level."

British data also show (see table below) that the average daily number of cigarettes smoked by smokers who vape is not very different to that by smokers who do not vape.

5 Average daily cigarette consumption among adults, by e-cigarette status, Great Britain, 2014

All cigarette smokers aged 16 and over	Means		
	Those who currently use e-cigarettes		All others
Average daily cigarette consumption	10.1	vs	11.8
Weighted Base (000s)	1,024		8,625
Unweighted Sample	110		880

Source: Opinions and Lifestyle Survey, Office for National Statistics

These data echo the editor-in-chief of the journal *Addiction*'s comments to the BBC nearly two years earlier.

Prof Robert West, BBC "Inside Health" Feb 2016
http://www.bbc.co.uk/programmes/b070dq8h

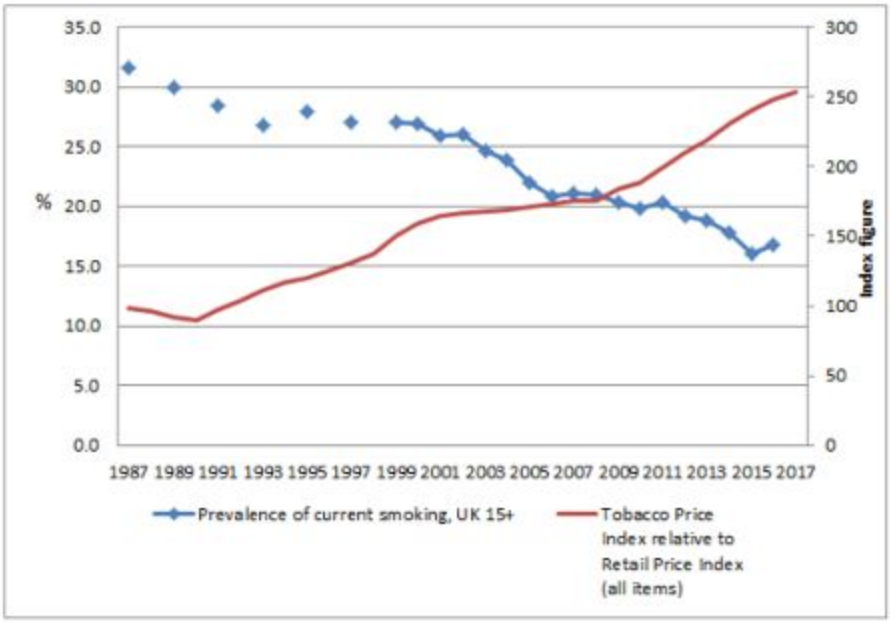
Quitting "actually been relatively small"

- 7m44-8m.01: "Now, that raises and interesting question. If they [ecigs] were the game changer, if they were going to have the massive effect on, you know, everyone switching to ecigarettes and stopping smoking, we might have expected to see a bigger effect than we've seen so far, which has actually been relatively small."

Cutting down "not much"

- 10m40s: "We know that most people who use ecigarettes are continuing to smoke and when you ask them they tell you that they are mostly doing that to cut down the amount they smoke. But we also know they are smoking, it's not really that much different from what they would have done since they started using ecigarettes."

However, if we look at the data on smoking prevalence and changes in tobacco price in the UK, we can see a rather different picture. Smoking prevalence was falling well before vaping commenced and there is an inverse relationship between the rise in the price of tobacco and the fall in smoking prevalence. Vaping grew rapidly from around 2011 in Britain and did not change the trajectory of decline in smoking prevalence in any significant way.



ToR-C: the established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment

Many of the submissions to this inquiry so far published have been from individuals who say they have been able to permanently quit smoking after starting to vape. It is certainly true that around the world there are many such cases. But it is an elementary precept of science that the plural of anecdote is not evidence. Just as we would never conclude that drink-driving was not risky after counting the number of people who drove after drinking and suffered or caused no harm, we should never conclude that any given method is an effective way to quit smoking by listening only to those who say they have benefitted from it. There is a long and varied history of such claims and enthusiastic promotion of other cessation approaches that have worked for some individuals. We need to look at sustained cessation rates among randomly selected smokers using various strategies in real world usage contexts and then compare the impact of particular methods against background cessation rates that occur in the absence of those methods.

The following reviews of the evidence published since 2017 have concluded that e-cigarettes have *not been demonstrated to be effective* for smoking cessation:

(2020) European Commission's Scientific Committee on Health, Environmental and Emerging Risks "there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit"

(2020) United States Surgeon General report on smoking cessation "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."

(2020) Ireland's Health Research Board "there is no evidence of a difference in effect on incidences of smoking cessation. There is a low-level of certainty in these results due to low successful event rates and high rates lost to follow-up in all studies".

(2020) Australian National University Review preliminary report ("there is insufficient evidence that nicotine-delivering e-cigarettes are efficacious for smoking cessation, compared to no intervention, placebo existing nicotine-replacement therapy or other best-practice interventions."

(2020) Thoracic Society of Australia and New Zealand "Smokers who enquire about using e-cigarettes as a cessation aid should be provided with appropriate information about approved medication in conjunction with behavioural support (as these have the strongest evidence of efficacy to date). E-cigarettes are not the first-line treatment for smoking cessation."

(2020) Grebovac et al (Effectiveness of Electronic Cigarettes in Smoking Cessation: a Systematic Review and Meta-Analysis) "nicotine-ECs may be more effective in smoking cessation when compared to placebo ECs or NRT. When compared to counselling alone, nicotine ECs are more effective short-term but its effectiveness appears to diminish with later follow-ups. Given the small number of studies, heterogeneous design and the overall moderate to low quality of evidence, it is not possible to offer clear recommendations."

(2020) Public Health England "The data presented here suggests that vaping has not undermined the declines in adult smoking". Note that they presented no evidence that vaping, endorsed by PHE and widely promoted, had accelerated the decline in smoking in the UK. This is to our knowledge the first time that PHE has taken such a lukewarm position on the impact of vaping on smoking rates.

(2019) European Respiratory Society "There is not enough scientific evidence to support e-cigs as an aid to smoking cessation "

(2018) US National Academies of Science, Engineering and Medicine -- a "review of reviews". ("Conclusion 17-1. Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.")

(2018) European Public Health Association ("e-cigarettes may help some smokers quit but, for most, e-cigarettes depress quitting")

(2018) CSIRO "There is currently no evidence that quit rates for smoking have decreased as a result of e-cigarette use. Long-term success with cessation was not measured in trials."

Many claims about e-cigarette effectiveness in smoking cessation derive from cross-sectional ("snapshot") survey data where former smoking vapers report being abstinent from tobacco use. Cross-sectional studies do not allow consideration of relapse back to smoking any time after the day the survey was completed. Relapse to smoking is very prevalent. (A UK 15 month follow-up of vapers found that overall 39.6% had relapsed to smoking, with those using tank systems faring worst (45.6%).)

For this reason, population cohort studies with long-term follow up of large numbers of vapers provide the best available evidence of how these products work in real world patterns of usage. The US Population Assessment of Tobacco and Health (PATH) project (funded by the Food and Drug Administration and the National Institutes of Health) has been collecting national cohort data since 2013.

A PATH paper by Coleman et al reported on a 12 month follow-up (wave 1 to wave 2) of 2932 vapers. The table below shows that for every person vaping at Wave 1 who benefited across 12 months by quitting smoking, there were 2.1 who either relapsed to or took up smoking. Most disturbingly, in this adult cohort, nearly one in four of those who had never been established smokers took up smoking after first using e-cigarettes.

Summary of e-cigarette transitions from Wave 1 to Wave 2 by cigarette smoking status (n=2932)		
Positive outcome at Wave 2 n=524 (17.9%)	**Negative outcome at Wave 2** n=1116 (38%)	**Remained the same** n=1291 (44%)
143 dual users who quit EC and smoking	886 dual users who relapsed to smoking exclusively	902 dual users continuing as dual users
104 dual users who became EC users only	109 EC only but now smoking	389 EC users continuing as exclusive EC users
277 EC only who quit EC	121 EC only who progressed to dual use	

Another PATH longitudinal paper reported that former smokers who had quit a long time ago but who vaped were far more likely than those who had never vaped to relapse back to smoking and that vapers were far more likely than those who had never vaped to have transitioned from being never smokers to smokers:

> "Distant former combustible cigarette smokers who reported e-cigarette past 30-day use (9.3%) and ever use (6.7%) *were significantly more likely than those who*

> *had never used e-cigarettes (1.3%) to have relapsed to current combustible cigarette smoking at follow-up* (*P* < .001). Never smokers who reported e-cigarette past 30-day use (25.6%) and ever use (13.9%) were significantly more likely than those who had never used e-cigarettes (2.1%) to have initiated combustible cigarette smoking (*P* < .001). A*dults who reported past 30-day e-cigarette use (7.0%) and ever e-cigarette use (1.7%) were more likely than those who had never used e-cigarettes (0.3%) to have transitioned from never smokers to current combustible cigarette smokers* (*P* < .001). E-cigarette use predicted combustible cigarette smoking in multivariable analyses controlling for covariates.

A just-published paper from the ITC-4CV four country (Australia, USA, UK, Canada) cohort survey found that after 18 months:

> "smokers with established concurrent use [smoking and vaping] were not more likely to discontinue smoking compared to those not vaping … it is clear that the rates of transitioning away from smoking remain unacceptably low, and perhaps current vaping tools at best bring the likelihood of quitting up to comparable levels of less dependent smokers. The findings of our international study are consistent with the findings of the US PATH transition studies, and other observational studies, in that most smokers remain in a persistent state of cigarette use across time, particularly the daily smokers."

Randomised controlled trials

A recent Cochrane update of the evidence from randomised controlled trials (RCTs) on e-cigarettes in smoking cessation concluded that "there was "moderate-certainty evidence, limited by imprecision, that quit rates were higher in people randomized to nicotine EC than in those randomized to nicotine replacement therapy (NRT) (risk ratio (RR) 1.69, 95% confidence interval (CI) 1.25 to 2.27; I2 = 0%; 3 studies, 1498 participants).

In terms that the general public might better understand "For every 100 people using nicotine e-cigarettes to stop smoking, 10 might successfully stop, compared with only six of 100 people using nicotine-replacement therapy or nicotine-free e-cigarettes, or four of 100 people having no support or behavioural support only." Or putting it another way if we take 100 smokers participating in an RCT, 90 would still be smoking six months later if they used e-cigarettes, compared with 94 who used NRT, and 96 who just tried to quit alone or got some "behavioural support".

There can be few if *any* other drugs, used for *any* purpose, which have even close to a more dismal success rate than e-cigarettes or NRT in achieving its main outcome. If we went

along to a doctor for a health problem and were told "here, take this. It has a 90% failure rate. But I'm describing it as successful", we would understandably take the view that "success" when used in this context was not the way that it is used in any other treatment context.

Moreover, in this commentary, one of us (SC) has reviewed why results obtained from RCTs do not reflect those obtained in real world use where "success" is often even much worse. RCTs exclude many people from high smoking prevalence population sub-groups (those with mental health problems, drug and alcohol problems; participants in RCTs are subject to a wide range of cohort retention strategies to prevent them dropping out of the trial (as happens very commonly in real world use); and participants are paid and given free quit smoking medication (including e-cigarettes).

One study reviewed 54 RCTs smoking cessation trials for criteria for exclusion and found 25 separate criteria being used across these trials. They then applied 12 of the most commonly used of these criteria to 4,962 adults with nicotine dependence in the past 12 months from a US national survey on alcohol use (NESARC) and to a subgroup of participants motivated to quit. They found two-thirds of participants with nicotine dependence would have been excluded from clinical trials by at least one criterion, with 59% of the subgroup of motivated to quit smokers also excluded.

Real-world studies have found high levels of premature discontinuation of medication use. A four nation study of 1,219 smokers or recent quitters who had used medication in the last year (80.5% NRT, 19.5% prescription only, found most (69.1%) discontinued medication use prematurely (71.4% of NRT users and 59.6% of bupropion and varenicline. NRT users who obtained their patches or gum over-the-counter without prescription were particularly likely to discontinue (76.3%).

When considered together, all the above problems make RCTs on smoking cessation a very, very far cry from the way smokers use NRT and e-cigs in the real world. But this will not stop wide-eyed commentaries about "effectiveness", as if these artificially constructed trials bore any resemblance to the spread and conditions of use in the real world.

A separate and critical issue with the relevant RCTs is the failure to properly document and report adverse events. As noted by the Ireland Health Research Board, respiratory adverse events, including shortness of breath and cough, appear to be higher with e-cigarettes than standard treatment. That report further notes that cardiovascular and psychiatric adverse event reporting were not captured systematically as recommended by the European Medicines Agency and that these trials lack a systematic means to assess whether serious adverse events were treatment-related. These serious adverse events include deaths and

severe pneumonia requiring hospital care that were numerically more common with e-cigarettes.

It remains true that, as summarised in the 2020 US Surgeon General's report on smoking cessation, and cited as recently as October 2020 in an authoritative article by the heads of the US Centres for Disease Control (CDC), Food and Drugs Administration (FDA), and National Cancer Institute (NIH) in the New England Journal of Medicine, "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation".

ToR-D: the established evidence on the uptake of e-cigarettes amongst non- smokers and the potential gateway effect onto traditional tobacco products

It is now established beyond any rational questioning that sole e-cigarette use or dual smoking and e-cigarette use in youth increases the likelihood of future experimental and established combustible tobacco use. The preliminary report from the Australian National University report commissioned by the Commonwealth Department of Health reported on observational evidence from three systematic reviews and 25 primary research studies, concluding:

> "A meta-analysis of data from these studies showed that never smokers who have used e-cigarettes were, on average, around three times as likely as those who have not used e-cigarettes to try smoking conventional cigarettes and transition to regular tobacco smoking. All studies found evidence of an increased risk, with wide variation in the magnitude of this risk."

This conclusion was very similar to an evidence review recently published by the Irish Health Research Board (2020)

> "We found a four-fold association between ever using e-cigarettes and initiating smoking tobacco cigarettes in adolescents in a combined analysis of nine cohort studies conducted with follow-up periods between 4 and 24 months. Sensitivity and subgroup analysis support the association between ever using e-cigarettes and initiating smoking tobacco cigarettes. The study design used to assess the relationship between e-cigarette use and initiation of cigarette smoking does not allow us to say there is a definitive causal relationship, but it does allow us to say that the findings builds a case towards a causal relationship as the findings are consistent across all studies included in the meta-analysis."

Vaping advocates are often dismissive of claims about vaping being a gateway or on-ramp to smoking in youth. They often argue that "common liability theory" or a "propensity" to use nicotine in any form explains nicotine progression from initial vaping to cigarette smoking. By this reasoning, all we need to say about anyone who uses nicotine regularly is the circular tautology that they had a *propensity* to do so ("kids who will try stuff, will try stuff" and "kids who will smoke, will smoke"). If this simplistic hard determinism was all that was needed to be invoked in understanding smoking uptake, how then do we explain the dramatic *falls* in uptake that have been seen in nations which have robust tobacco control programs? What eroded that allegedly fixed "propensity"? Clearly, just as there are factors which promote reductions in smoking, so are there predisposing, reinforcing and enabling factors which can promote nicotine use and progression.

Critics of possible gateway relationships between initial vaping and later smoking also argue that the gateway hypothesis is incompatible with evidence of declining adolescent smoking in nations where many young people vape. The argument here runs that vaping has been rising while smoking continues to fall, so vaping cannot be causing smoking to any significant degree at the adolescent population level. This argument relies on an ill-considered assumption that the population-wide net impact of any putative gateway effect of e-cigarette use would be larger than the combined net impact of all other policies, programs and factors which are responsible for reducing adolescent smoking prevalence (for example, tobacco tax and retail price, measures of the denormalisation of smoking, exposure of children to adult-targeted quit campaigns, school education programs, retail display bans, health warnings and plain packaging). This is a purposely ridiculously high bar that gateway critics demand that anyone suggesting gateway effects must jump over.

It is clearly possible that significant numbers of vaping teenagers who might otherwise not have smoked could take up smoking in an environment where there was a larger preventive effect occurring in response to comprehensive efforts to reduce smoking uptake. The combined impact of such factors in preventing uptake could thereby easily mask considerable smoking uptake that might have not occurred in the absence of e-cigarettes.

ToR-E: evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures that Australia could adopt to minimise youth smoking and vaping

Smoking rates in Australian teenagers have never been lower, a phenomenon also seen in other nations like the USA, Canada and the UK which like Australia, also have had comprehensive tobacco control policies for decades. Like the tobacco industry, the business model for the vape industry (which includes all major tobacco companies) is not just about promoting its products

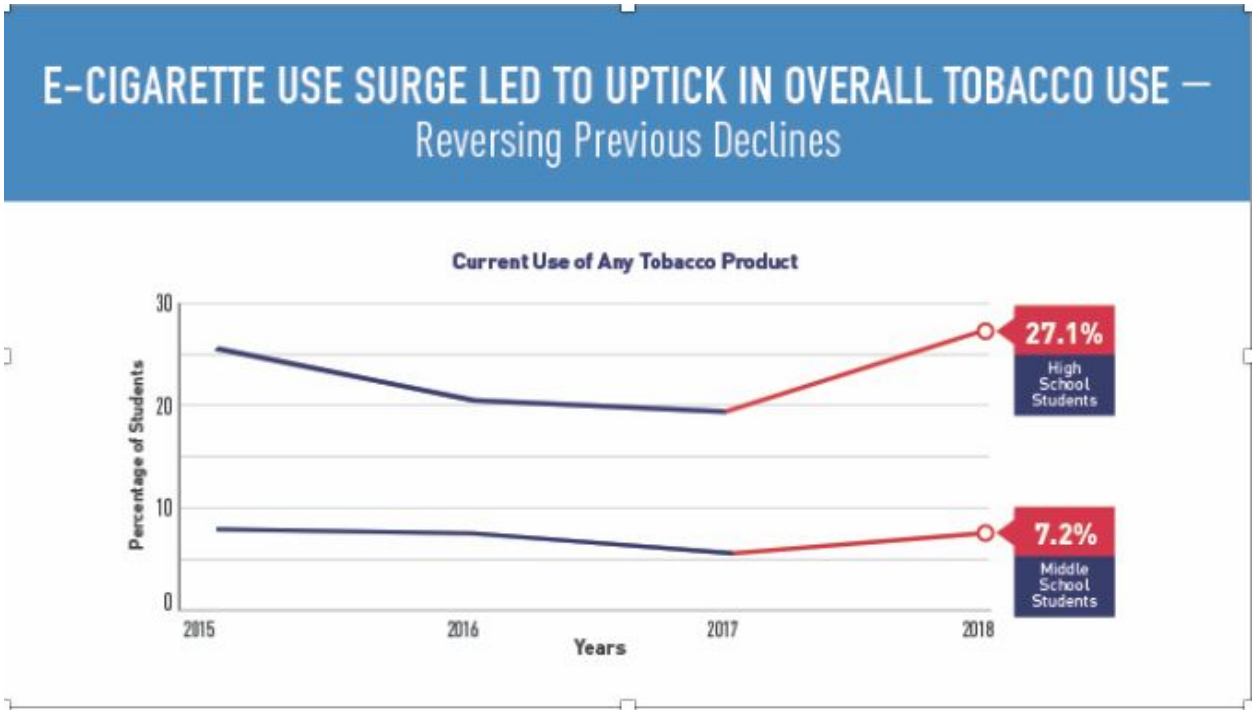
to current adult smokers. Just as any car company which ignored young first car buyers would outrage its shareholders, all tobacco and vaping companies are well aware of the critical role that new (and especially young) nicotine addicts have in their long term commercial prospects. 45% of US vaping retailers and 39% of English shops sell to underage customers.

Vaping advocates are usually sensitive to the reception that any expressed complacency about teenage vaping will ignite, and so concentrate talk about their mission to help smokers switch. But as the evidence about youth vaping uptake has accumulated and become undeniable, they fall back to "well, isn't it better that they vape than smoke?" Here we see a seemingly endless line of revisionism from these advocates seeking to run from emerging inconvenient data about underage use:

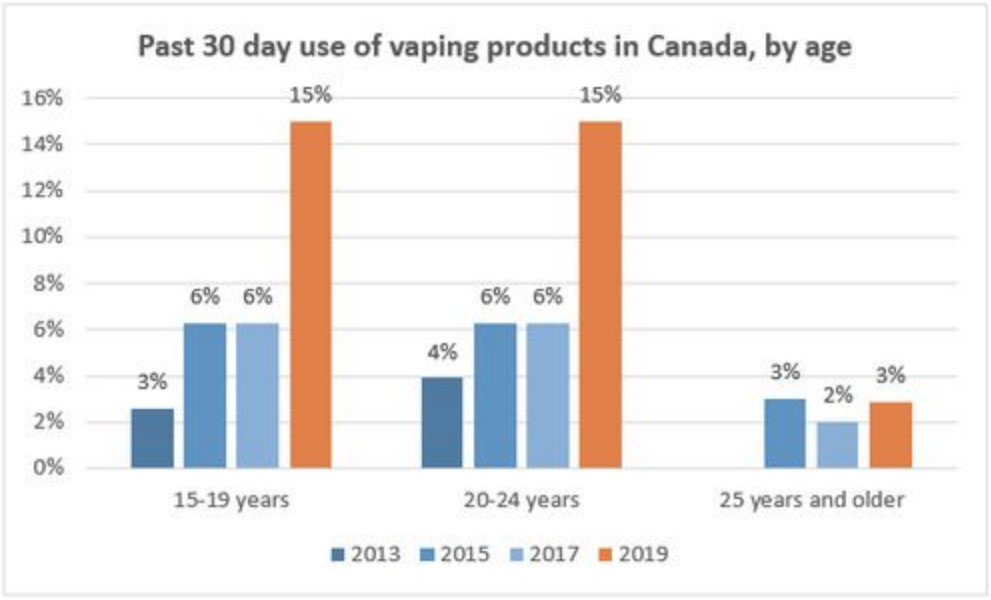
1. Kids aren't taking up e-cigarettes
2. OK, they are but there's no *substantial* e-cigarette use by kids
3. OK, there is substantial use, but there's *little regular use* by kids
4. OK, there regular use by kids, but there's *no substantial use by kids who were not already smoking*
5. OK, there *is* lots of use by kids, but t*his is preventing them smoking*
6. OK, there *is* use by kids who weren't smoking and who then start smoking, *but it's not regular smoking*
7. OK, there is consistent vaping by kids who weren't smoking but then started smoking, *but these kids would have smoked anyway!*

Many totally nicotine naïve youth are now regularly – not just experimentally – vaping. In the USA

> "The significant rise in e-cigarette use among both student populations has resulted in overall tobacco product use increases of 38 percent among high school students and 29 percent among middle school students between 2017 and 2018, negating declines seen in the previous few years." The US Surgeon General refers to "*the epidemic of youth e-cigarette use".*



In Canada where e-cigarettes are openly accessible, there is now rising alarm about the rapid growth in regular (past 30 days) vaping by young people (see graph below)



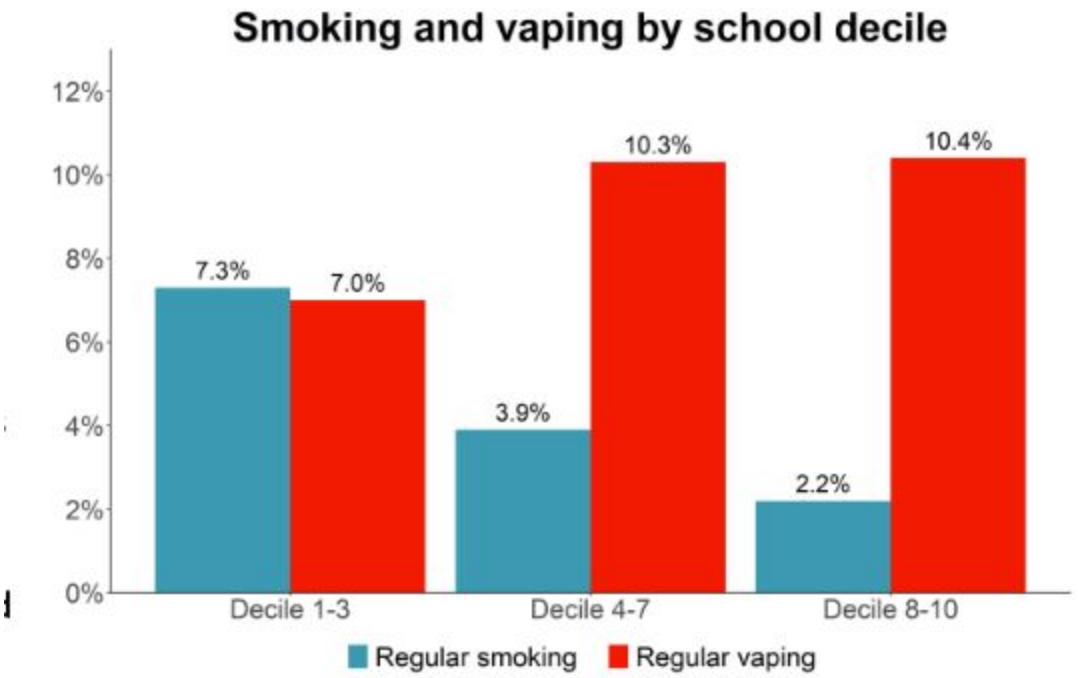
Source: CTADS 2013, 2015, 2017; CTNS 2019

In New Zealand, we are already seeing the same thing happening. 2019 data on 7700 13-18 year old students from 52 New Zealand schools shows that regular (9.8%) and weekly (5.8%) vaping now well exceeds regular (3.8%) or weekly (2.4%) smoking.

Youth19: Smoking and vaping in secondary students

		Has ever smoked	Regularly smokes	Smokes weekly or more often	Has ever vaped	Vapes regularly	Vapes weekly or more often
		N=7178 % [95% CI]	N=7169 % [95% CI]	N=7169 % [95% CI]	N=7179 % [95% CI]	N=7161 % [95% CI]	N=7161 % [95% CI]
	Total	14.8 [12.7-17.0]	3.8 [2.9-4.7]	2.4 [1.7-3.1]	37.9 [35.0-40.8]	9.8 [8.0-11.5]	5.8 [4.4-7.1]
Sex	Female	14.5 [11.5-17.5]	3.8 [2.6-5.0]	2.2 [1.3-3.1]	34.9 [31.4-38.5]	8.3 [6.2-10.5]	4.5 [3.1-5.9]
	Male	15.1 [12.7-17.6]	3.7 [2.6-4.9]	2.5 [1.5-3.5]	41.8 [38.6-45.1]	11.4 [9.8-13.1]	7.2 [5.7-8.8]

The same study shows regular vaping is most prevalent in higher socio-economic area schools.



ToR-F: access to e-cigarette products under Australia's current regulatory frameworks

Sale of vapable nicotine is illegal in Australia. However, it is an open secret that many vaping retailers sell nicotine juice and pods. For example, NSW Health visited 227 NSW e-cigarette retailers between 2015-2018 and found that 40% were selling nicotine juice, with 63% of samples falsely labelled as nicotine free found to contain nicotine. Such open contempt for the law when tempted by sales opportunities to children of course has always happened also with cigarette retailing. This widespread illegal activity is one of the most critical factors underscoring the need for regulatory reform of access so that we do not repeat the failure to keep retailers from selling addictive products to children.

The other major way vapable nicotine is accessed by Australians is via personal importation. When vapers or retailers import nicotine from overseas, they run risks of purchasing preparations manufactured in conditions that are far from the standards set for pharmaceutical grade drugs. This US study found bacterial and fungal endotoxins in vape juice. This study of German sourced e-juice found ethylene glycol as the dominant compound in five products. Ethylene glycol is associated with markedly enhanced toxicological hazards. Those involved in the kitchen sink and bathtub amateur "labs" mixing up juice to supply the personal import trade are understandably highly anxious about the prescription access proposal.

Underage access easy

Children are currently well able to purchase vapable nicotine via unscrupulous retailers and on-line by using pre-paid cards that can be purchased from supermarket gift card stands for example at Woolworths, Coles, Big W, Kmart or the Post Office. This New Zealand vaping site acknowledges that: "Kids discover online vape shops without age verification. They then use prepaid cards to buy e-liquid or nicotine pods in bulk, and they sell those products to their friends."

This Google search shows many, many sites coaching underage vapers in how to obtain vaping supplies on-line.

ToR G: tobacco industry involvement in the selling and marketing of e-cigarettes

All major tobacco companies are now marketing so-called "harm reduction" products and have repeatedly claimed to hope that smokers will switch to these products and abandon cigarette use. Yet all of these companies continue to engage in actions that are incompatible with these

expressed hopes: they lobby directly and indirectly and even litigate against any evidence-based measures known to be effective in reducing smoking, including advertising and promotional bans, plain packaging and graphic health warnings; tobacco tax increases; strong, sustained and adequately funded public education programs; and smokefree measures. They aggressively promote cigarettes through any remaining avenues such as retailer incentives, social media and other internet promotions, and Formula One motor racing sponsorship. (see here, here, here and here). As well as public relations and lobbying agencies, they fund front organisations to promote their objectives. And notwithstanding their claims of concern about reducing harms, they continue to promote their "core" product aggressively wherever possible, with a special focus on developing countries and vulnerable populations, including youth.

No tobacco company has set target dates for getting out of tobacco.

British American Tobacco Australia, Philip Morris International and Imperial Brands all support liberalising access to "harm reduction" products in Australia and in this, they are in lock-step with smaller e-cigarette companies and vaping advocates. The major tobacco companies are also actively developing and promoting a range of further novel products, all cause for concerns ranging from health harms to uptake by children and young people (but clearly being promoted to these target groups in various countries), and all also clearly seen as a complement to their "core" cigarette products, rather than a replacement.

With youth smoking rates being the lowest ever recorded in Australia, the impact of each young birth cohort moving through to smoking age and not taking it up is devastating to the tobacco industry's future customer base. This is the context for their embrace of putative reduced harm products and their (unspoken) hopes that vaping and use of other novel products will proliferate in nicotine naive youth. The tobacco industry of course made the same disingenuous public "we don't want youth to smoke" statements over many decades that they now make about vaping.

With their ongoing global engagement in manufacturing and marketing tobacco, the most plausible business model being embraced by the tobacco industry is promoting smoking *as well as* vaping and use of other novel tobacco products, not use of these *instead of* smoking.

A new US study of trends in e-cigarette use from 2014 to 2018 examined data from the National Health Institute to pinpoint trends in younger (18-29 years), middle-aged (30-49 years), and older (≥ 50 years) populations, with cigarette smoking histories classified as current smokers, recent quitters (quit < 1 year ago), near-term quitters (quit 1-8 years ago), and never smokers. They found that e-cigarette use had more than doubled in younger adults who had

never smoked. (1.3%–3.3%) with the extrapolated absolute population increase in this demographic jumping from 0.49 million to 1.35 million.

ToR-H: any other related matter.

In this section we comment on six other matters relating to so-called harm reduced nicotine delivery devices.

- Are e-cigarettes much less dangerous than cigarettes?
- What are the main conclusions of recent reports of the health effects of vaping?
- Is nicotine a benign substance?
- Are there many smokers who are "hardened" nicotine addicts and cannot or will not quit smoking?
- Cigarettes can be legally sold to those aged 18 and older in any retail environment in Australia. Should not governments make so-called harm reduced products equally accessible?
- What needs to be done about the regulation of e-cigarettes and vapable nicotine in Australia

1. Are e-cigarettes much less dangerous than cigarettes?

The commonly cited claim that e-cigarettes are "95% less harmful" than cigarettes was first made in a 2014 report chaired by Professor David Nutt, notable and perhaps unique in making the cavalier claims that e-cigarettes are "the most significant advance [in medicine] since antibiotics" and would be "the greatest health advance since vaccinations." The report was written by a selected group of 12 individuals, some with a history of association with tobacco interests, who each were asked to estimate the relative harmfulness of e-cigarettes and other nicotine containing products compared to cigarettes. Their "big number" was repeated in a 2014 report by Public Health England, which again endorsed it in a 2015 update where it once again cited the Nutt report as a source, but again provided no transparent workings of how this figure was actually calculated. This is all PHE deigned to tell us in 2015:

> "It had previously been estimated that EC [electronic cigarettes] are around 95% safer than smoking [10, 146]. This appears to remain a reasonable estimate."

Reference #146 in the above update stated "The precise extent of harm from long-term use is not known but has been estimated at around 1/20th that of smoking tobacco cigarettes (5)" with the reference supporting that statement again being the Nutt report!

In its 2018 updated review PHE nudged the 95% even further toward certainty by slipping in "at least":

> "Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. The previous estimate that, based on current knowledge, vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping."

The 2016 report of the Royal College of Physicians had this to say about the 95% less harmful figure:

> "An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking,(112) and a recent report by Public Health England supported this conclusion.(113) With appropriate product standards to minimise toxin and contaminant exposure in e-cigarette vapour, it should be possible to reduce risks of physical health still further. It is also possible, although unlikely, that other, unexpected harm from inhaling e-cigarette vapour over the longer term might yet emerge. Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." (p84)
>
> "There appear to be few, if any, significant short-term adverse effects of e-cigarette use, but adverse health effects from long-term exposure to constituents of vapour cannot be ruled out. Although unknown, the hazard to health arising from long-term vapour inhalation is unlikely to exceed 5% of the harm from tobacco smoke." (p185)

Reference #112 cited by the RCP was, yet again, the Nutt report. Indeed, all roads from the 95% estimate since 2015 have led back again and again to the Nutt report, or in the case of the PHE 2018 update, to no references at all tied to the calculation.

But what did the Nutt report itself say about its now famous number? Critically, the Nutt group conceded that "*A limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria*".

Despite this most sweeping and fundamental of *caveat emptor* statements about the lack of hard evidence, a senior Public Health England official told an Australian Parliamentary inquiry in

October 2017 that "We are very clear that this is just one of the figures that we have used, and there are plenty more. *We say what really matters is the evidence underlying this figure from the Nutt report*". (my emphasis).

So where then, is this "what really matters" underlying evidence which is not cited in the Nutt report nor in Public Health England's reports? Where can we read and critically appraise the calculations that tipped the figure out into the ether?

Certainly in this video where a representative of Public Health England explains how the magic number was conjured, there is no reference to anything other than the consensus process used by the assembled Nutt meeting invitees, of which he was one.

Interviewer: Describe for us the evidence in the report and what is the science behind the 95% less harmful determination.

Dockrell: "...95% less harmful or 5% of the harm is a good way of expressing that – that subsequently appeared in the Royal College of Physicians report, It first appeared in a report published in 2014. It was led by Professor David Nutt. And David had done this kind of study before where it was a professional consensus process where you get a bunch of experts in the room. .. and we looked at what data we had for example on fires ... we looked at what evidence we had about cancer risk and toxicant exposure and we had some data on that. And on the basis of the data we had [describes which nicotine containing products were compared] ..them the computer churns out a figure and we see .. e-cigarettes coming out at 5% of the risk...

Interviewer: You've got the 5% of potential harm ... how conservative is that? Like if you were to go through everything today would it be the same number?

Dockrell: Well we published that study 5 years ago and now we have 5 years, more than 5 years more data. We have these excellent biomarkers studies. We know much more about e-cigarette vapour and how that might affect bystanders — not at all is the shorthand for that one. *And so, yeah it would depend on the experts you got around the table* [our emphasis] but I think that looking at the data that we've got even it would be less than 5%. It would be substantially less than 5%."

A factoid is "an item of unreliable information that is repeated so often that it becomes accepted as fact." The "95% safer" statement is nothing but an emperor-like factoid with suspiciously few clothes.

2. What are the main conclusions of recent reports of the health effects of vaping?

The respiratory, cardiovascular and cancer harms caused by smoking rarely manifest clinically in the short term. Instead they take decades to first appear as symptoms because of lagged effects. This is part of the reason why these diseases are called chronic rather than acute health problems. However, rarely a week passes when new studies or reviews of early markers for these diseases are not published about vaping.

With such uncertainty about the diseases that e-cigarettes might cause, continuing to treat nicotine e-juice as a hands-off, unregulated commodity is recklessly irresponsible. Below is a small selection of recent papers describing areas of concern.

Recent studies on harms from e-cigarettes

ECIG aerosols are harmful to living cells *in vitro* and *in vivo*.

Chung S, Baumlin N, Dennis JS, et al. Electronic cigarette vapor with nicotine causes airway mucociliary dysfunction preferentially via TRPA1 receptors. *Am J Respir Crit Care Med* 2019. doi: 10.1164/rccm.201811-2087OC.

Ganapathy V, Manyanga J, Brame L, et al. Electronic cigarette aerosols suppress cellular antioxidant defenses and induce significant oxidative DNA damage. *PLoS One* 2017;12(5):e0177780. doi: 10.1371/journal.pone.0177780.

Madison MC, Landers CT, Gu B, et a. Electronic cigarettes disrupt lung lipid homeostasis and innate immunity independent of nicotine. *J Clin Invest 2019;* doi: 10.1172/JCI128531. Epub 2019 Sep 4.

Raez-Villanueva S, Ma C, Kleiboer S, Holloway AC. The effects of electronic cigarette vapor on placental trophoblast cell function. *Reprod Toxicol* 2018;81:115-121. doi: 10.1016/j.reprotox.2018.07.084.

Shaito A, Saliba J, Husari A, et al. Electronic cigarette smoke impairs normal mesenchymal stem cell differentiation. *Sci Rep* 2017;7(1):14281. doi: 10.1038/s41598-017-14634-z.

Zahedi A, Phandthong R, Chaili A, Leung S, Omaiye E, Talbot P. Mitochondrial stress response in neural stem cells exposed to electronic cigarettes. *iScience*. 2019;16:250-269. doi: 10.1016/j.isci.2019.05.034.

Evidence for ECIG harm to users.

Antoniewicz L, Brynedal A, Hedman L, Lundbäck M, Bosson JA. Acute effects of electronic cigarette inhalation on the vasculature and the conducting airways. *Cardiovasc Toxicol* 2019. doi: 10.1007/s12012-019-09516-x.

Carnevale R, Sciarretta S, Violi F, et al. Acute impact of tobacco vs electronic cigarette smoking on oxidative stress and vascular function. *Chest* 2016;150:606-12. doi: 10.1016/j.chest.2016.04.012.

Ghosh A, Coakley RC, Mascenik T, et al. Chronic e-cigarette exposure alters the human bronchial epithelial proteome. *Am J Respir Crit Care Med* 2018;198(1):67-76. doi: 10.1164/rccm.201710-2033OC.

King JL, Reboussin BA, Wiseman KD, et al. Adverse symptoms users attribute to e-cigarettes: Results from a national survey of US adults. *Drug Alcohol Depend* 2019;196:9-13. doi: 10.1016/j.drugalcdep.2018.11.030.

Li D, Sundar IK, McIntosh S, et al. Association of smoking and electronic cigarette use with wheezing and related respiratory symptoms in adults: cross-sectional results from the Population Assessment of Tobacco and Health (PATH) study, wave 2. *Tob Control* 2019. doi: 10.1136/tobaccocontrol-2018-054694.

Moheimani RS, Bhetraratana M, Peters KM, et al. Sympathomimetic effects of acute e-cigarette use: role of nicotine and non-nicotine constituents. *J Am Heart Assoc* 2017;6. doi: 10.1161/JAHA.117.006579.

Reidel B, Radicioni G, Clapp PW, et al. E-cigarette use causes a unique innate immune response in the lung, involving increased neutrophilic activation and altered mucin secretion. *Am J Respir Crit Care Med* 2018;197:492-501. doi: 10.1164/rccm.201708-1590OC.

Flavouring chemicals

In 2014, there were 7764 unique vaping flavour names available online. It is likely there are many more in 2020. The peak flavour manufacturers association in the USA Flavor and Extracts Manufacturers Association (FEMA) stated earlier this year:

> **1.** There is no apparent direct regulatory authority in the United States to use flavors in e-cigarettes. In this context, it is important to note that the "generally recognized as safe" (GRAS) provision in Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA) applies only to food as defined in Section 201(f) of the Act.

2. None of the primary safety assessment programs for flavors, including the GRAS program sponsored by the Flavor and Extract Manufacturers Association of the United States (FEMA), evaluate flavor ingredients for use in products other than human food. FEMA GRAS status for the uses of a flavor ingredient in food does not provide regulatory authority to use the flavor ingredient in e-cigarettes in the U.S.

3. E-cigarette manufacturers should not represent or suggest that the flavor ingredients used in their products are safe because they have FEMA GRAS status for use in food because such statements are false and misleading.

3. Is nicotine a benign substance?

The late addiction researcher Michael Russell stated in 1976 that "People smoke for the nicotine but they die from the tar". This statement has become a mantra for vaping advocates who take it as read that nicotine is an almost entirely benign substance.

But Russell made that statement 44 years ago and since then, in addition to the well-known literature on nicotine and addiction, further evidence on harms from nicotine includes an extensive body of evidence published suggesting that nicotine, while not being carcinogenic, is a tumour promoter. For example:

> "Although nicotine itself is regularly not referred to as a carcinogen, there is an ongoing debate whether nicotine functions as a 'tumour promoter'. Nicotine, with its specific binding to nAChR, deregulates essential biological processes like regulation of cell proliferation, apoptosis, migration, invasion, angiogenesis, inflammation and cell-mediated immunity in a wide variety of cells including foetal (regulation of development), embryonic and adult stem cells, adult tissues as well as cancer cells. Nicotine seems involved in fundamental aspects of the biology of malignant diseases, as well as of neurodegeneration."

This 2015 review of research relevant to nicotine and the adolescent brain looked at "how acute exposure to nicotine impacts brain development and how drug responses differ from those seen in adults." The authors discussed "the persistent alterations in neuronal signaling and cognitive function that result from chronic nicotine exposure, while highlighting a low dose, semi-chronic exposure paradigm that may better model adolescent tobacco use" and argued "that nicotine exposure, increasingly occurring as a result of e-cigarette use, may induce epigenetic changes that sensitize the brain to other drugs and prime it for future substance abuse".

There is also emerging evidence that nicotine may play a role in the development of schizophrenia. For example:

Scott JG, Matuschka L, Niemelä S et al. Evidence of a causal relationship between smoking tobacco and schizophrenia spectrum disorders. Front. Psychiatry, 20 November 2018 |

> Abstract: There has been emerging evidence of an association between tobacco smoking and schizophrenia spectrum disorders (SSD) **...**There was substantial though inconclusive evidence supporting a causal relationship between tobacco smoking and increased risk of SSD. If a causal relationship does exist, nicotine is most likely responsible for this association. This raises serious public health concerns about the increasing use of e-cigarettes and other products, particularly by adolescents whose nicotine use may increase their risk of SSD. Research is urgently needed to examine the association between e-cigarette use and incident psychosis, particularly in adolescents and young adults.

Gurillo P, Jauhar S, Murray RM, MacCabe JH. Does tobacco use cause psychosis? Systematic review and meta-analysis. Lancet Psychiatry 2015;2: 718–25.

> From abstract: "For prospective studies, we calculated an overall relative risk of new psychotic disorders in daily smokers versus non-smokers of 2.18 (95% CI 1.23–3.85). Daily smokers developed psychotic illness at an earlier age than did non-smokers (weighted mean difference –1.04 years, 95% CI –1·82 to –0.26). Those with psychosis started smoking at a non-significantly earlier age than did healthy controls (–0.44 years, 95% CI –1·21 to 0·34).
>
> Interpretation: Daily tobacco use is associated with increased risk of psychosis and an earlier age at onset of psychotic illness. The possibility of a causal link between tobacco use and psychosis merits further examination. [Note: the discussion section of this paper includes a detailed consideration of the possible role of nicotine in the development of psychosis].

Niemelä S, Sourander A, Surcel H-M et al Prenatal nicotine exposure and risk of schizophrenia among offspring in a national birth cohort. Am J Psychiatry. 2016 Aug 1;173(8):799-806.

> From Abstract: Results: A higher maternal cotinine level, measured as a continuous variable, was associated with an increased odds of schizophrenia (odds ratio=3.41, 95% confidence interval, 1.86–6.24). Categorically defined heavy maternal nicotine exposure was related to a 38% increased odds of schizophrenia. These findings were not accounted for by maternal age, maternal or parental psychiatric disorders, socioeconomic status, and other covariates. Conclusions: To the authors' knowledge,

> this is the first study of the relationship between a maternal smoking biomarker and schizophrenia. It provides the most definitive evidence to date that smoking during pregnancy is associated with schizophrenia. If replicated, these findings suggest that preventing smoking during pregnancy may decrease the incidence of schizophrenia.

4. **Is it true there many smokers who are "hardened" nicotine addicts and cannot or will not quit smoking?**

This claim derives from the so-called hardening hypothesis which states that, as smoking prevalence falls ever lower, the remaining smokers will be die-hard addicted "refractory" smokers who just can't quit. They are impervious to the suite of tobacco control policies and campaigns that have driven hundreds of millions of smokers around the world to quit. Vaping advocates argue that it's time we acknowledged that these smokers cannot quit and that we are condemning many of them to death if we don't put policies in place that will help them quit smoking with e-cigarettes. To do anything else would be unethical, they try to argue.

Aside from the evidence referred to earlier that e-cigs are poor in helping people quit, the entire premise of the hypothesis is an evidence-free house of cards.

Whenever this hypothesis has been tested against the evidence it has been found wanting. In nations or states where smoking prevalence has fallen most, one would expect (if the hardening hypothesis was correct) that indices of hardened smokers (such as mean number of cigarettes smoked per day) would be rising because the remaining smokers would be over-represented by heavy, addicted smokers.

Unfortunately for this argument, John Hughes, one of the world's most prolific researchers on smoking cessation, recently deflated the hardening hypothesis tyres in a paper in Nicotine and Tobacco Research. He reviewed 26 studies on hardening and found:

> "None of the 26 studies found that conversion from current to former smoking, number of quit attempts, or success on a given quit attempt decreased over time and several found these increased over time." He concluded "Some have argued that a greater emphasis on harm reduction or intensive treatment approaches is needed because remaining smokers are those who are less likely to stop with current methods. The current review finds no or little evidence for this rationale."

A very recent Australian analysis concluded "The observed trends in the prevalence of hardcore smokers (i.e., either stable or declining depending on the definition) suggest that the Australian smoking population is not hardening. These results do not support claims that remaining smokers are becoming hardcore."

In conclusion, as has always been the case, there clearly are smokers who find it very difficult to quit. But it is very wrong to imply that all who are vaping today are former and current smokers who are vaping to quit smoking. The just-published paper from the ITC-4CV four country (Australia, USA, UK, Canada) cohort survey found that "among smokers who also vaped, 46% planned to quit smoking within 6 months, 30% planned to quit in the future, but beyond 6 months, with the remaining 24% reporting that they did not know or did not plan on quitting, suggesting low motivation to quit smoking among many of the concurrent [both smoking and vaping] users." Many who vape are not at all desperate to quit smoking.

5. **Cigarettes can be legally sold to those aged 18 and older in any retail environment in Australia. Is it not reasonable that governments now make so-called harm reduced products equally accessible?**

If the worst examples of public health policy in the past 120 years were ever to be nominated, decisions to allow tobacco products to be freely sold and for the ingredients to be completely unregulated would be a very strong contender for the policy responsible for more deaths than any other single policy failure.

Those who argue that e-cigarettes should be at least as unregulated and accessible as cigarettes are effectively arguing like this:

> "we made every possible mistake in failing to strictly regulate tobacco (because at the beginning of the twentieth century we had no data or knowledge about the health impacts of smoking which did not become available until the 1950s). We believe we should take the same path again and fail to regulate vaping products, knowing that today we are in a similar situation with our lack of data on the health impacts of vapable nicotine and tobacco products. "

Quite obviously this reasoning is the exact opposite of what responsible governments should do. We have an opportunity to strictly regulate access to vapable nicotine via the proposed prescription access model being proposed. The clear historical lesson is that our approach to allowing access to tobacco has been disastrous and that if we are to learn from history, we should not make the same mistakes again.

ATHRA director Dr Alex Wodak has argued publicly that **"**Vaping is to smoking what methadone is to street heroin." This analogy has significant imperfections but, most fundamentally, Wodak failed to note that methadone is only available via special prescription authority, dispensed at some pharmacies and clinics. In 2011, 46,446 patients were being prescribed methadone by 1,444 doctors across Australia. The TGA plan will make vapable nicotine available in the much the same way. Those assessed by their doctor as having been unsuccessful at quitting smoking

via other ways of stopping, would be given an authority to access vapable nicotine via a pharmacist, in exactly the way that all scheduled therapeutic goods are accessible in every but the most chaotic nations where almost any drug can be bought by anyone.

We are not aware of Dr. Wodak advocating that methadone should be available to whoever wants to buy it from any retailer wanting to sell it, in just the way that cigarettes are sold.

6. What needs to be done about the regulation of e-cigarettes and vapable nicotine in Australia?

In this section, we set out our views on the TGA proposal that adult smokers could legally access vapable nicotine via a doctor's prescription.. We have always argued that the obvious umpire in this matter should be the TGA. This is because (1) claims for the therapeutic utility and safety of vapable nicotine are extremely commonly made or implied by vaping advocates and manufacturers (2) therapeutic claims require TGA oversight and regulation and 3) bypassing the TGA would set a disturbing precedent for many putatively therapeutic substances also promoted by their manufacturers as life-saving.

The argument that e-cigarettes are not therapeutic substances is often made by vaping advocates trying to walk on both sides of the regulatory street. They argue strenuously that e-cigs are superior to other regulated ways of quitting smoking, but then try to say that this is not a therapeutic claim and that these products should be treated like "consumer goods" for which therapeutic claims also cannot be made.

Very much *not* a ban on vapable nicotine

We have noted much commentary in which the proposed TGA via prescription proposal is described as a "ban" on nicotine vaping in Australia. This is palpable nonsense. The proposal is no more a ban on vapable nicotine than the TGA scheduling of all prescribed drugs is a "ban" on accessing the vast array of prescription medicines that are used every day by millions of Australians who have obtained authority to do so by their doctor.

As the Senate has no authority to direct the independent TGA in regard to therapeutic scheduling nor the operation of this scheduling, we will confine ourselves to commenting on the proposal announced by the Minister for Health Greg Hunt in June 2020 that there should be a prohibition on personal importation of nicotine.

Without the introduction of a ban on *both* the ex-pharmacy sale of vapable nicotine and its personal importation (as well as other strict controls and monitoring), the proposed prescribed

access proposal will fail. Those now importing will continue to do so and vaping advocates and exporters will continue to advise users on how to do this online.

Sale of nicotine outside of therapeutic scheduling or in the form of tobacco is prohibited in Australia. We strongly support this continuing until and unless such time as sufficient long term, high quality data *may* have accumulated to show that vapable nicotine poses an acceptable risk profile to allow it to be sold without prescription.

Any ban on ex-pharmacy sales to persons without a prescription and on personal or unauthorised commercial quantity importation of vapable nicotine would need to include very significant deterrent penalties for those breaking these laws. Without such penalties, many would calculate that it was low risk activity and break the law.

Since March 2019 it has been illegal to import tobacco products into Australia (other than cigars, chewing tobacco and snuff intended for oral use up to 1.5kg) through couriers or mail.

As we described in ToR-F above, the current access de facto free-for-all for nicotine in Australia is allowing children easy access to vapable nicotine and carries significant quality and safety risks. A prescribed access scheme would preclude access by children (other than rare exceptions who had very strong smoking addiction).

Vaping apparatus can be used to vaporise many substances

Much global publicity occurred in August 2019-Feb 2020 about the incidence of EVALI (e-cigarette, or *vaping*, product use-associated lung injury) cases (2807) and deaths (68). Vaping vitamin E acetate, which has been added to vaping products as a diluent and tetrahydrocannabinol-containing products is thought to be responsible for most of these cases and deaths.

Nicotine vaping advocates have been steadfast in arguing that there is “nothing to see here” in terms of any link with nicotine vaping. This is a myopic view. The widespread availability of vaping equipment ostensibly sold to vape nicotine has allowed some of that equipment to be used to vapourise other substances, some of which have proven deadly. Just as fires caused by discarded cigarettes are collateral damage caused by their availability, these non-nicotine vaping deaths are collateral harms caused by the emergence and proliferation of nicotine vaping equipment. This Lancet article also argues that vaping is most likely exacerbating the harms of COVID19.

CONCLUDING COMMENTS AND RECOMMENDATIONS

It is important that this Committee and its Inquiry be seen in the appropriate context. Smoking causes more than 8 million deaths each year around the world, and more than 20,000 in Australia, where it remains our largest single preventable cause of death, as well as much ill health and suffering and substantial costs to the community. There has been clear evidence that smoking kills for more than 70 years. The single key cause and vector is the global tobacco industry. As the late Senator Robert Kennedy said as long ago as 1967, "Cigarettes would have been banned years ago were it not for the tremendous economic power of their producers.....The cigarette companies have demonstrated a total inattention to public responsibility."

In addition to overwhelming evidence about the lethal consequences of smoking and the activities of the tobacco industry, there is compelling evidence about the action required to reduce smoking, to the extent that it is ultimately phased out. There is no single "magic bullet" – rather, as with so much in public health, a need for a comprehensive approach entailing regulation, public education, taxation and cessation support. This approach is set out in the WHO Framework Convention on Tobacco Control (FCTC), which came into force in 2005, and to which Australia is one of 181 signatories. The FCTC also notes in Article 5.3 that "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law", and further, in its Guidelines, that "There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests".

As we noted above, the tobacco companies and their associated organisations have opposed and wherever possible delayed and undermined all evidence-based measures to reduce smoking in Australia. Despite this, as a result of strong medical and health recommendations and support, the action taken in Australia has resulted in encouraging trends among both adults and children and young people. It is critically important that this momentum be maintained, and that measures known to be effective are implemented, both for the wider community and working with and in support of disadvantaged groups.

We wish to draw the attention of the Committee to the need for stronger action in some key areas, notably public education (where there has been no national mass media campaign for close to a decade, and the current total allocation for the next three years is a meagre $20 million: this compares with recommended funding of $40 million p.a., and tax revenue of over $15 billion p.a.); ii) special programs addressing the needs of disadvantaged groups; iii) comprehensive cessation support activities at all levels; iv) legislation to enable regulation of the product itself, and any packaging or other features likely to attract children and young people; v) addressing the development and promotion of RYO (roll-your-own) products; vi)

banning political donations from tobacco companies and requiring tobacco companies to publish details of their lobbying, marketing and public relations activities.

It is a matter of great concern to us that publicity and promotion of e-cigarettes and other novel products has been successful in distracting attention away from the evidence-based action that has and will reduce smoking, and from further publicity about the harms of smoking. We have no doubt that this is a major motivation for the tobacco industry's promotion of these products, and for its funding for a range of further organisations and activities.

We urge the Committee to reiterate its support for the comprehensive, evidence-based program of action recommended by the World Health Organization through the FCTC, and for a continuing commitment to Article 5.3.