THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Professor Wayne Hall
Director
Centre for Youth Substance Abuse Research

CRICOS PROVIDER NUMBER 00025B

Chair,
Standing Committee on Health, Aged Care and Sport
House of Representatives,
Parliament of Australia, Canberra ACT

6 July 2017

Dear Chair

We wish to make a submission to the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia.

We are public health researchers who have undertaken research on e-cigarettes and non-combustible alternatives to smoked cigarettes such as low nitrosamine smokeless tobacco or snus.

Coral Gartner is an Associate Professor at the University of Queensland and a NHMRC Career Development Research Fellow. She has over 20 years of experience in public health and has undertaken research in tobacco control for over a decade, including several clinical trials of e-cigarettes for smoking cessation. She has authored over 100 academic works in peer-reviewed journals and books and is ranked 4th internationally for number of publications with the keyword "e-cigarettes" (source; Web of science 26/05/2017).

Wayne Hall is a Professor at the University of Queensland and the National Addiction Centre, Kings College London. He has over 30 years of experience as a researcher and policy adviser in mental health and public health. He has authored over 1000 academic works in peer-reviewed journals and books. He has published extensively in leading medical journals and advised the World Health Organization.

We confirm that we have never accepted funding from the tobacco industry.

The submission includes an executive summary and our responses to each of the Committee's terms of reference. We are prepared to attend public hearings to answer any questions on our submission if that would assist the Committee in conducting its Inquiry.

Yours sincerely

[redacted]

Coral Gartner
School of Public Health
The University of Queensland

[redacted]

Wayne Hall
Centre for Youth Substance Abuse Research
The University of Queensland

In our submission we use the following terminology:

Nicotine-containing products: Products that contain nicotine, including therapeutic and non-therapeutic products.

Nicotine replacement therapy (NRT): Therapeutic nicotine products, such as nicotine gum, patches, and inhalers that are marketed with explicit claims of safety and efficacy as smoking cessation aids.

Tobacco harm reduction: approaches that attempt to reduce tobacco-related harm by encouraging smokers to switch completely from combustible cigarettes to less harmful forms of obtaining nicotine such as, NRT, smokeless tobacco and e-cigarettes or other electronic nicotine delivery systems (ENDS).

Vaping products: vaporisers and liquids (or e-liquids) used for inhaling.

ENDS: electronic nicotine delivery systems (or vaporisers) that avoid tobacco smoke by delivering nicotine to smokers in an aerosol (commonly referred to as vapour) formed by heating a carrier fluid such as glycerine or propylene glycol containing nicotine.

Cigalike devices: older style ENDS that resemble conventional cigarettes and attempted to deliver equivalent doses of nicotine via a vapour.

Tank devices: These are ENDS that have a refillable tank that typically deliver higher doses of nicotine than cigalikes in doses more comparable to those of combustible cigarettes.

Summary of Our Submission

We believe that the Australian policy towards the regulation of ENDS is unnecessarily restrictive. It prohibits adults from using ENDS products that contain nicotine by only allowing these products to be sold, possessed and used in Australia if they have been approved as therapeutic products by the TGA. Since no ENDS products have been approved by the TGA, this policy prohibits use by adults and treats ENDS much like illicit drugs.

Current Australia policy has the following major defects:

- It is an incoherent policy that bans the sale of less harmful nicotine products while allowing the most harmful - combustible cigarettes - to be freely sold.
- It unjustly prevents adult smokers from using ENDS to reduce tobacco-related harm.
- It treats ENDS products like a dangerous drug when there is increasing evidence that they are much less dangerous than smoking cigarettes, they have assisted smokers to quit, and they do not deter smokers from quitting smoking.
- Australian smokers who have switched to vaping must obtain nicotine products on the black market in the absence of any regulation of nicotine products.

Our Suggested Alternative Approach

We support the requirement that makers of any ENDS products that make therapeutic claims should be required to present evidence of their safety and efficacy to the TGA and be approved for sale for as therapeutic goods.

We would, however, lift the ban on the sale of non-therapeutic ENDS to adults which would align Australia with all other comparable countries (e.g. New Zealand, Canada, USA, UK, Europe). We would allow sales of ENDS that met minimum standards of consumer safety to adult smokers with some restrictions. Nicotine solutions would only be supplied in child-resistant containers and no promotion would be allowed except at points of sale, such as specialist vape stores, tobacconists, adult stores and/or pharmacies. We would not allow ENDS to be sold by general retailers to reduce their public visibility and access by under-aged purchasers. We would monitor ENDS use among young people.

As an interim measure, we would support restrictions on ENDS use in public indoor settings. This would reduce concerns about highly visible public ENDS use and minimise any health risks (however minor) for nonsmokers from second-hand exposures to ENDS vapour. These restrictions could be relaxed in some settings if there was evidence that there were no risks to nonsmokers from second-hand vapour exposure in these environments.

This approach is similar to policies that have been adopted in most countries that have comparable tobacco control policies to Australia. This includes Canada and New Zealand which have recently decided to abandon the Australian approach in favour of our proposed dual-track regulatory approach to nicotine-containing vaping products.

As an interim measure Australian adults should be permitted to access ENDS that have not been approved by the TGA via existing mechanisms such as the Special Access Scheme.

Responses to the Committee's Terms of Reference

1. The use and marketing of e-cigarettes and personal vaporisers to assist smokers to quit

Ideally, evidence for the efficacy of e-cigarettes/electronic nicotine delivery systems (ENDS) as therapeutic smoking cessation aids should be provided by randomised controlled clinical trials that compare the effectiveness of ENDS with that of approved therapeutic nicotine replacement therapy (NRT) products (such as gums and patches) in enabling smokers to successfully quit. A small number of these trials have been done with 'cigalike' ENDS, small e-cigarettes that resemble combustible cigarettes in appearance. They have lower nicotine delivery than more advanced larger models of ENDS. These trials indicate that cigalikes are approximately equivalent to NRT in assisting smokers to quit. A review of these studies by the Cochrane Collaboration [1] concluded that:

> "Combined results from two studies, involving 662 people, showed that using an EC containing nicotine increased the chances of stopping smoking in the long term compared to using an EC without nicotine."

The value of these clinical trials was limited by two major factors: (1) the relatively small numbers of smokers included in the trials limited confidence in their findings; and (2) the trials only evaluated cigalike devices that are known to be less effective at delivering nicotine than the modern tank devices that are now predominantly used by vapers. We need more controlled clinical trials with larger samples that compare these newer ENDS products with NRT in their effectiveness for smoking cessation.

Large scale surveys in the UK indicate that ENDS have been used by a substantial proportion of smokers either to successfully quit smoking or as a complete replacement for smoking. Brown and colleagues reported that smokers who used newer tank style e-cigarettes in their most recent quit attempt were more likely to successfully quit than smokers who used either NRT or who quit cold turkey [2].

The findings of Brown et al are consistent with recent population trends in the prevalence of cigarette smoking in England. In 2010, the prevalence of smoking was 1-2% higher in England than in Australia (depending upon which Australian survey was used). In 2016, the prevalence was the same as that in Australia because there was a steeper decline in smoking in England between 2013 and 2016 than in Australia (see Figure 1). The greater decline in England occurred in the absence of large increases in taxes on cigarettes and the plain packaging of cigarettes that were introduced in Australia over the same period (see Table 1).

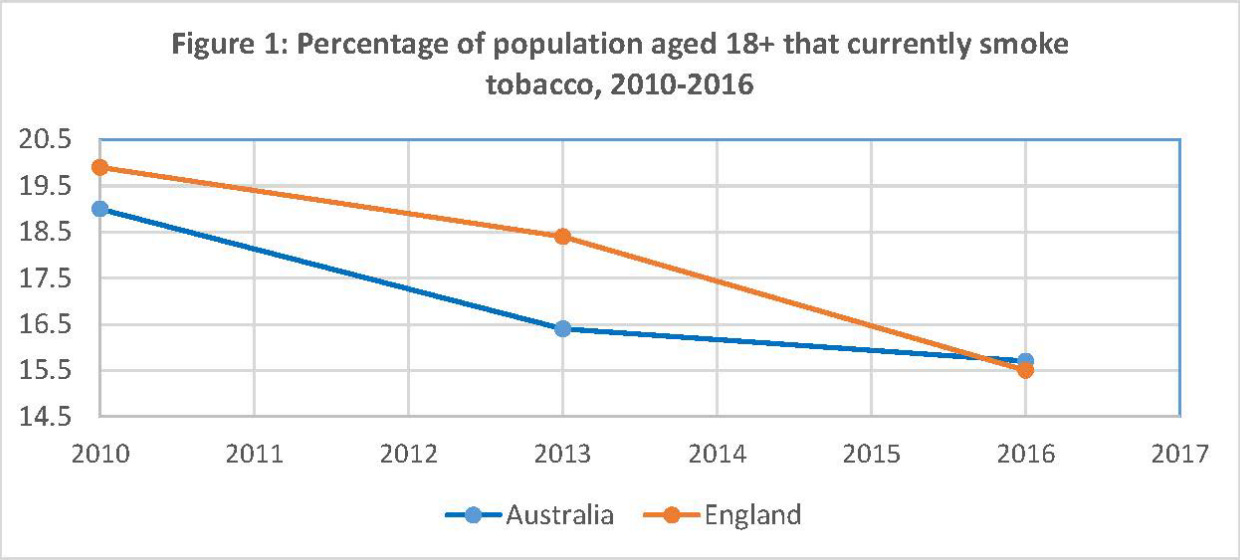

Figure 1 Footnote: Data are for any current smoking among the population aged 18+ as reported in the Australian Institute of Health and Welfare 2016 National Drug Strategy Household Survey Supplementary Data Tables (Australia) [3] *and Office for National Statistics Statistical bulletin: Adult smoking habits in the UK: 2016 (England)* [4].

The decline in cigarette smoking in England occurred over the same period in which the use of ENDS increased among smokers in England. It was also a period in which smokers were encouraged to use ENDS either as a short-term smoking cessation aid or as a long-term substitute to smoking cigarettes by the UK government (via Public Health England), Action on Smoking and Health (a leading English anti-smoking group), the Royal College of Physicians, and Cancer Research UK (an anti-cancer charity).

The slower decline in smoking prevalence in Australia between 2013 and 2016 occurred during a period in which there were large annual tobacco taxation increases. This suggests that Australia is unlikely to see further substantial declines in smoking prevalence by relying solely on traditional demand reduction measures, among which increasing tobacco taxes is considered to be the most effective strategy [5].

Table 1: Tobacco control policies implemented in Australia and England from 2010-2016

Year	Australia	England
2010	tax increase 25%	tax increase 1%
2011	-	tax increase 2%
2012	plain packaging fully implemented	tax increase 5%
2013	tax increase 12.5%	tax increase 2%
2014	tax increase 12.5%	tax increase 2%
2015	tax increase 12.5%	tax increase 2%
2016	tax increase 12.5%	tax increase 2%; plain packaging implementation commenced 20 May 2016

2. The health impacts of the use of e-cigarettes and personal vaporisers

Health benefits of ENDS

ENDS have been a consumer product for a little over a decade and over this time their design characteristics have evolved considerably. This means that both their benefits and any adverse effects of their long term use are not fully understood. There is nonetheless promising evidence that ENDS use causes substantially less harm than cigarette smoking. This evidence is summarised in reports by Public Health England [6], the Royal College of Physicians [7] and a recent review for the Canadian Institutes of Health by the Canadian Centre for Addictions Research British Columbia [8].

Briefly the research reviewed in these reports has shown that:

- The vapour from ENDs contains far fewer toxins and much lower levels of carcinogens than the smoke from tobacco cigarettes [9]. This is shown in studies that have compared the chemical composition of tobacco smoke and nicotine vapour from various ENDs products [6-8]. It is confirmed by biochemical studies which find much lower levels of carcinogens and toxins in the bodily fluids of vapers than cigarette smokers [8].

- Smokers with serious respiratory diseases such as asthma and COPD who have switched wholly from smoking to e-cigarettes show very substantial improvements in their respiratory health [8].

- Surveys in the UK indicate that ENDS have primarily been used by smokers and ex-smokers [2]. Their use has been very rare among non-smokers. As noted above, the use of ENDS by smokers appears to have contributed to increased rates of successful quitting among UK smokers without discouraging quit attempts [10].

Potential harms of ENDS

Proponents of bans on ENDS have made a number of claims about the potential dangers of ENDS use to cigarette smokers and public health [11]. These include claims: that ENDS vapour is much more toxic than the estimates made by Public Health England and the Royal College of Physicians; that allowing access to ENDS will cause nicotine poisoning and other adverse health effects independently of the effects of cigarette smoking; that nicotine is a carcinogen, despite it not being classified as such by the International Agency for Research on Cancer; that failures of batteries in ENDS devices have caused fires and explosions; that ENDS will discourage quit attempts among smokers who will engage in the dual use of cigarettes; and that there is evidence that ENDS will serve as a gateway to cigarette smoking among adolescents and young adults. We briefly evaluate the evidence for each of these claims.

Toxic emissions in ENDS aerosols

Comprehensive reviews of studies on the toxicity of e-cigarette vapour by Public Health England, the Royal College of Physicians and the University of Victoria Centre for Addictions Research of BC in Canada have all concluded that the harms of using ENDS are very low compared to smoking cigarettes.

The two UK reviews concluded that the harms were unlikely to exceed 5% of the harms of smoking cigarettes. ENDS opponents have disputed this figure and misleadingly claimed that it is based only on an expert panel consensus study. This is incorrect: the UK reviews were based on research studies that compared the toxic constituents of ENDS vapour and cigarette smoke. Other studies using different methodology, such as the US Environmental Protection Agency health risk assessment model, have supported the conclusion of Public Health England [12].

ENDS aerosols contain some potentially harmful chemicals but there are fewer of these and they are present at much lower levels in vapour than in tobacco smoke [7-9]. Some critics of ENDS implicitly demand that ENDS products must contain zero levels of harmful chemicals before they can be sold as consumer goods. This is an impossible standard that is not applied to any other consumer product. Rather a risk based approach should be adopted that takes into account who will use the product, how it will be used, what measures can be implemented to minimise any risks and also the risk associated with the product it is designed to replace.

Misleading scientific evidence is often selectively cited by critics on potential toxic exposures from vaping devices. This evidence often does not reflect typical user exposures because it involves over-heating e-liquids to produce potentially harmful chemicals. For example, these studies often operate ENDS products at higher power settings than are used by vapers [8], including studies that have reported high levels of formaldehyde in ENDS vapour [13].

It is clear that vaping is much less harmful than smoking even if it is difficult to accurately estimate the exact relative risk of vaping compared to smoking in the absence of long-term epidemiological data. More data from appropriately designed research studies, such as biomarker studies, could help further refine our understanding of the relative risks of vaping compared to smoking. However, critics of the 95% less harmful estimate have not provided any plausible evidence-based alternative estimate that would support their implicit claim that there are only minor differences between the health risks of smoking tobacco cigarettes and using ENDS to deliver nicotine.

Battery-related incidents

A number of accidents have been reported in the literature and media related to the lithium ion batteries used in vaping devices. There are a wide variety of brands with varying quality control and most reports do not identify the particular devices that have been associated with these accidents. Nor do the reports indicate whether users may have modified the devices.

These incidents provide good reasons for regulating ENDS as consumer devices. A ban of all ENDS would be an over-reaction, however, because the number of accidents is very small compared to the

number of devices that are used globally. Some manufacturers include safety features to prevent over-heating, fire and explosions. A reasonable approach would be to require *all* manufacturers to implement safety features that reduce these risks and regulate them like other consumer products that contain lithium ion batteries. Vaping devices that do not contain nicotine can be legally sold in most Australian States and Territories. These devices are regulated by the Australian Competition and Consumer Commission (ACCC) in the same way as all consumer products that contain lithium ion batteries. It would be sensible to subject all vaping products, including those that contain nicotine, to this same oversight given that the ACCC already has responsibility for the safety of a wide range of consumer products that contain lithium ion batteries, of which vaping devices represent a very small percentage.

Risks of poisoning from liquid nicotine

The risks of poisoning from liquid nicotine are very low with appropriate regulation. For example, a liquid nicotine product, Nicorette Quickmist mouth spray, has been sold over the counter in Australia since 2012 by general retailers and supermarkets. Each bottle of Nicorette Quickmist contains 150 mg of nicotine in a propylene glycol base, similar to nicotine vaping liquids. It has been sold widely with few restrictions in Australia because it is exempt from drugs and poisons scheduling. There have been no reports of widespread child poisonings caused by this product. Sensible regulatory requirements, such as requiring child-resistant packaging and simple labelling advice (Keep out of reach of children), have been sufficient to minimise the risks of poisoning from this product. The same regulations could ensure the safety of nicotine solutions used in ENDS.

Dual use and quit attempts by smokers

Many critics of ENDS are concerned that the dual use of ENDS and cigarettes will have similar adverse public health effects as light and low tar cigarettes. They argue that ENDS will discourage smokers from making quit attempts by enabling them to use ENDS when they cannot smoke cigarettes (e.g. in public places) and to smoke cigarettes at other times.

This claim ignores one major difference between ENDS and light and low tar cigarettes: switching to ENDS will reduce smokers' exposure to harmful constituents of tobacco smoke (as noted above). Light and low tar cigarettes, by contrast, did not reduce harm because smokers engaged in compensatory smoking to obtain their desired levels of nicotine. This meant that they maintained their exposure to tar and toxicants at the same or greater level as they would have if they had continued to smoke regular cigarettes [14].

Critics of ENDS cite cross-sectional surveys which show that many, if not most, smokers who report using ENDS continue to smoke cigarettes, i.e. engage in 'dual use'. This finding is to be expected because cross sectional surveys do not distinguish between: smokers who are trialling ENDS, smokers who are using ENDS to cut down before a quit attempt, and smokers who engage in long term dual use. We need longitudinal studies that follow ENDS users over time to see how many make quit attempts, what proportion are successful in quitting or switching wholly to ENDS, and what proportion continue to engage in dual use.

A number of longitudinal studies have followed smokers who do and do not use ENDS over time to answer these questions. These studies suggest that smokers who use ENDS do not make fewer quit attempts than those who do not use ENDS and that the proportion of ENDS-using smokers who quit or switch to ENDs increases over time [15-17]. This does depend on the type of ENDS products that are used: smokers who use tank type ENDS products regularly (daily) are more likely to successfully quit than smokers who occasionally use cigalikes.

Studies of UK smoking trends over the past decade do not support the claim that use of ENDS discourages smokers from quitting. Instead, they find that use of ENDS does not reduce the proportion of smokers who make a quit attempt and their use increases the chance of successful quitting. Self-reported rates of quit attempts among UK smokers have not changed since the introduction of ENDS in the England but rates of successful smoking cessation have increased at a faster rate in the UK than in Australia (see data above).

From a public health perspective we need to discourage long term dual use of ENDS and cigarettes by smokers. We need to encourage smokers to use ENDS with the intention of either using them as a short-term quit aid or switching to their full time use by giving a clear educational messages that the largest health benefits from using ENDS occur if the use of ENDS wholly, rather than partially, replaces smoking. A misleading health message that there are minimal health differences between using ENDS and smoking cigarettes may unintentionally encourage smokers who use ENDS to continue to engage in long term dual use, or worse still, to return to cigarette smoking.

E-cigarette use by adolescents

A number of prospective cohort studies of adolescents have reported an association between experimenting with e-cigarettes and experimentation with tobacco cigarettes (see [8] for a review). Some critics of ENDS have interpreted this as evidence that using ENDS increases the risks of adolescents becoming regular smokers [18]. However, there are a number of factors that need to be considered with respect to these studies. Firstly, because of the very low prevalence of smoking in these age groups, these studies classify any smoking, including just a single puff of a cigarette, as ‘smoking’. Not all of these cigarette experimenters will progress to regular smoking. The second issue is that at least some proportion of these young people would have gone on to experiment with smoking even without experimenting with ENDS first. Adolescents who are most likely to experiment with ENDS are also those who are at higher risk of experimenting with cigarettes for other reasons e.g. sensation seeking, risk-taking, oppositional and rebellious [8,19]. It is plausible that there may be a proportion of young people who do become more sensitised to smoking via experimentation with ENDS which could lead them to also experiment with smoking, however this is most likely to occur in settings where there are no age restriction on the sale of ENDS. It should be noted that these longitudinal studies have generally been conducted in settings where there were no age restrictions on the purchase of ENDS at the time of the baseline data collection. The authors of these reports quite reasonably suggest that their findings support restricting youth access to ENDS such as by applying the same age restrictions that apply to cigarette sales and restrictions on broadcast advertising. They do not go so far as to suggest that these results are sufficient to justify banning the sale of ENDS to adults. It should also be noted that many Australian states and territories

(e.g. Qld, NSW, ACT, Victoria) already ban the sale of vaping products to people under age 18, a measure that we support.

Finally, there is little evidence from epidemiological monitoring that ENDS have increased regular cigarette smoking among young people by serving as a gateway to smoking [8]. The evidence in fact is to the contrary: in the UK smoking rates among young people have declined as steeply as they have in Australia, despite the increased use of ENDS by adult smokers in the UK and high rates of ENDS uptake among young adults who smoke [20].

3. International approaches to legislating and regulating the use of e-cigarettes and personal vaporisers

A number of options are available to regulate ENDS that are listed below in order of increasing intrusiveness. These involve treating ENDS:

1. as consumer goods and regulating them to ensure consumer safety and minimise misleading advertising;

2. as tobacco products and regulating them in much the same ways as we do tobacco products e.g. age restrictions on sales, bans on advertising and use in public areas;

3. as a therapeutic good for smoking cessation that requires evidence of efficacy and safety before they are approved for use as a therapeutic good;

4. as dangerous drugs by prohibiting their sale or use by adults for nonmedical use.

We can also use two or more of the above approaches in a dual- or multi-track system that imposes different regulations on ENDS products depending upon whether they are marketed as consumer goods or therapeutic goods.

Australia's Regulatory Approach

Australia has adopted a combination of options **3** and **4** to regulating ENDS. They can be used and sold as therapeutic products if they are approved by the TGA as therapeutic goods. With this exception, all non-therapeutic nicotine products (except for tobacco cigarettes) are treated in the same way as illicit drugs like heroin and cocaine, that is, the possession and use of non-therapeutic nicotine products is banned using state and territory drugs and poisons legislation which prohibits their sale or use without authorisation. Under Federal legislation ENDS products can be imported for personal use as an unapproved cessation aid with a medical prescription but there have been reports on social media of vapers in Queensland being threatened with prosecution by the state health department for importing nicotine-containing vaping liquids for personal use.

The way that Australia regulates ENDS is much more restrictive than the way that it now regulates medical use of cannabis, an internationally controlled substance. Cannabis products are allowed to be used by patients for a wide range of conditions in the absence of evidence of their safety and efficacy for many of these putatively therapeutic uses, provided that an approved medical practitioner is prepared to prescribe them for the patient [21].

Australian ENDS regulations raise important ethical issues for the substantial proportion of smokers who have tried and failed to quit smoking [22]. Many smokers want to stop using all nicotine products and some achieve that goal, often after a number of attempts but some smokers find stopping extremely difficult or unachievable. This is often the case for smokers from socially disadvantaged populations, such as those of low socioeconomic status [23], those who are

unemployed and those living with serious mental illnesses [24]. For many of these smokers, it can take a large number of quit attempts over periods of years before they succeed. Those who fail to quit often die of a tobacco-related disease.

For smokers who are unable to quit, switching to a less harmful way of obtaining nicotine that resembles smoking is likely to be substantially easier than stopping altogether. This shift may help these smokers to quit sooner and avoid accumulating more smoking-related harm than they would if they continued to smoke. It may also assist some smokers to become smoke-free who would never quit smoking in the absence of an acceptable substitute. It is arguably unethical and unjust to deny smokers who have great difficulty ending their nicotine addiction from using less harmful alternatives while we continue to allow them ready access to the most harmful nicotine products (combustible tobacco cigarettes) [22].

The series of large annual tobacco tax increases enacted by the Australian government has exacerbated these social inequities. As we can see in Figure 1 and Table 1, recent tax increases produced modest rates of quitting in Australia between 2013 and 2016. While tobacco tax increases are an effective way of reducing demand for cigarettes, a growing number of tobacco control professionals are concerned about the effects of high tobacco prices on disadvantaged smokers who struggle to quit smoking [25]. Australian research shows that some disadvantaged smokers give a higher priority to purchasing cigarettes than food because of their strong nicotine addiction [26]. Access to a less harmful and lower cost ENDS product could greatly reduce the social inequities produced by increased tobacco taxes.

Regulatory Approaches in other Advanced Tobacco Control Countries

Australia's approach to ENDS regulation differs markedly from those in many other developed countries with advanced tobacco control policies. English-speaking countries which previously adopted similarly restrictive policies towards ENDS have recently decided to allow regulated access to ENDS for nonmedical use. They have adopted standard forms of consumer protection and imposed restrictions on where these devices can be sold, used and how they can be promoted. We briefly describe these alternative policy approaches which we support.

UK and Europe

When ENDS were first marketed in the UK in 2006, they were sold only as general consumer products. On 12 June 2013, the UK Medicines & Healthcare Products Regulatory Agency announced that from 2016 all nicotine-containing products, including e-cigarettes would be regulated as medicines. However, with the adoption of the European Union Tobacco Products Directive 2014/14/EU (TPD) [27], the UK adopted a dual-track regulatory system. This allowed nicotine-containing ENDs products to continue to be sold as non-therapeutic products so long as they did not make therapeutic claims and they complied with standards set out in the EU TPD (e.g. maximum of 20mg/mL nicotine concentration, maximum volume of 10mL for bottles of refill fluid with child-resistant closures, maximum tank capacity of 2mL, leak-proof design etc). Sponsors who want to

market products with a higher nicotine concentration or as therapeutic products must apply for medicines licensing.

A similar approach has also been adopted by other countries in the European Union that initially proposed to regulate ENDS as medicines, such as Sweden, Denmark, and Belgium. These countries have now adopted a dual-track regulatory system which allows nicotine-containing products such as ENDS to be sold if they comply with TPD requirements and are notified to the government.

The USA

In the USA, the Food and Drug Administration attempted to regulate ENDS as medicinal products (drug delivery devices) in 2009. However, the Federal Court of Appeal ruled in 2010 that the FDA could only enforce medicines regulations if the product was marketed as a therapeutic product (e.g. as a smoking cessation aid). As a result, the USA has also adopted a dual-track regulatory system under which sponsors can apply to market ENDS as medicinal products (if they wish to make therapeutic claims) or to market them as tobacco products. New regulations for vaping products that were due to come into force on 8 August 2017 have been delayed by three months.

Canada

Canada had a similar regulatory approach to Australia. Vaping products that did not contain nicotine could be legally sold as consumer products if they did not make therapeutic claims. Nicotine-containing vaping products were not legal unless they were approved as medicinal products. However, a new bill passed in Canada (1 June 2017) [28] exempts vaping products that do not make therapeutic claims from the definition of a 'drug' or 'device' within the *Food and Drugs Act*, regardless of whether they contain nicotine or not. Instead, these products will be regulated under the *Tobacco and Vaping Products Act* which will permit the sale, possession and use of non-therapeutic nicotine-containing vaping products. Therefore, Canada has also now adopted a dual-track regulatory system.

New Zealand

On 29 March 2017, the New Zealand Government announced that it would legalise the sale of nicotine-containing vaping products as consumer products [29]. Previously, New Zealand had a similar policy to Australia with the difference that smokers were allowed to import nicotine vaping products for personal use and possession. The proposed laws place a number of restrictions on the sale and marketing of vaping products (e.g. they prohibit sales to people under 18, prohibit broadcast advertising of products, and require child-resistant closures etc). The changes are expected to come into force in the middle of 2018. Hence, New Zealand is also moving to a dual-track regulatory system for nicotine-containing vaping products.

Summary

Most high income countries that have comparable tobacco control policies to Australia (e.g. UK, most of Europe, USA, Canada, and New Zealand), have either already adopted, or are in the process

of adopting, a dual-track regulatory approach to nicotine-containing vaping products. This approach allows ENDS to be sold, possessed and used by adults as either therapeutic or non-therapeutic products, depending on the claims the manufacturer makes about the efficacy of the product as a smoking cessation aid.

There are a growing number of smokers who have switched to ENDS. They now number in the millions, and this is likely to increase as the bans in Canada and New Zealand are lifted. The current Australian policy which bans possession and use of ENDS may have a detrimental impact on Australia's international reputation if international visitors to Australia who use ENDS products have them seized or are threatened with prosecution for an activity that is legal in their home countries. International tourists may be forced to quit vaping and potentially return to smoking while visiting Australia.

4. The appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia

Australian policy prohibits adults from using ENDS products that contain nicotine by only allowing nicotine-containing ENDS products to be sold, possessed and used in Australia if they have been approved as therapeutic products by the TGA. Since no ENDS products have been approved by the TGA their use by adults is prohibited in Australia and ENDS are treated much like illicit drugs.

We accept that the TGA is the appropriate body to assess therapeutic claims and regulate therapeutic goods but we do not accept that this is the only way that adult smokers should be allowed to access ENDS. We do not believe that the Australian government has to choose between prohibiting ENDS and allowing an unregulated free market. We therefore reject the claim that the following alarmist scenario would be the inevitable outcome of allowing the sale of ENDS as consumer products [30]:

> "This would open the way for e-cigarettes to be sold openly alongside groceries and confectionary; the door opened to what are now over 8000 flavouring chemicals, many with beguiling kid-friendly names; low tax to encourage use; advertising allowed to adults (some magic barrier prevents such advertising also being seen by children); and vaping permitted in any place where smoking has long been banned."

Most Australian states and territories have already enacted legislation that restricts the sale, use and promotion of vaping products. For example, in Queensland, vaping products are subject to the same restrictions as smoked tobacco products in terms of sale, promotion and use. They may only be sold to adults, retail displays of vaping products are banned (all sales must be under the counter) and vaping is not permitted in public smokefree areas. Vaping products that do not contain nicotine are allowed to be sold in most Australian states and territories and state health departments are already restricting where they can be sold and how they can be promoted. Those states that have not yet introduced legislation to regulate sale, promotion and use of vaping products are likely to do so. They would be especially likely to do so if a ban on nicotine-containing vaping products was lifted by the federal government.

We believe that current Australian approaches to the regulation of ENDS is poor public policy because it has the following major defects:

- It is an incoherent public health policy in that it bans the sale of less harmful nicotine products while allowing the most harmful - combustible cigarettes - to be freely sold.
- The policy prevents smokers from using ENDS to reduce tobacco-related harm.
- It is difficult to defend a policy that treats ENDS as a prohibited and dangerous drug like heroin when there is increasing evidence of their health benefits for smokers and little or no support for alarmist claims made about their adverse public health impacts.
- The 20% of Australian smokers who tried vaping, and the 7% who used in the past year [31], have to obtain their nicotine ENDS products on the black market. This produces the lack of

regulation and DIY production of nicotine products decried by those who support a ban on ENDS sales.

- Current policy makes it more likely that only ENDS owned by big tobacco are ever likely to be approved by the TGA. Pharmaceutical companies have shown little interest in developing ENDS as cessation aids which makes it more likely that only ENDS products owned by Big Tobacco will be approved by the TGA. Big Tobacco has less interest in moving smokers completely to ENDS than would ENDS producers who were not also marketing tobacco cigarettes.

An alternative regulatory approach

We support a regulatory approach to ENDS that avoids the extremes of ENDS prohibition and a free market (see Table 2). We support the requirement that any ENDS products that make therapeutic claims should be required to present evidence of their safety and efficacy to the TGA and be approved by the TGA for sale for as therapeutic goods.

We would, however, lift the ban on the sale of non-therapeutic ENDS to adults. We would allow limited sales of ENDS that met minimum standards of consumer safety to adult smokers. Nicotine solutions would be supplied in child-resistant containers and no promotion would be allowed except at licensed points of sale, such as specialist vape stores, tobacconists, adult stores and/or pharmacies. We would not allow ENDS to be sold by general retailers in order to reduce their public visibility to and access by under-aged purchasers.

We would monitor sales and ENDS use among young people. If certain types of flavours were found to be associated with increased use among non-smoking youth, then we would favour restrictions on flavoured products to minimise the attractiveness to non-smoking young people.

As an interim measure, we would recommend restrictions on ENDS use in public indoor settings. This would reduce concerns about highly visible public ENDS use renormalising a behaviour that resembles smoking and it would minimise any health risks (however minor) that non-smokers may experience from second-hand exposures to ENDS vapour. These restrictions could be relaxed in future for certain settings, such as vape shops, if there was sufficient evidence presented that there were no risks to non-smokers from second-hand vapour exposure in these environments.

Interim measures to allow Australian adults to use ENDS

As an interim measure, we recommend that adults in all Australian States and Territories who wish to use ENDS for achieving or maintaining abstinence from smoking be legally permitted to access vaping products containing nicotine that have not been approved by the TGA via existing mechanisms such as the TGA Special Access Scheme and/or Personal Importation Scheme. There is no public health value in prosecuting people who are currently using these products to remain abstinent from smoking as this may result in them returning to smoking tobacco, which has much greater health risk.

Table 2: Regulatory options to minimise risks of ENDS	
Nicotine	A maximum concentration, such as 3.6%, with higher concentrations requiring specific approval from ACCC.
Packaging	Child resistant closures and a spout to reduce spills should be required for bottles of nicotine containing e-liquid.
Labelling	• "Keep out of Reach of Children" should be required plus a simple warning to alert consumers to the presence of nicotine, which can be addictive. • Safety instructions could include "Do not drink", "If spilled on skin, wash with soapy water", "Avoid contact with eyes". • Ingredients should be listed. • Labelling that can be seen as overtly attractive to children should be prohibited.
Battery safety	• Already regulated by ACCC. Importers could be educated on their responsibility to ensure the products are safe. • Guidance could be given on recommended safety features to reduce risks. • Potentially an Australian Standard could be developed.
Restrictions on sale	• Sale only to people aged 18 or over. • Restrictions on where products can be sold (e.g. specialist vape shops, tobacconists, Adult stores, pharmacies).
Advertising & promotion	Restricted to point of sale
Restrictions on use	• Indoor public use bans. • Some exemptions could be allowed for specialist vape stores if evidence can be provided that allowing use indoors will not harm employees.
Monitoring	• Require regular reporting of details of vaping products sold with volumes of sale reported. • Targeted surveys to monitor use by key populations, such as adolescents. • Require ENDS-related incidents (e.g. battery explosions, over-doses) to be reported to the regulator.

5. Any other related matters.

Lack of public debate on ENDS policy

We welcome a parliamentary inquiry into the regulation of ENDS because the current Australian approach has been developed with minimal public discussion or debate. Previous consultations on the topic have been conducted behind closed doors with only invited participation [32]. The last Commonwealth Department of Health review of the regulatory framework for these products was conducted by a consortium that included individuals who have taken a very public anti-ENDS position. Selecting a more neutral consultancy team would have given the consultation more credibility.

Some advocates for current policy have attempted to prevent the case for tobacco harm reduction from being objectively discussed in professional meetings. They have attacked the motives and integrity of anyone who questions the ban on the sale of ENDS, portraying them as either witting or unwitting agents of the tobacco industry. They do so without offering any credible alternative approach for reducing the harms of nicotine use among those disadvantaged populations who continue to smoke despite the increasing cost of cigarettes, such as people living with mental illness or other co-morbidities.

Refusal to consider smoking harm reduction

The current policy is inconsistent with the Australian Tobacco Control Policy Framework [33] which includes harm reduction as one of the three policy pillars in reducing tobacco related harms. Australia currently has no strategic plan for how to end tobacco smoking as a major public health issue. Some opponents of tobacco harm reduction, believe that current strategies, such as high rates of taxation and policies that further stigmatise smoking (and smokers) will be sufficient to end the smoking epidemic. We believe that a reliance on these demand reduction strategies ignores their unintended consequences for disadvantaged populations, among whom smoking is increasingly concentrated, as noted above.

Implementing a population-wide harm reduction policy would complement current demand and supply reduction strategies. It would enable policies that aim to shift as many smokers as possible to less harmful nicotine products while encouraging smokers who can do so to quit. Such a policy would recognise that cigarettes are a nicotine delivery system[1] that is highly defective and harmful because it delivers many harmful toxins and carcinogens to the smoker along with the nicotine. As described above, ENDS are a much less harmful nicotine delivery system because they deliver fewer toxins at much lower levels than tobacco cigarettes.

[1] "The cigarette should not be construed as a product but a package. The product is nicotine. Think of a puff of smoke as the vehicle for nicotine." [William L. Dunn Jr., Philip Morris researcher, after taking part in a 1972 Caribbean meeting held by the Council for Tobacco Research.]

There is currently no intention in most countries, including Australia, to ban the sale and adult use of tobacco cigarettes, the most harmful nicotine delivery system. Given this, it makes no sense to continue to ban less harmful nicotine delivery systems (including ENDS). There is even less rationale for continuing to ban the sale and use of low nitrosamine smokeless tobacco products [34]. Current policy ensures that consumers can only access the most harmful non-therapeutic nicotine products.

It is difficult, if not impossible, to imagine another example of a consumer product which is regulated in this way, i.e. by banning the sale of a lower risk product while allowing the most high risk products to be freely sold. It would be like prohibiting the sale of lead-free house paint while allowing paint with high levels of lead to be widely sold. A more sensible regulatory approach would allow the less harmful product to compete with the more harmful product under similar regulatory rules. A case can also be made for using lower prices and easier access to encourage consumers to use the less harmful product while making the more harmful product progressively more expensive and difficult to access.

References

1 Hartmann-Boyce, J., McRobbie, H., Bullen, C., Begh, R., Stead, L. F., Hajek, P. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2016; **9**: CD010216.

2 Brown, J., Beard, E., Kotz, D., Michie, S., West, R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction* 2014; **109**: 1531-40.

3 AIHW. National Drug Strategy Household Survey 2016 Data tables. Canberra: Australian Government; 2017. Available from: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/.

4 Office for National Statistics. Statistical bulletin: Adult smoking habits in the UK: 2016. London: UK Statistics Authority; 2017. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2016.

5 World Health Organization. Raise taxes on tobacco: MPOWER brochure. Geneva: WHO; n.d. Available from: http://www.who.int/tobacco/mpower/publications/en_tfi_mpower_brochure_r.pdf.

6 Britton, J., Bogdanovica, I. Electronic cigarettes: A report commissioned by Public Health England. UK Centre for Tobacco and Alcohol Studies, Division of Epidemiology and Public Health, University of Nottingham. London: Public Health England; 2014. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf.

7 Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP; 2016. Available from: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0.

8 O'Leary, R., MacDonald, M., Stockwell, T., Reist, D. Clearing the air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. Victoria, BC: Centre for Addictions Research of British Columbia; 2017. Available from: http://ectaofcanada.com/clearing-the-air-a-systematic-review-on-the-harms-and-benefits-of-e-cigarettes-and-vapour-devices/.

9 Glasser, A. M., Collins, L., Pearson, J. L., Abudayyeh, H., Niaura, R. S., Abrams, D. B., *et al.* Overview of electronic nicotine delivery systems: a systematic review. *American Journal of Preventive Medicine* 2017; **52**: e33-e66.

10 Beard, E., West, R., Michie, S., Brown, J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation

pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. *British Medical Journal* 2016; **354**: i4645.

11 National Health and Medical Research Council. NHMRC CEO Statement, 3 April: Electronic Cigarettes (E-Cigarettes) (NHMRC ref # DS13a). Canberra: Australian Government; 2017. Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf.

12 Chen, J., Bullen, C., Dirks, K. A comparative health risk assessment of electronic cigarettes and conventional cigarettes. *International Journal of Environmental Research and Public Health* 2017; **14**: E382.

13 Nitzkin, J. L., Farsalinos, K., Siegel, M. More on hidden formaldehyde in e-cigarette aerosols. *New England Journal of Medicine* 2015; **372**: 1575.

14 Stratton, K., Shetty, P., Wallace, R., Bondurant, S., editors. Clearing the smoke: Assessing the science base for tobacco harm reduction. Washington, DC: National Academy Press; 2001.

15 Biener, L., Hargraves, J. L. A longitudinal study of electronic cigarette use among a population-based sample of adult smokers: association with smoking cessation and motivation to quit. *Nicotine and Tobacco Research* 2015; **17**: 127-33.

16 Manzoli, L., Flacco, M. E., Ferrante, M., La Vecchia, C., Siliquini, R., Ricciardi, W., *et al.* Cohort study of electronic cigarette use: effectiveness and safety at 24 months. *Tobacco Control* 2017; **26**: 284-92.

17 Zhuang, Y. L., Cummins, S. E., J, Y. S., Zhu, S. H. Long-term e-cigarette use and smoking cessation: a longitudinal study with US population. *Tobacco Control* 2016; **25**: i90-i5.

18 Chapman, S. E-cigarettes: does the new emperor of tobacco harm reduction have any clothes? *European Journal of Public Health* 2014; **24**: 535-6.

19 Kozlowski, L. T., Warner, K. E. Adolescents and e-cigarettes: objects of concern may appear larger than they are. *Drug and Alcohol Dependence* 2017; **174**: 209-2014.

20 NHS Digital Statistics Team. Statistics on Smoking, England - 2017. London: NHS Digital; 2017. Available from: http://www.content.digital.nhs.uk/catalogue/PUB24228.

21 Therapeutic Goods Administration. Access to medicinal cannabis products. Canberra: Australian Government; 2017. Available from: https://www.tga.gov.au/access-medicinal-cannabis-products.

22 Hall, W. D., Gartner, C., Forlini, C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**: 1061-7.

23 Mathews, R., Hall, W. D., Gartner, C. E. Is there evidence of 'hardening' among Australian smokers between 1997 and 2007? Analyses of the Australian National Surveys of Mental Health and Well-Being. *Australian and New Zealand Journal of Psychiatry* 2010; **44**: 1132-6.

24 Gartner, C., Hall, W. Tobacco harm reduction in people with serious mental illnesses. *Lancet Psychiatry* 2015; **2**: 485-7.

25 Hirono, K. T., Smith, K. E. Australia's $40 per pack cigarette tax plans: the need to consider equity. *Tobacco Control* 2017.

26 Guillaumier, A., Bonevski, B., Paul, C. 'Cigarettes are priority': a qualitative study of how Australian socioeconomically disadvantaged smokers respond to rising cigarette prices. *Health Education Research* 2015; **30**: 599-608.

27 European Parliament, Council of the European Union. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. Official Journal of the European Union. Luxembourg: European Commission; 2014: 1-38. Available from: http://ec.europa.eu/health//sites/health/files/tobacco/docs/dir_201440_en.pdf.

28 Parliament of Canada. An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts, as passed by the Senate, June 1 2017. Ottawa, Ontario: Parliament of Canada; 2017. Available from: http://www.parl.ca/DocumentViewer/en/42-1/bill/S-5/third-reading.

29 New Zealand Ministy of Health. E-cigarettes to be regulated as consumer products: release (29 March). Wellington: Government of New Zealand; 2017. Available from: http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes.

30 Chapman, S., Call for a 'light touch' on nicotine regulation is outrageous: Keep TGA control of e-cigarettes or risk repeating the smoking health disaster. *Sydney Morning Herald* 2017; June 21, p. 20.

31 Gravely, S., Fong, G. T., Cummings, K. M., Yan, M., Quah, A. C., Borland, R., *et al.* Awareness, trial, and current use of electronic cigarettes in 10 countries: Findings from the ITC project. *International Journal of Environmental Research and Public Health* 2014; **11**: 11691-704.

32 Freeman, B., Kite, J., Buckley, N., O'Hara, B., Chapman, S., Walsberger, S., *et al.* Discussion paper: Options to minimise the risks associated with the marketing and use of electronic nicotine delivery systems [ENDS] in Australia. Prepared by Dr Becky Freeman, James Kite, Prof Nicholas Buckley, Dr Blythe O'Hara, Prof Simon Chapman, Scott Walsberger, Prof Bill Bellew, and Prof Adrian Bauman for the Intergovernmental Committee on Drugs; 2016: 66p. Available from: http://catallaxyfiles.com/files/2016/05/ENDS-Discussion-paper.pdf.

33 Intergovernmental Committee on Drugs Standing Committee on Tobacco. National Tobacco Strategy 2012-2018. Canberra: Commonwealth of Australia; 2012. Available from: http://www.health.gov.au/internet/main/publishing.nsf/content/tobacco-strategy.

34 Gartner, C. E., Hall, W. D. Should Australia lift its ban on low nitrosamine smokeless tobacco products? *Medical Journal of Australia* 2008; **188**: 44-6.