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CRICOS PROVIDER NUMBER 00025B

The Chair,

Senate Select Committee on Tobacco Harm Reduction

The Senate, Canberra, ACT, 2600

4 November 2020

Dear Chair

We wish to make a public submission to the Senate Select Committee on Tobacco Harm Reduction. We do so as public health researchers who have undertaken research on e-cigarettes and other non-combustible alternatives to smoked cigarettes.

Coral Gartner is an Associate Professor at the University of Queensland. She has over 20 years of experience in public health and has undertaken research in tobacco control for over a decade. She has authored over 100 academic works in peer-reviewed journals and books.

Wayne Hall is a Professor in the National Centre for Youth Substance Use Research at the University of Queensland. He has over 30 years of experience as a researcher and policy adviser in public health. He has published over 400 academic works in peer-reviewed journals, books and technical reports, including papers in leading medical journals. He has advised the World Health Organization on drug-related issues.

We confirm that we have never accepted funding from the tobacco or e-cigarette industries or from any foundations funded by the tobacco industry. Our research on the topics of the submission has all been publicly funded.

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

Yours sincerely

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Definitions of key terms used in our submission

In our submission we use the following terminology:

Nicotine-containing products: Products that contain nicotine, whether intended for therapeutic or non-therapeutic use.

Nicotine replacement therapy (NRT): Therapeutic nicotine products, such as nicotine gum, patches, and inhalers, that have been shown to be safe and effective smoking cessation aids.

Tobacco harm reduction: This approach attempts to reduce tobacco-related harm by encouraging smokers to replace smoking tobacco cigarettes with less harmful ways of obtaining nicotine such as, NRT, smokeless tobacco, and e-cigarettes or 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) that is formed by heating a carrier fluid (glycerine or propylene glycol) that contains nicotine.

Cigalike devices: the original ENDS products that resembled and were used much like conventional cigarettes but failed to deliver equivalent doses of nicotine in vapour.

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

In our submission we use the term ENDS as a short hand for all types of electronic cigarettes. The arguments that we make for allowing smokers to access these products apply equally to low nitrosamine smokeless tobacco products which are also banned in Australia.

Summary of our submission

Australia does not have a current National Tobacco Strategy (NTS). Multiple previous NTS have endorsed harm reduction as an equally important pillar of Australia's approach to minimising the harms from tobacco use but this has not translated into policy. Rather, the current Australian approach actively discourages tobacco harm reduction by creating barriers to accessing lower risk alternatives to tobacco cigarettes, such as nicotine liquid for use in Electronic Nicotine Delivery Systems (ENDS) or low nitrosamine smokeless tobacco products, such as snus.

Australia's policy only allows ENDS to be sold, possessed and used if they have been approved as therapeutic goods by the Therapeutic Goods Administration (TGA), or are accessed via one of the exemption pathways with a medical prescription (personal importation, Special Access Scheme, Authorised Prescriber Scheme). Since no ENDS products have been approved, they cannot be sold in Australia. They can be imported for personal use as an unapproved therapeutic good with a medical prescription. However, the government has announced its intention to remove this pathway and only leave the Special Access Scheme and Authorised Prescriber routes.

The Therapeutic Goods Administration (TGA) has recently proposed a "streamlined pathway" to allow access to ENDS using the Special Access Scheme and Authorised Prescriber scheme. This may, in principle, provide a way for people who smoke to access these products. There are, however, major doubts about whether it will work in practice because many medical practitioners appear to be reluctant to prescribe nicotine and pharmacists may not be prepared to dispense nicotine via these routes. Further consultation with medical practitioners and pharmacists is needed.

Australia's current and proposed ENDS policies have been justified as precautionary on two grounds, namely that:

1. allowing ENDS to be sold without a prescription would increase smoking in the population by deterring quitting and recruiting adolescents who will take up cigarette smoking;

2. ENDS are not effective smoking cessation aids and they will be used by the tobacco industry to undermine smoke free policies.

The epidemiological evidence is inconsistent with the first claim. In countries that have allowed the sale of ENDS or low nitrosamine smokeless tobacco (e.g., snus), the prevalence of cigarette smoking has declined in adults and adolescents over the period in which ENDS use has increased. ENDS have primarily been used by people who have smoked; use is very rare among people who have never smoked.

The second claim is inconsistent with evidence from randomised clinical trials that suggest ENDS are at least as effective as NRT as cessation aids. Newer ENDS products are more effective than NRT for smoking cessation. Observational studies in the UK also show that ENDS devices have assisted people to quit smoking.

Even if evidence supported these two arguments, the precautionary principle would not justify prohibiting adults from accessing ENDS when a more harmful nicotine product (tobacco cigarettes) is widely available in general retail outlets throughout Australia. It would, at most, justify restrictions on what kinds of ENDS can be sold, and where and how they can be sold.

We believe that the sale of ENDS that meet consumer safety standards to adults should be allowed under tight regulation. Nicotine would be supplied in child-resistant containers, promotions would be banned except at points of sale, such as specialist vape stores, tobacconists and/or pharmacies. We believe that the regulation of lower risk alternatives to tobacco cigarettes, such as ENDS and low nitrosamine smokeless tobacco, should be proportionate and take into account the full continuum of nicotine and tobacco products, with a view to phasing out the most harmful products.

The treatment of nicotine vaping products and smokeless tobacco in Australia, the United Kingdom, New Zealand, the European Union and the United States of America.

In principle ENDS can be regulated as:

1. Consumer goods to ensure consumer safety and minimise misleading advertising;
2. Tobacco products in much the same ways as we do tobacco cigarettes e.g. with age restrictions on sales, bans on advertising and no use permitted in enclosed public areas;
3. Therapeutic aids for smoking cessation;
4. Dangerous poisons or drugs prohibited for use by adults.

Australia has regulated ENDS using a combination of regulatory approaches **2**, **3** and **4.** ENDS can be sold domestically as therapeutic products if they are approved by the TGA (i.e., are listed on the Australian Register of Therapeutic Goods). With this exception, the possession of all other nicotine products (apart from tobacco cigarettes) is banned under state and territory drugs and poisons legislation unless they are used with an authorisation. Under Federal legislation, ENDS can be imported for personal use as an unapproved therapeutic good with a medical prescription. However, there has been confusion amongst the public and state regulators about this pathway (e.g., see Saw et al, 2019). The recently proposed changes to the Poisons Standard (awaiting a final decision), which will remove the Dangerous Poisons (S7) classification for ENDS, should remove this confusion.

Australian ENDS regulations discriminate against the substantial proportion of people who have tried and failed to quit smoking (Hall et al, 2015). Many of these people want to stop using all nicotine products and some succeed, often after a number of failed attempts but many find it extremely difficult to stop. This is often the case for people who are socially or economically disadvantaged (Matthews et al, 2010), and those living with serious mental illnesses (Gartner and Hall, 2015). Many people who are unable to quit smoking will die of a tobacco-related disease.

For people who are unable to quit smoking, switching to a less harmful way of obtaining nicotine may enable them to quit sooner and reduce the smoking-related harm they would experience if they continued to smoke. It is arguably unethical and unjust to deny people who have great difficulty ending their nicotine addiction from using less harmful alternatives while they continue to have ready access to tobacco cigarettes (Hall et al, 2015).

Steep annual increases in tobacco taxes by the Australian government have exacerbated social inequities in smoking. These tax increases have produced modest changes in smoking prevalence in Australia between 2013 and 2019. Some tobacco control professionals are concerned about how high tobacco prices will affect

disadvantaged populations who struggle to quit smoking (Hirono and Smith, 2017). Australian research shows that some people on low incomes give a higher priority to purchasing cigarettes than food because of their strong nicotine addiction (Guillamier, Bonevski and Paul, 2015). Access to a less harmful and lower cost ENDS product could greatly reduce the social inequities produced by increased tobacco taxes.

ENDS policies in other countries

Australia's approach to ENDS regulation differs markedly from those in many other comparable countries with good tobacco control policies. This includes other English-speaking countries which previously adopted restrictive policies towards ENDS like those in Australia. They have decided to allow regulated ENDS access for nonmedical use with standard forms of consumer protection and restrictions on where ENDS can be sold, used and promoted. These countries do not require a medical prescription to purchase ENDS.

UK and Europe

ENDS were initially marketed in the UK in 2006 as general consumer products. On 12 June 2013, the UK Medicines and Healthcare Products Regulatory Agency proposed that ENDS would be regulated as medicines in 2016. However, after the adoption of the European Union Tobacco Products Directive 2014/14/EU (TPD) (European Parliament, 2014), the UK adopted a dual-track regulatory system. This allowed ENDS to be sold as consumer products if they did not make therapeutic claims and complied with standards in the EU TPD. These included a maximum of 20mg/mL nicotine concentration, maximum volume of 10mL for bottles of refill fluid, child- resistant closures, maximum tank capacity of 2mL, and leak-proof design. Sponsors who wanted to market products with a higher nicotine concentration or as therapeutic products had to apply for medicines licensing. A similar approach was adopted by other countries in the European Union that initially proposed to regulate ENDS as medicines, e.g. Sweden, Denmark, and Belgium. These countries have adopted a dual-track regulatory system which allows 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 smoking cessation aid. As a result, the USA adopted a dual-

track regulatory system under which sponsors can apply to market ENDS as medicinal products (if they make therapeutic claims) or market them as tobacco products.

Canada

Canada had a similar regulatory approach to Australia. Nicotine-containing vaping products were not legal unless they were approved as medicinal products. However, a bill passed in Canada (1 June 2017) (Parliament of Canada, 2017) exempted vaping products that do not make therapeutic claims from the definition of a 'drug' or 'device' within the *Food and Drugs Act*. Instead, these products are regulated under the *Tobacco and Vaping Products Act* which permits the sale, possession and use of non-therapeutic nicotine-containing vaping products. Canada has also adopted a dual-track regulatory system.

New Zealand

On 29 March 2017, the New Zealand Government announced that it would legalise the sale of ENDS as consumer products (New Zealand Ministry of Health, 2017). New Zealand previously had a similar policy to Australia with the difference that people 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 came into force in mid-2018 and New Zealand now has a dual-track regulatory system for ENDS.

Summary

Most high income countries that have comparable tobacco control policies to Australia (e.g., the UK, most of Europe, the USA, Canada, and New Zealand) have adopted a dual-track regulatory approach to ENDS that allows ENDS to be sold, possessed and used by adults as an alternative to tobacco cigarettes without a prescription. Their use can be either for therapeutic or non-therapeutic purposes, depending on whether the manufacturer claims that the product is a smoking cessation aid or not.

The impact of nicotine vaping products on smoking rates in these countries, and the aggregate population health impacts of changes in nicotine consumption.

Ideally the efficacy of ENDS as therapeutic smoking cessation aids should be established in randomised controlled clinical trials that compare the effectiveness of ENDS with that of nicotine replacement therapy (NRT) products (such as gums and patches) in enabling quitting.

A small number of trials have been done with 'cigalike' ENDS, which are small e-cigarettes that resemble combustible cigarettes in appearance but have lower nicotine delivery than more later models of ENDS. Overall, these indicate that cigalikes are more effective than NRT in assisting people to quit smoking (Hartmann-Boyce et al, 2016). The value of these clinical trials was limited because: (1) the relatively small numbers of participants included in the trials; and (2) the fact that cigalike devices that are less effective at delivering nicotine than the tank devices that are now predominantly used by people who vape regularly.

More recent, larger controlled clinical trials (Hajek et al, 2019; Walker et al, 2020) have compared newer ENDS products with NRT and found ENDS to be more effective than NRT for smoking cessation. A recent Cochrane Collaboration review of ENDS trials and observational studies (Hartmann-Boyce et al, 2020) concluded that:

> *"There is moderate-certainty evidence that ECs with nicotine increase quit rates compared to ECs without nicotine and compared to NRT. Evidence comparing nicotine EC with usual care/no treatment also suggests benefit, but is less certain. More studies are needed to confirm the degree of effect…. The main limitation of the evidence base remains imprecision due to the small number of RCTs, often with low event rates."*

The results of the clinical trials are supported by large scale surveys in the UK. These indicate that ENDS have been used by a substantial proportion of people who smoke either to quit smoking or as a replacement for smoking. Brown and colleagues reported that those who used newer tank style e-cigarettes in their most recent quit attempt were more likely to successfully quit than those who used either NRT or who quit cold turkey (Mendelsohn and Hall, 2020).

The findings of the controlled trials and observational studies are consistent with 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 the Australian survey). In 2013, the prevalence was the same as in Australia while smoking in England between 2013 and 2016 declined more steeply. The greater decline in England occurred in the absence of the large increases in cigarette taxes and plain packaging of cigarettes that were introduced in Australia over this period. It also coincided with an increased use of

ENDS among people who smoke in England when the public were encouraged to use ENDS as a smoking cessation aid or as a long-term substitute to smoking cigarettes by the UK government, Action on Smoking and Health, the Royal College of Physicians, and Cancer Research UK (Mendelsohn and Hall, 2020).

The uptake of e-cigarettes by people who do not smoke

Most youth who have tried ENDS also smoke cigarettes or have experimented with cigarette smoking. In the 2017 Australian Secondary Students' Alcohol and Drug Survey, two in three 12–17 year-olds who had used ENDS had smoked (Guerin and White, 2018). In the US National Youth Tobacco Survey in 2015, 87.7% of ENDS users who had smoked more than 100 cigarettes said they tried cigarettes first. In only 7.6% was ENDS their first nicotine product (West, Brown and Jarvis, 2019). In the US Population Assessment of Tobacco and Health Study from 2013–2016, Berry et al found that 85% of people aged 12–15 years who currently smoked had not used ENDS before they smoked cigarettes (Berry et al, 2018). In a study of over 32,000 11–16 year-olds in Wales, de Lacy et al found that 85% of weekly smokers who had used ENDS, had smoked before using ENDS (de Lacy, Fletcher, Hewitt, Murphy and Moore, 2017).

Regular use of ENDS is generally 1% or less among people who haven't smoked in surveys. In Australia in 2017, 0.3% of 12–17 year olds who had never smoked had used ENDS on 3 or more days in the last month (Guerin and White, 2018). In New Zealand, 0.4% of year 10 students who had never smoked reported daily ENDS use in 2018 (ASH New Zealand, 2018). Data from five large UK national surveys of 60,000 11–16 year olds (Bauld, MacKintosh, Ford and McNeill, 2016) and found rates of at least weekly ENDS use by youth who had never smoked in all surveys ranged between 0.1 and 0.5%. In the 2018 US National Youth Tobacco Survey, 13.8% of all students (9–19 years) reported ENDS use in the past 30-days but only 0.4% of those who didn't smoke did so more than 20 of the last 30 days (Glasser, Johnson, Niaura, Abrams and Pearson, 2020)

Are ENDS a gateway to tobacco smoking in youth?

Prospective studies of adolescents have found an association between experimenting with ENDS and tobacco cigarettes (see Chan et al, 2020 for a review). Some people claim that this shows that ENDS use increases smoking among adolescents (Chapman, 2014). There are a number of reasons to question this causal claim (Mendelsohn and Hall, 2020).

Firstly, there is a very low prevalence of cigarette smoking in these studies so researchers have classified any young person who smokes a single puff of a cigarette as a 'smoker'. This over-estimates the association because most adolescents who

experiment with ENDS will not take up regular use of e-cigarettes or tobacco cigarettes (Mendelsohn and Hall, 2020).

Secondly, adolescents who are most likely to experiment with ENDS are those who are at higher risk of using cigarettes (and other drugs). This is because they are more likely to have the traits of sensation seeking and risk-taking, and be inclined to engage in oppositional and rebellious behaviour (Chan et al, 2020; Kozlowski and Warner, 2017).

Third, these studies were conducted in countries when there were no age restrictions on the purchase of ENDS. Many Australian states and territories (e.g. Qld, NSW, ACT, Victoria) already ban the sale of vaping products to people under age 18 (Gartner et al, 2015).

Finally, epidemiological monitoring studies indicate that ENDS use has *not* increased regular cigarette smoking among young people, as would be the case if they were a gateway to cigarette smoking (NHS Digital Statistics Team, 2018). In the UK, smoking rates among young people have declined as steeply as they have in Australia, despite increased ENDS use by adult smokers and high rates of ENDS uptake among young adults who smoke (NHS Digital Statistics Team, 2017; Mendelsohn and Hall, 2020).

Potential harms of ENDS use

Some people claim that the aerosol produced by ENDS is much more toxic than the estimates of Public Health England (McNeill et al, 2018) and the Royal College of Physicians (2016); that allowing access to ENDS will increase nicotine poisoning and other adverse health effects; that nicotine is a carcinogen, despite it not being classified as such by the International Agency for Research on Cancer; and that ENDS will discourage quit attempts among smokers who will engage in the dual use of cigarettes.

Toxic emissions in ENDS aerosols

Comprehensive reviews of the toxicity of ENDS vapour by Public Health England (McNeill et al, 2018), the Royal College of Physicians (2016) and the University of Victoria Centre for Addictions Research of British Columbia in Canada (O'Leary et al, 2017) have concluded that the harms of using ENDS are very low compared to those of smoking cigarettes. The two UK reviews concluded that the harms were unlikely to exceed 5% of the harms of smoking cigarettes.

Opponents of ENDS have disputed the 95% reduction in risk estimate, making the misleading claim that it is based only on a single consensus study of experts, some of

whom received tobacco industry funding. This is incorrect: the UK reviews were based on research comparing the levels of toxic constituents in ENDS vapour and cigarette smoke. Other studies e.g., using the US Environmental Protection Agency health risk assessment (Chen et al, 2017) and a calculation of cancer potency of ENDS vapour compared to cigarette smoke (Stephens, 2018), have supported the estimates of Public Health England.

ENDS aerosols do contain some harmful chemicals but many fewer and at much lower levels than tobacco smoke (Royal College of Physicians, 2016; Glasser et al, 2017; O'Leary et al, 2017). Some critics of ENDS demand that ENDS products must contain zero levels of these chemicals before they can be sold as consumer goods. This is a standard that is not applied to other products, particularly cigarettes which is the existing product that ENDS are intended to replace. A risk based approach should take into account who will use the product, how it will be used, what can be done to minimise these risks and the risks of any products it is designed to replace.

Dual use and effects on quit smoking attempts

Critics of ENDS argue that the dual use of ENDS and cigarettes will discourage people from making quit attempts in much the same way as light cigarettes encouraged people to switch brands rather than to quit smoking. They argue that people will be able to use ENDS when they cannot smoke cigarettes (e.g. in public places) and continue to smoke cigarettes at other times. The evidence does not support this claim.

First, there is a major difference between ENDS and light and low tar cigarettes: switching to ENDS reduces exposure to harmful constituents of tobacco smoke. Light and low tar cigarettes, by contrast, did not because people engaged in compensatory smoking to obtain their desired nicotine dose, maintaining their exposure to tar and toxicants (Stratton et al, 2001). That is, they altered their puffing behaviour to ensure they obtained the same amount of nicotine as from a regular cigarette.

Second, the fact that many people who use ENDS also smoke cigarettes in cross sectional surveys (i.e. engage in 'dual use') is potentially misleading. These surveys do not distinguish between people who are trialling ENDS, people who are using them to cut down before quitting, and people who are engaging in long term dual use.

Third, we need studies that follow people who use ENDS over time to see how many make quit attempts, what proportion succeed or switch wholly to ENDS, and what proportion engage in long-term dual use. A number of such studies suggest that people who smoke and use ENDS do not make fewer quit attempts than those who only smoke. More importantly, they suggest that the proportion of people who use ENDS and smoke who quit or switch to ENDs increases over time (Mendelsohn, Hall and

Borland 2020). The extent of the latter depends on the type of ENDS products used: people who use tank type ENDS products daily are more likely to successfully quit smoking than people who use cigalikes.

Fourth, studies of smoking trends in the UK over the past decade do not support the claim that ENDS discourage quit attempts; rather, their use increases the chance of successful quitting, with rates of smoking cessation increasing at a faster rate in the UK than in Australia (Mendelsohn and Hall, 2020).

We should discourage long term dual use of ENDS and cigarettes. We should avoid misleading messages that there are no risk differences between using ENDS and smoking cigarettes because this may unintentionally encourage people who use ENDS and cigarettes to engage in long term dual use or return to cigarette smoking.

Measures that Australia could adopt to minimise youth smoking and ENDS use

Nicotine solutions should be supplied in child-resistant containers and no promotion allowed except at licensed points of sale. These should be restricted to specialist vape stores, tobacconists, adult stores and/or pharmacies to minimise youth access. All nicotine products should be stored behind the counter.

We should not allow ENDS to be sold by general retailers to reduce access by under-aged purchasers. We should monitor sales and ENDS use among young people. If certain types of flavours are associated with increased use among non-smoking youth, then we should restrict the use of these flavoured products to minimise their attractiveness to non-smoking young people.

Access to ENDS under Australia's regulatory frameworks

The reluctance of medical practitioners (acting on advice of the AMA) to prescribe nicotine for use in a vaporiser, makes it difficult for Australians to legally access ENDS. This means that Australians who want to use ENDS as a lower risk alternative to tobacco cigarettes have to purchase them on the illicit market or illegally import nicotine purchased on the internet.

Similar problems are likely to face the TGA's proposed pathway for accessing ENDS products via a streamlined version of the Special Access and Authorised Prescriber Schemes. Many GPs are reluctant to write a script for nicotine vaping liquid because they have been discouraged from doing so by prominent organisations such as the AMA. This will need to be addressed if this is to be a viable pathway.

A less restrictive approach would be to allow direct supply of nicotine at pharmacies by allowing nicotine liquids that meet an agreed standard (manufacturing quality and contents, packaging and labelling) to be approved for supply as a Schedule 3 medicine. This would still ensure supply within a health care setting (in accordance with current government policy preference) with a health practitioner as a gatekeeper who can provide advice on, and access to, other smoking cessation aids. The main uncertainty is whether this would be acceptable to those people who reject a medical model for switching from smoking to vaping. It still presents additional barriers to accessing nicotine liquid that are not imposed on tobacco cigarettes sales, however this may provide an option that will be acceptable to a greater proportion of the target population (people who smoke). Consultation with pharmacists and people who vape or smoke, is needed to understand if this is a viable model of supply.

Tobacco industry involvement in the selling and marketing of ENDS

Tobacco manufacturers own companies that produce ENDS, most often as a result of their takeover of the most successful ENDS producers, such as JUUL. Some have also developed their own products (e.g., BAT and Vype products). This has heightened the widespread concern in the Australian and international tobacco control community that ENDS are a tobacco industry plot to undermine public health by increasing cigarette smoking (Maziak, 2020). This belief has had several undesirable effects.

First, the hostility to ENDS has ignored the tobacco industry's much greater investment in developing and marketing heated tobacco products. Unlike ENDS, heated tobacco products such as IQoS have been developed solely by the tobacco industry to preserve its major investments in tobacco production and processing and to produce a tobacco product that is used in ways that are more like smoking tobacco cigarettes than are ENDS (Ratajczak, et al, 2020).

Second, it has protected the market for the most harmful nicotine product, the tobacco cigarette, from a lower risk competitor product.

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