

e-brief

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E-cigarettes: regulatory and policy options

by Gareth Griffith

Introduction

Electronic cigarettes (e-cigarettes or ENDS) are designed to deliver nicotine and/or other chemicals to the user via an aerosol vapour through devices designed to simulate the act of smoking tobacco cigarettes. They are currently the subject of legislative amendment and public debate. A 2014 World Health Organisation (WHO) report stated:

ENDS [electronic nicotine delivery systems] are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased. Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to denormalize tobacco use. ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates. ¹

Responding to a question in the Legislative Council on 13 May 2015, the Minister for Ageing John Ajaka said:

Unfortunately, a new threat has evolved: the popularity and use of e-cigarettes is growing rapidly across the world and again, sadly, among children and young people. In the United States current e-cigarette use tripled among middle and high school students from 2013 to 2014. Two million high school students reported current e-cigarette use in 2014. This is an alarming trend and one we do not want repeated in New South Wales. The threat of e-cigarettes includes exposure to chemicals used in e-liquids and the safety of e-cigarette devices.²

In the lead up to the 2015 State election both the Coalition parties and Labor said they would restrict access to e-cigarettes in some way. The Baird Government said it would "ban the sale of e-cigarettes and e-liquids to minors", whereas Labor said it would, in addition, outlaw advertising for electronic cigarettes and ban them in non-smoking areas.³ The same *Sydney Morning Herald* article noted a Newspoll survey of NSW

residents commissioned by the Heart Foundation which found that 80% supported a ban on sales to children and 70% wanted restrictions on "vaping" in public spaces.

In keeping with the Government's electoral commitment, on 6 May 2015 the Minister for Health Jillian Skinner introduced the Public Health (Tobacco) Amendment (E-cigarettes) Bill 2015 (the E-cigarettes Bill 2015) in the Legislative Assembly. Supporting the measure, but flagging amendments in line with her Party's broader electoral commitments, Labor Deputy Leader Linda Burney described the Bill as "a pre-emptive strike". Speaking in the Upper House, the Minister for Ageing commented on the fluidity of the situation:

I recognise that discussions have taken place with the crossbench and the office of the Minister for Health about bringing these proposed amendments further into line with tobacco laws governing the sale to minors. The Ministry of Health will continue to monitor these issues to assist in informing the need for any further regulation.⁵

This e-brief offers an overview of the legal position in respect to e-cigarettes, along with a summary of research findings and viewpoints in the contemporary debate. It starts with a descriptive comment on e-cigarettes, making the point that e-cigarettes come in many forms, some containing nicotine and some not. It should be emphasised that this e-brief is only an introduction to the many complex medical, legal and other issues raised by e-cigarettes in their various forms.

What are e-cigarettes?

E-cigarettes go by a number of names and come in various shapes and forms, varying in content and appearance. A 2014 report commissioned by Public Health England and written by Professor John Britton and Dr Ilze Bogdanvoica of the UK Centre for Tobacco and Alcohol Studies made these comments about the development of e-cigarettes:

Electronic cigarettes (also known as e-cigarettes or electronic nicotine delivery systems (ENDS)) were invented in China in 2003 and designed to provide inhaled doses of vaporized nicotine. Electronic cigarettes were first introduced to Europe in about 2005 and became increasingly popular since. The products have evolved and improved considerably, such that while most early models resembled cigarettes in shape and size (sometimes referred to as 'cigalikes'...), many later ENDS models are larger, at about the size of a conventional fountain pen, and are known (among other terms) as 'personal vapourisers', or PVs...⁶

In terms of what e-cigarettes are and do, <u>NSW Health</u> presents the following summary:

Electronic cigarettes are battery powered devices which heat liquid (also called e-liquid) into an aerosol which is inhaled into a person's lungs. The aerosol is often called 'vapour'. Electronic cigarettes are also called electronic nicotine delivery systems (ENDS), alternative nicotine delivery systems (ANDS), e-cigarettes or e-cigs.

Unlike tobacco cigarettes, where the smoke from burning tobacco is inhaled, the electronic cigarette user inhales an aerosol which may contain nicotine, propylene glycol and other chemicals into their lungs. Inhaling the

aerosol is usually called 'vaping'. When the electronic cigarette is being used, the user inhales and exhales the vapour which may give the appearance of smoke.

E-liquids are often flavoured, with over 7,000 flavours available such as tobacco, confectionery, fruit and chocolate. They may or may not contain nicotine and may or may not be labelled as containing nicotine.

Electronic cigarettes may be shaped and coloured to make them look like cigarettes or other tobacco products like cigars, cigarillos, pipes, hookahs or shishas. Electronic cigarettes are also sometimes made to look like everyday items such as pens or USB memory sticks.

Electronic cigarettes can either be disposable or re-useable. Most devices include a battery, an airflow sensor (to activate the power from the battery), an aerosol generator (to turn the e-liquid into an aerosol) and the e-liquid.

A 2014 UK <u>Action on Smoking and Health</u> (ASH) briefing defined three main types of electronic cigarettes or vapourisers, as follows:

- disposable products (non-rechargeable);
- an electronic cigarette kit that is rechargeable with replaceable prefilled cartridges; and
- an electronic cigarette that is rechargeable and has a tank or reservoir which has to be filled with liquid nicotine.

The same source commented that:

The first two types of electronic cigarette are often known as 'cigalike' products as they resemble cigarettes and often have a light at the end that glows when the user draws on the device to resemble a lit cigarette. The liquid in the devices usually contains nicotine suspended in propylene glycol and glycerine. The level of nicotine in the cartridges may vary and most also contain flavourings. When a user sucks on the device, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The vapour delivers the nicotine to the user. There is no side-stream smoke but some nicotine vapour is released into the air as the smoker exhales.⁷

Key public health issues

The World Health Organisation 2014 report, the focus of which was on ENDS [electronic nicotine delivery systems], raised three key public health issues in respect to e-cigarettes, namely: health risks to users and non-users; efficacy in helping smokers to quit smoking and ultimately nicotine dependence; and interference with existing tobacco-control efforts. These three issues, about which opinion differs, are used to structure the following commentary.

Health risks to users and non-users: The health impacts of long-term use of e-cigarettes containing nicotine are the subject of ongoing research and debate. However, the balance of research to date would seem to suggest that any health impacts are "probably lower" than those of smoking conventional cigarettes "because e-cigarette users do not inhale the carcinogens contained in tars". This conclusion was supported by the 2014

report commissioned by Public Health England. It commented that "nicotine is not a significant health hazard" and went on to say that:

Cigarettes deliver nicotine in conjunction with a wide range of carcinogens and other toxins contained in tar, including nitrosamines, acetone, acetylene, DDT, lead, radioactive polonium, hydrogen cyanide, methanol, arsenic and cadmium, and vapour phase toxins such as carbon monoxide. In contrast, electronic cigarettes do not burn tobacco, so any toxins in vapour arise either from constituents and contaminants of the nicotine solution, and products of heating to generate vapour. The principal component other than nicotine is usually propylene glycol, which is not known to have adverse effects on the lung but has not to our knowledge been tested in models that approximate the repeated inhalation, sustained over many years, that electronic cigarettes involve. We are aware of two cases of lipoid pneumonia attributed to inhalation of electronic cigarette vapour, one in the peer-review literature the other a news report.

The same report noted that, while some manufacturer's claim that ecigarettes are harmless, there is evidence that they "contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic to humans". There is also evidence that in some cases "vapour contains traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead". The report said that:

Although levels of these substances are much lower than those in conventional cigarettes, regular exposure over many years is likely to present some degree of health hazard, though the magnitude of this effect is difficult to estimate. ¹⁰

Its conclusion was that:

Overall...the hazards associated with use of products currently on the market is likely to be extremely low, and certainly much lower than smoking. They could be reduced further still by applying appropriate product standards. ¹¹

The advice from **Quit Victoria** is more cautious:

Electronic cigarettes are likely to be less harmful than cigarettes, but the short and long-term health impacts of using electronic cigarettes remain unknown. Products involving delivery of chemicals to the lung are normally only approved after extensive evaluation on safety and efficacy. This process also ensures that products come with specific instructions on safe use. Products currently on the market in Australia have not passed through this process and so their safety cannot be guaranteed.

In a similar vein <u>NSW Health</u> advised:

There is limited information available about how safe electronic cigarettes are. The products available in Australia use a wide variety of parts and are sourced from many different manufacturers, including overseas manufacturers where safety and quality controls are unknown.

There are concerns among health experts about the safety of electronic cigarettes and liquids because of unregulated doses of nicotine, other chemicals used in e-liquids, exposure to particulate matter and the safety of the electronic cigarette devices themselves. The limited available

evidence shows that the safety of electronic cigarettes, liquids and aerosols cannot be guaranteed for users and other people who are exposed to them.

Among the other health issues raised is that e-cigarettes, by their delivery of nicotine, can maintain addiction. On this issue, a recent report from Canada's House of Commons Standing Committee on Health said:

The differences of opinion with respect to health risks focussed primarily, although not exclusively, on the health risks associated with the use of nicotine. Again, there was widespread agreement as to the addictive nature of nicotine, although some witnesses suggested such an addiction was relatively benign, comparing it to a caffeine addiction while others suggested it is a phenomenon to be avoided by restricting access to sources of nicotine, including in electronic cigarettes. ¹²

In relation to nicotine, a warning note is sounded by Professor Simon Chapman of the University of Sydney who notes that "there is growing evidence about the role of nicotine in carcinogens and the International Agency for Research on Cancer has recently prioritised the assessment of nicotine's carcinogenicity". ¹³

As for potential harmful effects for non-users, the committee <u>reported</u> that:

there is not sufficient evidence about what impact, if any, electronic cigarette use might have on bystanders. Some witnesses cited research demonstrating only a minimal impact, while others raised concerns about possible or probable negative impacts. ¹⁴

<u>NSW Health</u> warns of the dangers posed in indoor spaces by particulate matter (PM) from e-cigarettes; this refers to very small solid particles and liquid droplets (aerosols) suspended in the air. It is said that:

There is good evidence that exposure to PM increases the risk of developing a range of harmful diseases, including lung diseases (such as asthma), and heart disease. Short term exposure (for a few days) can worsen already existing illnesses, while longer term exposure (for years) can increase the risk of developing a range of harmful diseases and shorten a person's life expectancy. 15

In its information sheet on e-cigarettes in the workplace, <u>Quit Victoria</u> states that, while the issue requires further research, "Early research concludes that indoor electronic cigarette use could expose non-users to nicotine and other potentially dangerous chemicals when they breathe in second hand vapour." ¹⁶

Different again is the conclusion reached in the 2014 report commissioned by Public Health England, which commented that:

Electronic cigarettes do not produce smoke so the well-documented effects of passive exposure of others to cigarette smoke are clearly not relevant. Exposure of non-smokers to electronic cigarette vapour poses a concern, though laboratory work suggests that electronic cigarette use in an enclosed space exposes others to nicotine at levels about one tenth generated by a cigarette, but little else. The health risks of passive exposure to electronic cigarette vapour are therefore likely to be extremely low. ¹⁷

This summary statement is provided by Australia's <u>National Health and Medical Research Council:</u>

Some experts also suggest that e-cigarettes, with or without nicotine, may be harmful. Some have been reported to contain chemicals such as propylene glycol, glycerol or ethylene glycol, which may form toxic or cancer-causing compounds when vaporised. Studies also show that e-cigarettes expose both users and bystanders to particulate matter (very small particles) that may worsen existing illnesses, or increase the risk of developing diseases such as cardiovascular or respiratory disease. Although these chemicals or particles are typically found in lower concentrations than in tobacco cigarettes, in some studies e-cigarettes and tobacco cigarettes were found to produce similar levels of formaldehyde. E-cigarette liquids or vapour may also contain potentially harmful chemicals which are not present in smoke from tobacco cigarettes. ¹⁸

Efficacy in helping smokers quit smoking: Again, there are mixed views and limited findings. From their review of the available research published in the June 2015 issue of the *International Journal of Drug Policy*, Doug Fraser and his colleagues arrived at the following summary of the state of findings as to whether e-cigarettes are an effective aid for smokers seeking to quit smoking:

Evidence from some surveys of experienced users have suggested their usefulness as cessation aids...as have a cross-sectional study in the United Kingdom...and a longitudinal study in the United States...One randomised controlled clinical trial found e-cigarettes to be as effective as nicotine patches...Another trial...found similar reductions in smoking between non-nicotine and nicotine e-cigarettes but did not have a comparison group without e-cigarettes. Adriaens, Van Gucht, Declerck and Baeyens (2014) found 44% of participants using a second generation e-cigarette had quit or reduced smoking after eight months despite no previous intention to quit. (references omitted)¹⁹

Conversely, the same review found that:

Other research has been less favourable...with some of this disparity potentially explained by the large variation in devices that are classed as ecigarettes. Effective nicotine delivery is thought to be a critical requirement for e-cigarettes to function as an acceptable substitute for combustible cigarettes, and low nicotine delivery has been cited as a reason for modest results in trials using early models...(references omitted)²⁰

From its review of the literature, the 2014 report commissioned by Public Health England reported that:

studies indicate that electronic cigarettes are moderately effective as smoking cessation and harm reduction aids, but that a significant component of that effect is due to the behavioural rather than nicotine delivery characteristics of the devices. However, most of the available evidence relates to early generation devices of unknown but almost certainly low nicotine delivery. More recent and future devices may prove much more effective.²¹

Again, this summary statement is provided by Australia's <u>National Health</u> and <u>Medical Research Council</u>:

Some argue that e-cigarettes have the potential to reduce the number of smoking-related diseases and deaths, by assisting smokers to quit, or by providing a safer alternative to tobacco cigarettes. This is based on the widely-held belief that e-cigarettes are likely to be less harmful than tobacco cigarettes, because they expose users to fewer toxic chemicals. There is some preliminary evidence that supports this view.

However, some experts have raised concerns that e-cigarettes are promoted as a safer option for smokers, when their long term health effects are unknown. ²²

For the <u>National Health and Medical Research Council</u> there is "not enough evidence" to demonstrate that e-cigarettes are effective in assisting people to quit smoking. The statement adds:

Although a recent systematic review conducted by the Cochrane Collaboration found that there is some evidence that e-cigarettes with nicotine may assist smokers to quit, the review authors had a low level of confidence in this finding, due to the small volume of evidence. The review also reported results from one study comparing e-cigarettes with nicotine replacement therapy, which found that both methods resulted in similar rates of smoking cessation at 6 months follow up. However, the reviewers noted that further research is required to enable confidence in these estimates.²³

Interference with existing tobacco control efforts: The 2014 World Health Organisation report described the main issues in terms of "gateway and normalization concerns". These were explained as follows:

- (a) The gateway effect refers to two potential circumstances:
- (i) the possibility that children (and generally non-smokers) will initiate nicotine use with ENDS at a rate greater than expected if ENDS did not exist; and
- (ii) the possibility that once addicted to nicotine through ENDS children will switch to cigarette smoking.
- (b) The renormalization effect refers to the possibility that everything that makes ENDS attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. ENDS mimic the personal experience and public performance of smoking and their market growth requires marketing that is challenging commercial communication barriers erected to prevent the promotion of tobacco products.²⁴

The report commented that:

The likelihood and significance of these two effects occurring will be the result of a complex interplay of individual, market and regulatory factors and is difficult to predict. They can only be assessed with empirical data, which at present are virtually non-existent.²⁵

Confirming the need for further research, Australia's <u>National Health and Medical Research Council</u> commented on this issue:

The appeal of flavoured e-cigarettes to children and adolescents is also of concern to some, with studies reporting rapid uptake of e-cigarettes among adolescents, in countries where they are readily available. These trends may provide cause for concern, given uncertainties about the long-term

safety of e-cigarettes. Concerns have also been raised about the potential for e-cigarettes to provide a gateway into nicotine addiction and tobacco cigarette smoking. A recent study provides preliminary evidence in support of this, with parallel increases in e-cigarette use and smoking prevalence observed among Polish youth in 2013-14, compared with 2010-11 data. However, further research is needed to establish whether this relationship is causative, and also to determine whether these findings hold true within the Australian context.²⁶

E-cigarettes and the law in Australia

The regulation of e-cigarettes in Australia forms a complex web of State and Commonwealth law. The regulatory position also varies depending, for example, on whether the e-cigarettes do or do not contain nicotine products, if they are sold commercially or owned only for personal possession, or if they purport to be of therapeutic value. NSW Health presents the following summary of the current legal position in this State:

E-cigarettes and the law in NSW

		•			
E-cigarette	Contains liquid nicotine	Makes therapeutic claim		this legal to ossess?	Is this legal to sell?
Evenenia 4	No	Na	V		Van
Example 1	No	No	Yε	es	Yes
Example 2	Yes	No	No	0	No
Example 3	No	Yes	Υe	es	No
E	V	V	N.	_	NI-
Example 4	Yes	Yes	No	0	No

In more detail, the following account is based on a <u>Quit Victoria</u> information sheet on the legal status of e-cigarettes in Australia, which divides its account into the following categories:

• Commercial retail sale and personal possession/use of ecigarettes which contain nicotine: the sale and personal possession or use of nicotine electronic cigarettes is currently unlawful in every jurisdiction in Australia unless specifically approved, authorised or licenced (see below). Most Australian jurisdictions achieve that outcome by adopting the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) which lists nicotine as a poison (Schedule 7), except in preparations for human therapeutic use or in tobacco prepared and packaged for smoking. NSW has its own poisons list, which basically follows the SUSMO model, the same exception being made for nicotine "in preparations for human therapeutic use" or "in tobacco prepared and packed for smoking".

NSW Health notes that the sale and possession of liquid nicotine, including in liquids in electronic cigarettes, without approval from the NSW Ministry of Health, is illegal under clause 20 of the NSW Poisons and Therapeutic Goods Regulation 2008. Under clause 7 of the same regulations it is an offence to sell a Schedule 7 product containing nicotine which is not labelled and packaged as a dangerous poison. Retailers, suppliers and manufacturers are

responsible for ensuring that their products comply with relevant legislation.

Commercial importation and retail sale of non-nicotine ecigarettes that make therapeutic claims: The importation or supply of goods that are marketed with therapeutic claims is unlawful in Australia unless the product is registered with the Therapeutic Goods Administration (TGA). NSW Health advises in this respect that "The sale of electronic cigarettes that make a therapeutic claim and are not registered with the TGA is illegal under national and NSW therapeutic goods legislation" — the Therapeutic Goods Act 1989 (Cth) and the Therapeutic Goods Act 1966 (NSW) respectively.

There are currently no electronic cigarette products, with or without nicotine, registered with the TGA as therapeutic goods.

 Commercial importation and retail sale of non-nicotine ecigarettes that do not make therapeutic claims: e-cigarettes that contain no nicotine content and make no therapeutic claims can be imported and sold by retailers in all Australian jurisdictions. However, restrictions may apply (see below) in connection with the general tobacco control laws.

Note, too, that most Australian jurisdictions, including NSW, prohibit the retail sale of products that resemble tobacco products, which means that the sale of e-cigarettes that contain no nicotine content and make no therapeutic claims may be illegal under these provisions. The issue is discussed below in relation to the WA case of <u>Hawkins v Van Heerden.</u>²⁷

- Importation of nicotine e-cigarettes for personal use: in some limited and defined circumstances nicotine e-cigarettes for personal therapeutic use (as an aid to quit smoking for example) may be exempt from the TGA requirements and therefore may be legally imported for that purpose into Australia. This exemption arises under the personal importation scheme provided for under Schedule
 5 of the Therapeutic Goods Regulation 1990 (Cth). The exemption only applies where the requirements of the TGA's personal importation scheme are satisfied, including the requirement for the importer to have a prescription from a medical practitioner registered in the relevant State or Territory (unless the importer carries the goods as a passenger on a ship or aeroplane). Further, the goods must be "imported for use in the treatment of the importer or the importer's immediate family".
- Importation of non-nicotine e-cigarettes for personal use: Non-nicotine e-cigarettes which are marketed with therapeutic claims can be imported for personal use, subject to the personal importation scheme described above. As the products do not contain nicotine, which is a prescription only medicine, a medical prescription is not required. However, all other conditions apply, including personal/family use only and that the quantity imported is no more than 3 months' supply.

Non-nicotine e-cigarettes which make no therapeutic claims are not covered by the TGA scheme, meaning that they can be imported for

personal and commercial purposes without needing to comply with laws relevant to therapeutic goods.

 Applicability of tobacco control laws: <u>NSW Health</u> advises that "Electronic cigarettes are not currently covered by NSW tobacco legislation. The sale and use of these products is not covered under either the *Public Health (Tobacco) Act 2008* (NSW) or the *Smoke*free Environment Act 2000 (NSW)".

Queensland is the first jurisdiction to expressly apply its tobacco control laws to e-cigarettes, whether containing or not containing nicotine. In that State the <u>Tobacco and Other Smoking Products Act 1998</u> was amended in 2014 to include use of "personal vaporisers" in the definitions of "smoke" and "smoking product" (s 5A and Definitions Schedule).²⁹ The legislation applies the same restrictions on the sale and use of non-nicotine e-cigarettes (or personal vaporisers) as those that apply to combustible tobacco cigarettes.³⁰ The Queensland Government <u>website</u> comments that "From 1 January 2015, electronic cigarettes cannot be used in existing non-smoking indoor and outdoor areas, sold to children under 18 years of age, or advertised, promoted or displayed at retail outlets".

Quit Victoria adds that: "In States and Territories other than Queensland, it is unlikely that electronic cigarettes fall within laws regarding smoke free areas; however, individual businesses and the public sector can develop their own policies on use of electronic cigarettes in their organisations". This is confirmed by advice from NSW Health stating that the use of e-cigarettes is not prohibited in public places, but that "individual establishments and workplaces may develop their own policies to ban the use of e-cigarettes on their premises".

Products that resemble tobacco products: A further aspect to the applicability of tobacco control laws relates to those provisions that refer to products that resemble tobacco products. This applies in South Australia, ³¹ Queensland ³² and WA; ³³ relevant provisions also apply under NSW law.

In NSW this falls under the definition of products resembling tobacco products under s 21 of the *Public Health (Tobacco) Act 2008*. Relevantly s 21(3) provides that:

- (3)A person must not sell:
- (a) any confectionery or other food, or
- (b) any toy, amusement or other product,

that resembles a tobacco product or is packaged to resemble a tobacco product.

According to the NSW Health <u>website</u> e-cigarettes are considered to fall outside this provision. This is because, under the definitions section of the NSW Act, the products covered are only those which contain tobacco and/or can be smoked (that is, involve an ignited product). The result is that e-cigarettes that do not contain tobacco and involve the use of vaporised (that is heated rather than ignited) liquid are not included.³⁴

This contrasts with the position in WA, further to the ongoing case of <u>Hawkins v Van Heerden</u>, which is currently before the WA Court of Appeal.

Under WA law the prohibition against products that resemble tobacco products is found under s 106 of <u>Tobacco Products Control Act 2006</u> (WA), which provides that:

A person must not sell any food, toy or other product that is not a tobacco product but is

- (a) designed to resemble a tobacco product or a package; or
- (b) in packaging that is designed to resemble a tobacco product or a package.

The key issue of law turned on the phrase "designed to resemble" under s 106(a). The question was whether, operating under the business name of Heavenly Vapours, Mr Van Heerden had sold via a website products "designed to resemble" a tobacco product, namely electronic cigarettes, contrary to s 106(a) of the <u>Tobacco Products Control Act 2006</u> (WA). The e-cigarettes in question did not contain nicotine.

In <u>Hawkins v Van Heerden</u>³⁶ a single judge of the WA Supreme Court concluded that the e-cigarettes in question were:

designed to resemble a tobacco product because they were intended to be used to inhale vapour in a manner very similar to the inhalation of tobacco smoke when using a cigarette. That the items were designed to resemble a cigarette in this way can be discerned from the description given to the products by the manufacturer (as electronic cigarettes), from the manner in which the items are used (both having regard to the manufacturer's user manual, to the admissions made by Mr Van Heerden and having regard to the website pages) and from the appearance of electronic cigarettes, such as the items, during use (particularly the conveyance of the electronic cigarette to the user's mouth using their hand, the inhalation and exhalation of the vapour, and the fact that the vapour is reminiscent of the smoke from a cigarette).³⁷

Upon sentencing, Pritchard J acknowledged that "at the time of the commission of the offence" Mr Van Heerden "honestly and reasonably believed" that the electronic cigarettes he had in his possession for sale were a healthy alternative to smoking cigarettes. Nonetheless, Mr Van Heerden was fined and ordered to pay costs. As noted, the matter is currently before the WA Court of Appeal.

According to the WA Department of Health website:

The Court decision highlights that products that resemble tobacco products, regardless of whether they contain nicotine or not, cannot be sold in WA and it is an offence under the *Tobacco Products Control Act* to sell these products.

The state of play in NSW: As for the implications of the case for NSW, the Sydney Morning Herald reported in April 2014 that:

Asked about the case, the NSW Ministry of Health confirmed it was "continuing to monitor" the case and was waiting to see "whether the decision may be appealed."

In the meantime, it confirmed more than a dozen Sydney retailers were facing legal action after being caught selling illegal nicotine-laced e-liquids, late last year.

"Prosecutions are being considered for breaches of the Poisons and Therapeutic Goods Regulation 2008 and evidence has been collected," a Health Department spokesman confirmed. 40

A year on, the <u>Sydney Morning Herald</u> reported that:

NSW health officials have failed to nab a single retailer for selling illicit electronic cigarettes, despite the department's own testing revealing 70 per cent illegally contain nicotine.

It comes as the government faces harsh criticism for failing to properly regulate the booming market in e-cigarettes, which are popular among young people as a quit-smoking aid.

Data obtained by Fairfax Media shows not a single NSW retailer has been prosecuted for selling e-cigarettes containing liquid nicotine, which is illegal under poisons legislation. 41

Public Health (Tobacco) Amendment (E-cigarettes) Bill 2015

The E-cigarettes Bill 2015: On 6 May 2015 the Minister for Health Jillian Skinner introduced the Public Health (Tobacco) Amendment (E-cigarettes) Bill 2015 (the E-cigarettes Bill 2015) in the Legislative Assembly. Its purpose was limited to prohibiting the sale of e-cigarettes and e-cigarette accessories to minors, making this an offence carrying a maximum penalty of \$11,000 for an individual or \$55,000 for a corporation, and for a second or subsequent offence \$55,000 for an individual and \$110,000 for a corporation (ss 22(2A) and (2B) of the Public Health (Tobacco) Act 2008).

According to the second reading speech:

The bill includes a broad definition of "e-cigarettes" and "e-cigarette accessories" so as to capture any device that releases or generates an aerosol or vapour by electronic means for inhalation in a manner similar to the inhalation of tobacco from a tobacco product... The definition of "e-cigarettes" under the bill includes devices and liquids that contain nicotine as well as those that do not contain nicotine. 42

Relevantly, inserted into s 4 of the *Public Health (Tobacco) Act 2008* are the following definitions:

e-cigarette means:

- (a) a device (other than a device of a kind excluded by the regulations) that is designed to generate or release an aerosol or vapour (whether or not containing nicotine) by electronic means for inhalation by its user in a manner that replicates, or produces an experience similar to, the inhalation of smoke from an ignited tobacco product or ignited non-tobacco smoking product, or
- (b) any other device of a kind prescribed by the regulations that is designed to be used by its user in a way that replicates, or produces an experience similar to, the use of a tobacco product or non-tobacco smoking product.

e-cigarette accessory means:

- (a) a cartridge, capsule or other container designed to contain a liquid, aerosol, gas, vapour or other substance for use in an e-cigarette, or
- (b) a heating element designed for use in an e-cigarette, or
- (c) any other component of an e-cigarette (or class of e-cigarettes) of a kind prescribed by the regulations.

By reference to new s 22(4) of the *Public Health (Tobacco) Act 2008*, the second reading speech stated:

However, the ban will not apply to legitimate stop-smoking aids that meet the definition of "e-cigarette" provided these are registered therapeutic goods or where there is an approval under the Poisons and Therapeutic Goods Act. 43

Proposed Opposition and Greens amendments: Both Labor and the Greens have foreshadowed proposed amendments to the Bill. Each of these can be explained separately.

Labor's proposed amendments would adopt the same broad definition of an e-cigarette, that is, to include those containing and not containing nicotine. It would expressly include the regulation of e-cigarettes in the Act's objects clause (s 3(2)(a)). The proposed amendments would also apply all restrictions and offences under Part 2, Division 2 of the *Public Health (Tobacco) Act 2008* to e-cigarettes (proposed s 8A). Further, by amendment of Part 3 of the Act the same restrictions on advertising and promotion would apply to e-cigarettes as to tobacco products (proposed s 15A).

The Labor Opposition would also amend the *Smoke-free Environment Act 2000* to include e-cigarettes in the definition of "smoke" thereby prohibiting their use in public places designated "smoke-free areas". Specifically, "smoke" would mean (in part):

in relation to an e-cigarette – use, hold, or otherwise have control over, the e-cigarette when it is generating or releasing an aerosol or vapour.

The amendments proposed by the Greens would add to the protection of minors in the E-cigarettes Bill 2015 by:

- prohibiting adults purchasing e-cigarettes or e-cigarette accessories on behalf of minors (proposed s 23(3));
- allowing for police to seize e-cigarettes in the possession of minors in a public place (proposed s 26(1)-(4));
- allowing for the Minister to make declarations prohibiting ecigarettes or a class of e-cigarettes (proposed s 29(1)); and
- prohibiting the use of an e-cigarette in a motor vehicle in the presence of a juvenile (proposed s 30(8)).

E-cigarettes and the law internationally

Internationally, the regulation of e-cigarettes varies considerably between countries, with the same level of caution needed in distinguishing between those e-cigarettes containing and not containing nicotine. The regulatory

landscape is also said to be "changing rapidly". 44 For a broad overview see this Cancer Council Australia website, this e-cigarettes laws worldwide website and this Wikipedia website.

In its 2014 <u>report</u>, where the specific concern was with ENDS (electronic nicotine delivery systems], the World Health Organisation found that:

- 31. The sale of ENDS with nicotine is banned in 13 of the 59 countries that regulate them. However, the majority of these 13 countries report that ENDS are available to the public, probably through illicit trade and cross-border Internet sales.
- 32. The survey also shows that:
- (a) comprehensive advertising, promotion and sponsorship bans on ENDS are in place in 39 countries (in which 31% of the world's population live);
- (b) use of ENDS in enclosed public places is banned in 30 countries (35%);
- (c) premarket review is required by 19 countries (5%);
- (d) vendor licences are required by nine countries (4%);
- (e) policies on ENDS sales to minors were confirmed by 29 countries (8%). Where specified, minimum required age for purchase ranged from 18 to 21 years. 45

United Kingdom: A summary of the current regulation of e-cigarettes in the UK and US is set out by Doug Fraser and his colleagues in their recent paper published in the *International Journal of Drug Policy*. In respect to the UK, and specifically for e-cigarettes containing nicotine, they noted that:

e-cigarettes have been regulated as consumer products under general consumer protection law. In 2013 the Medicines and Healthcare Products Regulatory Agency stated all e-cigarettes would be regulated as medicines from 2016. However, with the introduction of the European Union's Tobacco Products Directive in 2014, medicines licensing for all products will no longer be compulsory for products not exceeding 20 mg/mL of nicotine. ⁴⁶

Above that level, or if manufacturers and importers decide to opt into medicines regulation, such products will require authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA) as over the counter medicines in the same way as nicotine replacement therapy (NRT). In early 2014 the Cameron Government was reported to be in the process of drafting regulations under the *Children and Families Act 2014* banning the sale of e-cigarettes to minors; as at March 2015 the UK Government was still said to be planning to introduce a "formal ban" of this kind. The current position is summarised by the NHS Smokefree website, stating:

At present, e-cigarettes are only covered by general product safety legislation. This means they can legally be promoted and sold to children, and we cannot be sure of their ingredients or how much nicotine they contain. While negotiations continue on the European Tobacco Products Directive on the introduction of regulation across the EU, the MHRA is inviting e-cigarette producers to apply for a medicines licence under the existing framework.

United States: In respect to the US, and again for e-cigarettes containing nicotine, Fraser et al commented that:

In the US, e-cigarettes are currently unregulated at a federal level but state and local jurisdictions have varying restrictions on use and sale. However, the Food and Drug Administration (FDA) announced its intention to regulate them as tobacco products which would restrict marketing and sales and require manufacturers to register their products with the FDA and to accurately label them.⁵⁰

Canada: For Canada, the Quit Now website presented this summary of the legal position:

In March 2009, Health Canada issued an <u>Advisory to Canadians</u> NOT to use e-cigarettes as these products may pose health risks and have not been fully evaluated for safety, quality and efficacy by Health Canada.

Health Canada also issued a <u>notice to stakeholders</u> indicating that all electronic products intended to administer inhaled doses of nicotine are considered new drugs and as such fall under the Food and Drugs Act.

However, the Notice issued by Health Canada only applies to e-cigarettes "intended" to deliver nicotine, which has created a **regulatory grey zone** that has been widely exploited.

E-cigarettes that do not make any health claim and do not contain nicotine may legally be sold in Canada.

An article from the online magazine <u>Canadian Living</u> provides the following overview:

Electronic cigarettes that contain nicotine or come with health claims fall within the scope of the <u>Food and Drugs Act</u> and require market authorization by Health Canada prior to being imported, advertised or sold. No electronic cigarettes with nicotine have been authorized by Health Canada.

Reporting in March 2015, Canada's <u>House of Commons Standing</u> <u>Committee on Health</u> confirmed that:

As there is no existing federal regulation restricting the sale of either devices or the liquids that are used to flavour the vapour, both can be purchased legally by individuals of any age.⁵¹

The committee recommended that the federal government establish a new legal framework for e-cigarettes, sold with or without nicotine e-juice. It further recommended banning sales to minors, prohibiting use in federally regulated public places, restricting advertising of the products, barring the sale of e-juice flavours, such as candy flavourings, aimed at the youth market, and establishing limits on how much nicotine e-juice can contain. The Federal Government is yet to respond to the report.

In the ongoing debate, in May 2015 it was reported that Canada's Provinces are moving to regulate e-cigarettes, with Nova Scotia the first to ban them from in-door public spaces and for purchase by under 19 year olds. British Columbia, Ontario and Quebec are also said to be in the process of introducing relevant legislation.⁵²

New Zealand: The legal position is summarised by <u>Cancer Council</u> Australia which states that

Electronic cigarettes containing nicotine are regulated as medicines regardless of whether therapeutic claims are made. With respect to non-nicotine electronic cigarettes:

- Sales to minors: In New Zealand, it is unlawful to sell a product that looks like a tobacco product or smokers' pipe to people under 18 except where that product's primary purpose is to help people quit smoking.
- Smoke-free laws and policies: In New Zealand there is no national legislative framework on use in public places.
- Advertising and promotion: In New Zealand there are no specific laws regulating the advertisement of electronic cigarettes; however, like under Australian laws, arguments could be put that tobacco advertising prohibitions could apply to electronic cigarettes in some circumstances (for example, where an advertisement promotes "smoking behaviour".

Use and availability of e-cigarettes

According to Professor Simon Chapman, Australian data on "daily" ecigarette use are "unavailable". However, a 2013 national survey found that "15.4% of smokers aged 14 years or over had used them at least once in the past 12 months, despite the sale of nicotine liquid or "juice" being illegal here". ⁵³ Professor Chapman added:

In the United States, where ECs [e-cigarettes] are freely available and heavily marketed, rising EC use by youths has now surpassed their falling cigarette smoking prevalence. ⁵⁴

The recent work of Doug Fraser and his colleagues, published in the *International Journal of Drug Policy*, is based on an online survey completed by 705 e-cigarette users who were recruited online. They reported that most participants were male (71%), employed (72%) and highly educated (68% held post-school qualification). Nearly all participants (97%) reported that they had been daily smokers prior to using an e-cigarette. Participants purchased their e-cigarettes and associated equipment and refill solutions largely from online stores (89%) and/or directly from a seller or personal contact (20%). It was reported that "Comparatively few participants purchased their e-cigarettes from a permanent shop (8%)". The study found that most participants (90%) thought that e-cigarettes should be available for sale to anyone aged 18 and over. It also found that:

Very few participants (3%) thought there were any immediate health risks related to e-cigarette use, while 16% believed there could be long-term health risks. Most participants (96%) agreed that use of e-cigarettes should be encouraged as an alternative to smoking and that there was a need for more public education about e-cigarettes (91%). ⁵⁶

A different perspective on the availability of e-cigarettes is found in the warnings of the Cancer Council that of the 1,519 retailers audited in NSW, four out of five shops which sold e-cigarettes "placed them near the counter next to lollies and chocolates targeting children". ⁵⁷

Selected stakeholder views

Stakeholder views are again mixed, with anti-smoking groups generally supporting stricter regulatory standards than those advocated by ecigarette users and others. A key concern of those in the public health area is with the gateway effect for young people, fearing that e-cigarettes might reverse the trend of youth smoking, in decline since 1994 in England and since 1997 in the US and Australia.⁵⁸

As for the E-cigarettes Bill 2015, the Heart Foundation NSW welcomed its introduction as a first step. Heart Foundation NSW Chief Executive Kerry Doyle encouraged the Baird Government "to table further legislative changes which will regulate e-cigarettes in the same way that tobacco cigarettes are regulated", including banning their use in smoke-free public spaces.⁵⁹

The <u>Cancer Council NSW</u> position statement on e-cigarettes calls on the NSW Government to regulate the sale and use of e-cigarettes in a similar way to tobacco products by:

- Banning the sale of e-cigarettes to children
- Banning fruity, sweet and confectionery flavoured e-cigarettes and e-liquids
- Banning e-cigarette advertising and in-store promotions, including displays
- Requiring businesses wanting to sell e-cigarettes to register with the NSW Ministry of Health
- Restricting the use of e-cigarettes in indoor and outdoor areas where it is illegal to smoke tobacco products (e.g. in workplaces, on public transport, in restaurants, near children's play equipment)

A similar message is provided by <u>Cancer Council Queensland</u>, which "commended the Queensland Government for becoming the first state in Australia to subject e-cigarettes to the same laws as regular cigarettes". For further position statements along the same lines see for example:

- Cancer Council Australia
- Cancer Council WA

Among the reasons for a strict regulatory regime itemised by Cancer Council WA was that "There are concerns regarding the involvement of tobacco companies and the promotion and potential renormalisation of smoking".

Overseas, Canada's <u>Heart and Stroke Foundation</u> is an example of a body advocating a strict regulatory regime. It recommends that federal, provincial and municipal governments immediately adopt the following policies, for all e-cigarettes where jurisdictionally appropriate:

- **Prohibit use of e-cigarettes in public spaces** and workplaces where smoking is banned by law.
- Prohibit e-cigarette sales in locations where tobacco sales are banned.
- Prohibit e-cigarette sales to minors.
- Strictly regulate e-cigarette advertising and promotion.

- **Regulate the product**, including restricting flavours attractive to youth, and requiring that e-cigarettes be visually distinct from regular cigarettes.
- Should Health Canada approve the use of e-cigarettes with nicotine, it should then have a regulatory framework that include approval of products on a case by case basis, and development of labelling requirements. Restrict access by only allowing via prescription at the outset.
- Actively enforce the existing ban on e-cigarettes with nicotine to
 prevent illegal/non-approved nicotine based e-cigarette products from
 being available in Canada. The federal government, through Health
 Canada should apply penalties to retailers who supply illegal products and
 supplies to the Canadian market and deter others from making such
 products available.
- Dedicate research funding to enable a deeper understanding of the usage, potential benefits of e-cigarettes as a cessation device as well as their possible risks, including safety, gateway to addiction potential and renormalization.

As for e-cigarette users in Australia, Doug Fraser and his colleagues report that most are in favour of regulation as long as those regulations "do not impede their ability to obtain devices and refill solutions, which they view as important for them to remain smoke free". 60

More assertively libertarian, taking up the argument of JS Mill that there is in the world "an increasing inclination to stretch unduly the powers of society over the individual", ⁶¹ are the views of Senator David Leyonhjelm who argues that Australian proponents of regulation:

ignore their international counterparts such as the Royal College of Physicians, which concluded that e-cigarettes offer massive potential to improve public health by giving smokers a much safer alternative to tobacco.

They ignore how e-cigarettes are freely available in the European Union and the United States. And they ignore Australia's record of level-headed harm minimisation, such as our pioneering of the methadone treatment for hard-core heroin addicts.

It is hard to avoid the conclusion that their primary goal is to achieve a puritanical victory against nicotine rather than to save lives. It's not really about the smokers, it's about them. Like Marie Antoinette, they say to the smokers who could benefit: "Let them go cold turkey". 62

Similar in approach, advocating a free-market solution, is an article by Simon Breheny on the IPA <u>website</u>, which argues that e-cigarettes can save lives and should be made freely available "for thousands of Australians trying to quit smoking". 63

From an industry perspective, <u>British American Tobacco</u> has argued against "overly restrictive regulation". Setting out its preferred approach, it said that the following principles should underpin e-cigarette regulation:

- Ensure product quality and consumer safety quality standards need to be introduced, covering areas such as e-liquid content, emissions testing, labelling and child proofing.
- Appropriate levels of innovation, distribution and marketing to encourage growth – these will ensure that products have consumer

appeal, are widely and easily available and are marketed responsibly to adult smokers.

- Taxation that enables innovation and affordability e-cigarettes are different to conventional tobacco products and so the way they are taxed needs to take this into account. Excise tax will hinder their potential to benefit public health.
- **Protect under 18s** because nicotine is addictive, minimum age laws restricting sales to over 18s should be introduced and strictly enforced.

Conclusion

The downward trend in smoking, including smoking amongst young people, is a public health success story. It is understandable that public health professionals and others should seek to guard against any new innovation that might jeopardise the advances that have been made in this field. It is in that context that much of the debate about e-cigarettes occurs.

In essence, the question is not whether e-cigarettes should be regulated or not; rather, it is about the degree of regulation required for e-cigarettes of all kinds, those containing and those not containing nicotine. Should the same regulatory regime apply across the board to e-cigarettes as to conventional cigarettes? If so, is this because of the perceived harm associated with e-cigarettes, caused directly by the vaping of nicotine or other substances? Or is the concern rather that e-cigarettes, though not necessarily inherently harmful to health, may serve as a gateway to conventional smoking for young people in particular? Both issues are found in the current debate, as is the claim that e-cigarettes can assist smokers to quit. On all fronts, the need for further research is recognised.

Because e-cigarettes are presently unregulated their content can vary considerably, presumably with varying health risks to users. At the very least therefore there is a case for establishing standards as to content. The case for banning access to e-cigarettes for minors is made in the E-cigarettes Bill 2015. The argument for applying the same controls on advertising and promotion as apply to conventional cigarettes is made in the amendments proposed by the Labor Opposition, as is the case for banning e-cigarettes in public places designated "smoke-free areas". The debate has some way to go in NSW as in most other jurisdictions.

Views as to the right regulatory approach are sure to vary. One conclusion is that reached by Doug Fraser and his colleagues who write:

Governments should consider how regulation of e-cigarettes and refill solutions will affect current consumers, particularly those who are using e-cigarettes to remain abstinent from smoking. Maximising the benefits from encouraging smokers to switch to e-cigarettes while minimising the risk of potential adverse consequences, such as from young non-smokers initiating e-cigarette use, will require a considered approach to e-cigarette regulation.

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