

Australian Drug Law Reform Foundation
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Comment on:

Vaporised Nicotine Products Bill 2017

"We need to redouble efforts to help more smokers become tobacco-free. And, we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can't quit altogether. At all times, we must protect kids from the dangers of tobacco use." -- Scott Gottlieb, M.D | 23rd Commissioner of United States FDA - May 15, 2017.

Response prepared by:

Dr Alex Wodak AM, FRACP, FAChAM, MBBS | President - Australian Drug Law Reform Foundation

Evert Rauwendaal BSW | Member - Australian Drug Law Reform Foundation

Australian Drug Law Reform Foundation [ADLRF]

The Australian Drug Law Reform Foundation was established in 1993 as the umbrella organisation for drug law reform in Australia. The Foundation links a diverse group including clinicians, researchers, people who use drugs, lawyers and retired politicians to serving politicians and policy makers. The Foundation has also been involved in raising awareness of the need for drug law reform and articulating specific reform proposals.

About the authors:

Dr Alex Wodak AM

Dr Wodak has been President of the Australian Drug Law Reform Foundation for more than 10 years. He was Director of the Alcohol and Drug Service at St Vincent's Hospital from 1982 to 2012. Together with colleagues, he helped establish Australia's first needle syringe programme and first Medically Supervised Injecting Centre when both were pre-legal. In 1992, on behalf of the International Harm Reduction Association conference in Melbourne, Dr Wodak invited Professor Michael Russell to be a key note speaker on the subject of tobacco harm reduction. Dr Wodak also took part in a research project on smoking cessation among prison inmates.

Mr Evert Rauwendaal BSW

Mr Rauwendaal is a member of the Australian Drug Law Reform Foundation. He has worked in healthcare as a social worker for over 10 years and has specialised in providing smoking cessation advice and counselling for drug dependence. In the past he has worked for the NSW Quitline as an advisor and conducted smoking cessation education for people attending outpatient HIV and Hepatitis C services.

The Australian Drug Law Reform Foundation [ADLRF] welcomes the invitation to comment on and lends its full support to the introduction of the Vaporised Nicotine Products Bill 2017

This includes:

• excluding e-cigarettes from regulation by the Therapeutic Goods Administration, consistent with the existing exclusion of cigarettes from such regulation.

Smoking cigarettes, the most important cause of preventable death in Australia, is responsible for an estimated 15,000 deaths of Australians a year. Up to two out of three smokers will die from a tobacco related condition. Smoking causes more deaths and cost to the economy in Australia than all other drugs combined. An estimated one billion smokers will die from a tobacco related cause in the next 100 years.

The Australian Drug Law Foundation supports this proposal. E-cigarettes are customisable consumer products designed to consume nicotine in much the same way Nespresso pods/machines are a consumer product designed for people who wish to consume caffeine. They have not evolved as a standardised medical device designed to treat a medical condition. We regard it as inappropriate for the Therapeutic Good Administration to regulate consumer goods such as e-cigarettes unless the device has been submitted to the TGA for assessment as a therapeutic good or a therapeutic claim has been made.

The inappropriate scheduling of nicotine (as a controlled poison) stands in the way of more widespread use of e-cigarettes in Australia. *Nicotine should be exempt from the Poisons Standard (the SUSMP) in concentrations packaged for use in an Electronic cigarette.* This exemption would ensure that e-cigarette users are never put in the position where they become the target of law enforcement or have their nicotine liquids confiscated by authorities as they may relapse to smoking tobacco. Furthermore, e-cigarettes that do not contain nicotine are unlikely to be attractive to people already dependent on nicotine as a result of smoking tobacco.

• The Bill also confirms that the regulation of smoking at airports does not affect vaping (ie use of e-cigarettes) and that the ban on the advertising of smoking does not apply to the advertising of vaping.

Using an electronic cigarette to vaporise a nicotine liquid is different to burning organic material like tobacco. Legislation should acknowledge and reflect this fact. Nicotine in cigarettes is mainly responsible for cigarettes becoming so difficult to quit while the tars and other products of tobacco combustion are mainly responsible for the adverse health consequences of smoking. E-cigarettes provide nicotine without the products of tobacco combustion. Consequently the health risks of e-cigarettes are only a fraction of the health risks of smoking combustible cigarettes. The UK Royal College of Physicians and Public Health England estimated that the risks of e-cigarettes are likely to be less than 5% of the risks of smoking tobacco.

The regulations that have been applied to smoking tobacco should not automatically be carried across and applied to e-cigarettes. For example, forcing e-cigarette users to stand alongside people who smoke tobacco at airports, bars and in other places with indoor smoking restrictions exposes them to dangerous environmental tobacco smoke and may increase their risk of relapse to smoking tobacco.

Australia should review its restriction on marketing e-cigarettes. It is likely to reduce the uptake of e-cigarettes and lead to a perverse situation where adults and children are more likely to smoke or experiment with tobacco (the more dangerous product). The ADLRF is of the view that e-cigarettes will evolve as consumer products, gain further market share and eventually become more attractive to people than smoking tobacco if given regulatory space. Promoting e-cigarette use, promoting the use of TGA approved smoking cessation pharmacotherapies and campaigning against smoking tobacco can and should occur simultaneously. The main objective of e-cigarette policy should be to encourage smokers to switch to e-cigarettes while minimising the already small risk that young Australian non-smokers would commence using e-cigarettes regularly and progress to smoking cigarettes.

Tobacco control in Australia compares favourably with the approach taken in many other countries. In recent decades tobacco control policies in Australia have been very successful in reducing the prevalence of smoking. However, the prevalence of smoking in Australians aged 14 years and over in 2016 (12.2%) was not significantly different statistically from 2013 (12.8%) according to National Drug Strategy Household Survey. This 'flat lining' occurred despite plain packaging, high and increased cigarette prices and the vigorous implementation of other tobacco control policies. In contrast, smoking rates fell much faster in the UK and USA after 2010 when e-cigarettes started becoming more popular in an environment much more favourable to e-cigarettes than Australia. For the first time, smoking prevalence is now lower in the UK and USA than in e-cigarette hostile Australia. The policy adopted for e-cigarettes in Australia is now out of step with the policy adopted or being adopted in countries that Australia likes to compare itself with such as UK, NZ, USA and Canada. In Australia every significant health organisation opposed e-cigarettes including all nine health departments, TGA, NHMRC, AMA, RACP, RACS, RANZCP, RACGP and PHAA. In July 2017, RANZCP became the first significant health organisation in Australia to support e-cigarettes. The New Zealand Medical Association supports e-cigarettes.

Restricting e-cigarettes more than cigarettes is perverse. There is good evidence
to suggest that e-cigarettes are much less harmful than cigarettes, and no
credible evidence that e-cigarettes are more harmful than cigarettes.

The current regulatory environment (inappropriately) treats e-cigarettes like smoking tobacco and even more harshly in some cases. This may mislead smokers into thinking there are few benefits from switching from smoking tobacco to the exclusive use of an e-cigarette when, in-fact, the opposite is true. The simultaneous use of e-cigarettes and tobacco cigarettes ('dual use') is common and is usually a temporary transition from smoking to vaping e-cigarettes or quitting completely.

No compelling argument can be made for attempts to prevent the uptake of electronic cigarettes. Higher uptake of electronic cigarettes and complete substitution for smoking tobacco is a lofty goal that has the potential to substantially improve public health, reduce hospital admissions and reduce health costs. There is no credible evidence that electronic cigarettes are being used by large numbers of people who are not presently nicotine dependent as a result of smoking tobacco. As the e-cigarette user base is predominantly made up of people who have already been engaging in a high risk activity, smoking tobacco, there is no need for any public health alarm about e-cigarette uptake.

A perverse effect of current regulatory hostility to e-cigarettes in Australia is that it protects the tobacco industry.

All public education activities and resources should be directed towards anti-smoking activities, not anti-vaping activities. As no clear public health risks appear to have emerged from the use of electronic cigarettes a focus on prevention is unnecessary. To put the harms from e-cigarettes in perspective more people are injured from the use of hot water bottles on a regular basis. According to the ACCC each year "up to 200 Australians are admitted to hospital because of serious burns from hot water bottles". It seems strange to devote resources towards singling out and preventing the use of e-cigarettes when there is so little evidence of harm.

 There is evidence to suggest the availability of e-cigarettes assists people to quit smoking more than it leads people to take up smoking, and no evidence to suggest that the availability of e-cigarettes leads people to take up smoking more than it assists people to quit smoking.

Both Royal College of Physicians and the The Centre for Addictions Research of BC have conducted extensive reviews and have found persuasive evidence that e-cigarettes are replacing—rather than encouraging—the use of smoking tobacco. In addition, Sweden's experience with a form of smokeless tobacco called 'snus' provides evidence that most people will switch to less hazardous methods of consuming nicotine if given the option. The use of snus in Sweden has lead to a decline in the use of smoking tobacco and smoking related deaths and diseases. European countries where the sale of snus is prohibited have a higher prevalence of smoking compared to Sweden. Swedish men have the lowest smoking rate and the lowest rate of tobacco related deaths and disease in the European Union.

- The sale of e-cigarettes is legal in a growing number of developed countries and is being considered in others.
- (i) The UK and the USA have provided a positive policy and regulatory environment for some years;
- (ii) On 29 March 2017 the New Zealand Government announced that they would legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products;

- (iii) Canada is in the process of regulating E-cigarettes as a separate class of products rather than a tobacco product;
- (iv) On August 8, 2016 the Obama Administration introduced 'deeming' provisions which expanded FDA authority over vaporizers and electronic cigarettes. Compliance with these new provisions has been labelled "burdensome and opaque, and far more onerous than for cigarettes". However, the new FDA Director Dr Scott Gottlieb has announced that he sees "a potential opportunity for e-cigarettes to be a lower-risk alternative to smokers who want to quit combustible cigarettes" and has subsequently delayed the deeming provisions introduced under the Obama Administration until 2022.
- (v) The World Health Organisation [WHO] considers Electronic Cigarettes an: <u>"evolving frontier filled with promise and threat for tobacco control"</u>. It should be noted that the WHO was opposed to harm reduction and needle syringe programs for many years.
 - It is legal for Australians to import e-cigarettes for personal consumption, which makes the current ban on the sale of e-cigarettes in Australia equivalent to reverse protectionism. Australian businesses are prevented from making sales that foreign businesses are allowed to make.

The Electronic cigarette user and tobacco smoker are treated differently under the law. Commonwealth and state laws currently treat the possession and use of nicotine in Electronic cigarettes by adults as a punishable offence subjecting it to prohibition, not mere regulation. Far from posing as much risk to genuine state interests as those who smoke tobacco, adult 'vapers' pose less risk and yet they are treated more harshly under the law. The law's imbalance in this respect—its disproportionality— should be noted.

Regulation should be proportionate to the relative risk of tobacco free technologies like e-cigarettes. It is illogical that Australian businesses are permitted to sell tobacco for smoking and yet are punished for selling a less harmful product such as e-cigarettes. The most dangerous nicotine product (cigarettes) should not be easier to obtain than less dangerous products such as e-cigarettes.

The share price of Philip Morris International (PMI), the largest traded cigarette company in the world, increased more than 20% since January 2017 when it announced in a new website that it was making a transition to a smoke free future. PMI has invested \$US 3 billion into research involving 'reduced risk products'. Most other major tobacco companies are moving in the same direction. The increase in share price suggests that investors are confident that future earnings will be greater than past earnings. While the behavior of the tobacco industry has been reprehensible and is worse than reprehensible in developing countries today, it is much better that the tobacco industry is able to continue making large profits selling much less dangerous products than selling a product which is responsible for the deaths of two out of every three of its customers.

It is time that Australia terminated its hostile policy to e-cigarettes and focussed on a pragmatic approach to tobacco. Harm reduction is included explicitly in Australia's National Drug Strategy, Australia's National Tobacco Strategy and is also included in the Framework Convention on Tobacco Control which Australia has signed.