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Dr David Outridge FRACGP

03/08/2017

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam,

Re. Vaporised Nicotine Products Bill 2017

I am a registered Australian General Practitioner with 30 years' experience in general practice and an interest in addiction medicine for over 20 years. ***One of the most distressing chronic medical conditions*** *that I have witnessed is that of* ***end-stage chronic airways disease****.*

The reason vapourized nicotine should be widely available as a consumer product:
The only public health solution to smoking-induced severe lung disease is prevention; medical treatments are relatively ineffective and expensive, or are unavailable to most (as in lung transplantation). Unfortunately smoking cessation, whilst a highly desirable goal, either comes too late or is too difficult to achieve for many smokers. Lung cancer and cardiovascular disease are other equally dreadful diseases which also kill, often at a younger age. Reducing the harms of nicotine addiction is a legitimate form of public health policy. There is sufficient evidence to be certain that vapourized nicotine inhalation is vastly safer than tobacco smoking for all the conditions which it is proven to cause. Whilst not necessarily leading to cessation of nicotine use, this outcome is now not necessary for prevention of most of the harms from tobacco smoking.

The issues of concern around vapourized nicotine can be managed:
There is a legitimate, but manageable concern around widespread availability of vapourizing nicotine e-liquid (and heat-not-burn tobacco), around potential for poisoning in children. Nicotine vapourizing liquid is a dilute form of nicotine, however, given that the oral lethal dose of nicotine is around 10 mg/kg, (Mayer, 2014) a 10kg infant would need to ingest (and retain) only 5.5 ml of the 1.8% solution (a common strength) to be potentially fatal. Despite the viscosity, adverse taste, and the likelihood of vomiting, (all of which mitigate against poisoning), this volume is relatively small, and this underlines the need to limit potential exposure through packaging and delivery device design. It is to be noted that whilst calls to Poisons Hotlines regarding nicotine e-liquid cases are rapidly rising in the USA, (where regulation of packaging is poor) fatalities appears extremely rare, (based on my quick search of the literature, only two cases world-wide could be found).

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The issue of uptake by young people is also a legitimate concern, and has been researched to a reasonable extent. Findings suggest that of the small increase in adolescent experimentation, mostly only those young people already smoking try vapourized nicotine. Laws governing advertising and purchase age are additional deterrents to uptake.

Nicotine vapourizing liquid and 'heat-not-burn' tobacco products' classification under the Poisons Schedule:

Despite these concerns, vapourizable diluted nicotine's current inclusion as a Schedule 7 product under the current Poisons Standard (Therapeutic Goods Act 1989), would appear to be an inconsistency, when comparing it to other potential toxic ingestible consumer products such as alcohol and existing tobacco products, or over-the-counter products such as nicotine chewing gum/lozenges and paracetamol (both of which are available in supermarkets). In view of the relatively low risk of fatality given its diluted state (effectively increases the oral LD50 to >2000mg of a 5% solution), and that '…foreseeable harm to users can be reduced through strong label warnings, extensive safety directions and child-resistant packaging', an exception from Schedule 7 for nicotine in the dilute form (up to 5%) would seem reasonable and consistent with many other products.

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The community benefits of vapourizable nicotine availability:

The potential benefit to public health from widespread replacement of combustible tobacco by vapourized nicotine products is massive, and the potential savings to the community in costs of health services, lost years of productivity and personal costs are similarly enormous. Tobacco use is one of the most important modifiable health risks in the world, and the second commonest preventable cause of hospitalization.

The tax revenue from tobacco is also very considerable, and this would be maintained with retail sales of nicotine e-liquid, whilst reducing the amount lost in health and productivity. Currently the growth in mail-order purchases of nicotine e-liquid means that tax revenue from nicotine sales is being lost. More importantly, e-liquid refills coming from overseas are not controlled for quality or packaging, therefore pose potential risk that would be managed if retailed in Australia under local standards.

My practice experience:

At a professional level, I deal with many patients having Personality Disorders and Substance Use Disorders. Such patients have much greater difficulty giving up cigarette smoking. Unfortunately, these patients (who do get better over a twenty year period, unlike many with other mental illnesses), do not get to enjoy their long-fought-for stability in their 40s and 50s due to the damage wrought by smoking in

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their younger years. This is a tragedy for such patients as in many cases the original problems have been caused by childhood trauma.

In summary:

My opinion is that the balance of risks and benefits leans heavily towards enabling the availability of nicotine e-liquid for the tobacco consumer market, with appropriate regulations for child safety, age restrictions, consumer information and marketing; this would entail making an exception for dilute nicotine e-liquid (up to 5% strength) within the Poisons Schedule classification, such that it may become available as a consumer product, with appropriate product design, regulation and taxation.

Thank you for considering this submission,

Yours sincerely,

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Appendix of scientific references:

ENDS has become widespread since its development in 2003 by a Chinese pharmacist whose father died of lung cancer. It was first marketed in 2004 and in the USA in 2007.

Initiation of smoking usually occurs as a teenager; therefore prevention of uptake at that age is important in any public health strategy (Cancer Council Australia, 2016). The potential impact of ENDS on the initiation of young people into nicotine addiction is of concern, by 'normalization' of ENDS use. Studies have detected small increases in adolescents experimenting with ENDS, but 80-90% of these were existing tobacco smokers (Farsalinos & Polosa, 2014; Brandon, et al., 2015). In adults, similarly, ENDS is primarily used by tobacco smokers, with up to a third having tried ENDS. In those who have never smoked, there is

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only a 1% incidence of ever using ENDS suggesting low risk of creating a new dependency (Brandon, et al., 2015).

Smoking cessation impacts are another area of concern, insofar as ENDS may affect efforts to stop (Brandon, et al., 2015). Callers to Quitline who used ENDS, were less likely to be abstinent after seven months that those who had never tried ENDS (Vickerman, et al., 2013). However, ENDS delivers less nicotine that conventional cigarettes and it has been shown that even nicotine-free vapourizers can reduce craving effectively (Cahn & Siegel, 2011). A review of four RCTs showed that ENDS is an effective smoking cessation aid, but did not necessarily result in cessation of nicotine addiction, that is, participants may have continued to use ENDS (Lam & West, 2015). Compared to conventional smoking cessation therapies such as varenicline, ENDS has been shown to be less effective: 22-35% vs 7-9% respectively (Rom, et al., 2015).

Nicotine poisoning is a hazard especially to children due to handling of cartridges of high potency nicotine or ingestion of e-liquid from refills (Brandon, et al., 2015; Lam & West, 2015).

The effects of 'second-hand' or 'third-hand' vapour are cited as objections to ENDS. The ENDS vapour is unlikely to be a major risk provided that the vapour is treated the same way as cigarette smoke in exposure-reduction measures. The risk of accumulation of nicotine on surfaces, to which children may be exposed, has not been quantified (Brandon, et al., 2015).

<u>Suggested approaches</u>

- Legalizing the import and sale of vapourizable dilute nicotine, whilst applying taxation, providing accurate consumer information, and applying age restrictions on purchases.
- Regulation of the standards of ENDS and vapourizable nicotine packaging.
- Child-proof packaging of vapourizable nicotine.
- Further well designed studies of:
    - smoking cessation for individuals
    - population effects of ENDS, in relation to adolescent and adult uptake of nicotine use and cigarette use.
    - the long term safety of ENDS.
- Providing good quality information for all smokers presenting both sides of the argument for and against any use, use as a smoking cessation aid, and use as a harm-minimization aid.

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