

## **POST-PRINT**

This is a post-print (post-refereed, final accepted) version of the manuscript that has been published in *Lancet Respiratory Medicine*. The citation details and the link to the final publisher version are below.

Hall, Wayne and Gartner, Coral (2014) Should Australia reconsider its ban on the sale of electronic nicotine delivery systems?. *Lancet Respiratory Medicine*, 2 8: 602-604. doi:10.1016/S2213-2600(14)70155-9

**[http://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(14\)70155-9/abstract](http://www.thelancet.com/journals/lanres/article/PIIS2213-2600(14)70155-9/abstract)**

### **Should Australia reconsider its ban on the sale of Electronic Nicotine Delivery Systems?**

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Over the past 30 years, steep increases in tobacco taxes, advertising bans, and bans on smoking in public places have reduced the daily smoking rate among Australian adults to 16%.<sup>1, 2</sup> Australia was an early adopter of graphic health warnings on cigarette packs and mandatory plain packaging of cigarettes.<sup>2</sup> In 2011 Australia joined Brazil, Canada, and a number of other European countries in banning the sale of e-cigarettes or electronic nicotine delivery systems (ENDS).<sup>3</sup>

Unlike in other substance use fields, harm reduction (THR) strategies have never played a role in Australian tobacco policy. These strategies aim to reduce tobacco-related harm by encouraging smokers to use less harmful ways of obtaining nicotine, such as using smokeless tobacco or electronic nicotine delivery systems (ENDS). Australia's national tobacco strategy makes no mention of THR as a strategy and there are major legal and regulatory obstacles to THR,<sup>4</sup> including a ban on the sale of smokeless tobacco since 1991.<sup>5</sup>

The Australian laws covering ENDS are complex and vary between the states but they effectively ban their sale. Since 2011, personal importation of ENDS as an unapproved cessation aid has only been allowed on medical prescription. State drugs and poisons legislation prevent the retail sale, possession and/or use of nicotine for recreational purposes without a licence, approval or permit.<sup>6</sup>

Some states have also banned the sale of vaporising devices that do not contain nicotine. They have extended laws, originally designed to prevent the sale of cigarette-like confectionary and toys to children, to prohibit the sale of any products that 'resemble' tobacco products.<sup>6</sup> The national tobacco control strategy indicates that consideration is being given to "whether there is a need to increase restrictions on their availability and use".<sup>4</sup>

Despite these bans, the number of Australian smokers who have ever tried ENDS increased from 2.0% in 2010 to 16.8% in 2013.<sup>6</sup> Similar increases have been reported in other surveys.<sup>1, 7</sup> These rates of use are lower than those in the UK (where ENDS can still be legally sold as general consumer products) where ever use among smokers increased from 9.6% in 2010 to 38.8% in 2013.<sup>7, 8</sup>

The Cancer Council, National Heart Foundation<sup>6</sup> and many leading tobacco control advocates in Australia support the ban on the sale of ENDS<sup>9-12</sup> (see table 1 for a summary of their reasons). They argue that it: prevents the tobacco industry (which now owns some ENDS products<sup>10</sup>) from undermining smoke free policies by promoting dual use (i.e. encouraging smokers to keep smoking and only use ENDS when smoking is prohibited); prevents the widespread use of ENDS from renormalising smoking by increasing the visibility of a behaviour that resembles smoking; and prevents ENDS being used to promote cigarette smoking among adolescents and young adults.

There has been very little criticism of the ban within the Australian public health community. Nonetheless, the ban can be criticised on ethical and other grounds (see table 1). It is paternalistic because it denies adult smokers the right to use a less harmful form of nicotine in

order to prevent cigarette uptake among youth. It is also an incoherent form of risk regulation in banning a less harmful product (ENDS) while allowing the most harmful, tobacco cigarettes, to be freely sold. It disadvantages smokers who are heavily addicted and want to reduce the risks of their smoking. It has produced a black market in nicotine sold over the internet and ‘under the counter’. And it precludes any regulation of ENDS and nicotine refills to reduce risks to consumers and others.

### **A policy compromise?**

The public health harms feared by those who support a ban on ENDS are most likely to occur if the sale and promotion of these products is unregulated. This has arguably been the case by default in parts of Europe, the UK, and the USA for the past several years while different models of regulation have been debated.<sup>3</sup>

We do not have to choose between banning ENDS sales and allowing their unregulated sale. We can regulate sales in ways that address the legitimate concerns of those who support a ban, while still allowing smokers to buy ENDS.<sup>13</sup> For example, adult smokers could be allowed to buy approved ENDS products from a restricted number of licensed sales outlets. These sales could be regulated in ways that facilitate research to inform future decisions about how to regulate ENDS.

Advertising of ENDS products could be banned and consumer law could be used to ensure their safety to users and others (e.g. to children by requiring child-resistant containers for nicotine). At the point of sale, purchasers could be: advised to avoid dual use (except as a time-limited path to quitting); and clearly told that we do not have definitive evidence on the health effects of using ENDS as a long term alternative to cigarette smoking.

This type of regulation would facilitate research on the uptake and use of ENDS. Regulations could, for example, make reporting sales data and user characteristics (age, sex, smoker status) a condition of being licensed to sell ENDS. Researchers could be funded and facilitated to conduct long-term follow up studies of ENDS purchasers in order to discover: who uses ENDS and for how long; how many users cease smoking, engage in dual use and cease all nicotine use; and what the health effects in the medium term are of using ENDS, either alone, or in combination with tobacco smoking (dual use).

This policy respects smoker autonomy and eliminates the injustice of preventing smokers from accessing ENDS while allowing free access to cigarettes. It would also provide better consumer protection of ENDS users, regulate promotion of these products and reduce the size of the black market for ENDS products.

It could also be readily reversed if ENDS prove as disappointing as their critics predict. If, however, ENDS assist quitting and are much safer substitutes for combustible cigarettes, as their advocates claim, then these restrictions could be relaxed. This could be done while also increasing restrictions on the sale of cigarettes, e.g. by reducing the number of outlets in

which cigarettes can be sold; allowing ENDS to be sold in the same places so that they can compete with combustible cigarettes among current smokers; and reducing young people's access to both products to minimise the recruitment of new smokers and vapers among adolescents and young adults.

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## Table legends

Table 1: competing perspectives on a ban on ENDS and allowing limited sales by opponents and proponents of ENDS

Table 2: competing predictions about the effects of allowing ENDS by proponents and opponents of a ban

Policy on ENDS	A ban on ENDS	Allowing restricted sales
View of those who oppose sales	Avoids: <ul style="list-style-type: none"> <li>• Dual use</li> <li>• Renormalising smoking</li> <li>• New young recruits to ENDS and smoking</li> <li>• Adverse health effects of long term ENDS use</li> </ul>	Will: <ul style="list-style-type: none"> <li>• Deter quitting smoking</li> <li>• Encourage dual use</li> <li>• Renormalise smoking</li> <li>• Recruit new smokers</li> <li>• Recruit new young non-smoking ENDS users</li> </ul>
View of those who would allow sales	<ul style="list-style-type: none"> <li>• Paternalistic policy</li> <li>• Unfair to smokers</li> <li>• Incoherent risk management</li> <li>• Creates black market</li> <li>• No consumer regulation</li> </ul>	<ul style="list-style-type: none"> <li>• Will reduce cigarette smoking</li> <li>• Respects smoker autonomy</li> <li>• Fairer to smokers</li> <li>• More coherent risk management</li> <li>• Minimise black market</li> <li>• Provide consumer protection</li> </ul>

<b>Outcome</b>	ENDS Proponents	ENDS Opponents
% smokers quitting with ENDS	Much higher than NRT	No better than NRT
% smokers switching to ENDS	Most or at least a sizeable minority	Negligible
% smokers who engage in dual use	A minority	The majority
% nonsmokers who become smokers via ENDS	Negligible	Substantial
Adverse health effects of long term vaping vs smoking	Negligible	Substantial
<b>Net effect on tobacco-related harm</b>	A substantial reduction	A substantial increase