Chapter 2

Personal choice and electronic nicotine delivery systems

2.1 The evidence provided to the committee regarding the policy approaches for regulating electronic nicotine delivery systems (ENDS) revealed a significant rift between two philosophies: those who argued for 'tobacco control', and those who emphasised 'harm reduction'. As these perspectives inform the larger debate regarding ENDS, these principles will be explored before turning to more specific claims in the debate.

'Precautionary principle'

2.2 Those supporting the continued restriction of ENDS argued the devices should remain illegal until such time as more evidence is available to fully inform users of the associated health risks. This was labelled by some as the 'precautionary principle' or 'tobacco control' principle, in which the policy response is focussed on tightening tobacco regulation as much as possible to reduce availability, and consequently reduce harm to users.[1]

2.3 The precautionary principle was evident in submissions provided to the inquiry by medical and public health organisations.[2] It was argued that after many decades of policy and regulation against tobacco, relaxing restrictions on the use of ENDS would be a move that supports nicotine consumption, which could destabilise efforts to curb tobacco cigarette use. Furthermore, allowing the use of ENDS could be problematic to implement in the Australian policy environment, which is predominantly designed to restrict the use of tobacco. For example, as ENDS are designed to look like tobacco cigarettes, it could create uncertainty in how smoke-free policies are applied.[3]

2.4 The Department of Health (department) is following an approach in line with the precautionary principle. According to its submission, the department is 'taking a precautionary approach' and 'is continuing to examine the regulatory framework governing ENDS in Australia'.[4] It pointed instead to a number of nicotine replacement therapies subsidised by the government to assist smokers in quitting, and did not include ENDS in this list.[5] This suggests that the priority for the department is in

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1 Dr Alex Wodak, Australian Drug Law Reform Foundation, *Committee Hansard,* 9 March 2016, pp 10-11.

2 Royal Australasian College of Physicians, *Submission 261*, p. 7; Public Health Association of Australia, *Submission 172*, p. 10; Australian Health Promotion Association, *Submission 91*, p. 2.

3 See: World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016) p. 8.

4 Department of Health, *Supplementary Submission 444.1*, p. 5.

5 Department of Health, *Supplementary Submission 444.1*, p. 6.

tobacco control, and to further reduce rates of smoking using currently accepted and orthodox methods.

2.5 The Australian Medical Association (AMA) also follows this principle, as evidenced in its submission. It stated that tobacco control measures are widely accepted in the Australian community, and have successfully reduced tobacco smoking in the past two decades.[6] The AMA stated that it supported governmental regulation of tobacco smoking, and 'that these measures should extend to newer products such as e-cigarettes'.[7]

'Harm reduction principle'

2.6 Submitters and witnesses advocating to end the prohibition of ENDS argued that the precautionary principle was misguided. These stakeholders put forward the view that the 'harm reduction' principle should take precedence when applied to the ENDS debate, arguing that the public policy focus should be preventing further harm to people when it can be avoided.[8] Policies such as methadone clinics for heroin users and needle exchanges for drug users were cited as examples of harm reduction policy.[9]

2.7 Dr Alex Wodak, President of the Australian Drug Law Reform Foundation, argued that the harm reduction principle in relation to tobacco focussed on reducing the harmful effects on people:

> [T]he central objective is decreasing harm—that is, death, disease, crime, corruption, violence and so on. In this case also there is the huge economic cost of smoking. If people can find some way of still ingesting nicotine which is much less harmful than tobacco, so be it.[10]

2.8 Professor Gerry Stimson, Emeritus Professor at Imperial College London, concurred with Dr Wodak's perspective, arguing that the effects of smoking tobacco cigarettes have been disastrous for public health. Professor Stimson cited psychiatrist Michael Russell's statement that people 'smoke for the nicotine and die from the tar', illustrating his point that it is the combustive effect in cigarettes which causes the most harm rather than nicotine itself.[11] In relation to tobacco, Professor Stimson stated that

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6 Australian Medical Association, *Submission 112*, p. 3.

7 Australian Medical Association, *Submission 112*, p. 3.

8 See: Dr Alex Wodak, *Committee Hansard*, 9 March 2016, p. 10; Professor Gerry Stimson, *Committee Hansard*, 9 March 2016, p. 15.

9 Dr Alex Wodak, Australian Drug Law Reform Foundation, *Committee Hansard*, 9 March 2016, p. 10.

10 Dr Alex Wodak, Australian Drug Law Reform Foundation, *Committee Hansard*, 9 March 2016, p. 10.

11 Professor Gerry Stimson, *Submission 141*, p. 2; see also Dr Alex Wodak, Australian Drug Law Reform Foundation, *Committee Hansard*, 9 March 2016, p. 10.

harm reduction works primarily because it 'does not require a smoker to give up both smoking *and nicotine*'.[12] Further:

> Tobacco harm reduction—the availability of low risk alternatives to smoking for those who cannot or do not wish to quit using nicotine—recognises that smoking is primarily driven by seeking nicotine and that there are many people who are unable or unwilling to stop using nicotine.[13]

2.9 The recognition that some smokers would never be able to give up their addiction to nicotine was also noted by Dr Paul Martin, who argued that denying people the opportunity to use ENDS negatively impacted their health:

> The fact is that there are people who will *never* quit smoking—even if it were made illegal—and denying them the option to continue their nicotine habit, while minimising the harm to themselves and more importantly, to others, is far more dangerous.
>
> Our focus should be on *harm* minimisation—both for the individual and society—when creating such legislation.[14]

2.10 Minimising the harm caused by smoking, as opposed to eliminating it, was at the crux of this perspective. This methodology allows a flexible approach in legislating ENDS, and recognises how difficult it is to quit tobacco cigarette smoking. It also allows for personal choice in how to quit smoking and whether to continue to consume nicotine.

2.11 Furthermore, submitters advocating this approach argued that the damage caused by tobacco greatly outweighed the risks posed by ENDS. Professor Riccardo Polosa submitted:

> With any emerging behavior associated with exposure to inhalational agents, there is legitimate cause for concern and a need for study of potential harm. However, this potential risk must be taken in the context of known harm of cigarette smoking in individuals who are already smoking.[15]

2.12 This point was further illustrated by Dr Attila Danko, President of the New Nicotine Alliance Australia, who noted that by the end of this century, approximately one billion people worldwide may die of smoking-related diseases and illnesses.[16] Dr Danko further noted the studies demonstrating the significantly lessened harm to users of ENDS when compared to tobacco cigarettes.[17] The risk of maintaining the status quo was therefore argued to far outweigh the risks associated with ENDS, particularly in light of the substantially greater risk posed by tobacco cigarettes.

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12 Professor Gerry Stimson, *Submission 141*, p. 2 (emphasis in original).

13 Professor Gerry Stimson, *Submission 141*, p. 2

14 Dr Paul Martin, *Submission 123*, p. 2 (emphasis in original).

15 Professor Riccardo Polosa, *Submission 92*, p. 2.

16 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 9.

17 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 9.

Arguments in favour of relaxing restrictions on the use of ENDS

2.13 The key arguments put forward by submitters advocating for a relaxation of restrictions on the use of ENDS was that the current regulatory framework: causes harm to individuals and society as a whole by denying individuals a product which can assist them to quit tobacco smoking; prohibits the use of a product which is less harmful than legal tobacco products; and unnecessarily penalises (and even criminalises) individuals for behaviour that should not be illegal.

Using ENDS to quit tobacco cigarette smoking

2.14 Various submitters and witnesses argued that ENDS should be legalised as they are a successful tool to assist individuals quit smoking cigarettes. A number of these individuals explained their struggles with quitting tobacco cigarette smoking and the impact of ENDS.[18] Dr Ewa Huebner described her experience in her submission:

> I smoked my first cigarette at the age of 15. Very soon it became a habit, which lasted for 48 years. I never really wanted to quit, my motivation to try "something else" was the change in social attitude to smokers and the rising cost of cigarettes. I first used a personal vaporiser in December 2011. From the first puff I never again had the urge to smoke. Quitting cigarettes required no strong will, and no fight with withdrawal symptoms. It was one of the greatest surprises of my life. I have never smoked a single cigarette since, nor do I have any desire or inclination to do so.[19]

2.15 Several witnesses at the public hearing told the committee that they had not successfully quit smoking using other nicotine replacement products or quitting aids, and that ENDS was their successful last resort.[20]

2.16 In contrast to this evidence, the Public Health Association of Australia (PHAA) noted in its submission that a recent World Health Organisation (WHO) report into ENDS was less clear on the question of whether the use of ENDS can assist people to quit smoking.[21] The WHO report referred to by the PHAA stated that trials comparing the effectiveness of ENDS and nicotine patches had shown 'similar, although low, efficacy for quitting smoking', and further:

> At this level of efficacy, the use of ENDS is likely to help some smokers to switch completely from cigarettes to ENDS. However, for a sizeable number of smokers ENDS use will result in the reduction of cigarette use rather than in quitting. This will lead to dual use of ENDS and cigarettes. Given the likely greater importance of duration of smoking (number of years smoking) over intensity (number of cigarettes smoked per day) in

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18 See, for example: Ms Christine May, *Submission 99*; Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, pp 1-2, Dr Ewa Huebner, *Submission 77*, p. 1.

19 Dr Ewa Huebner, *Submission 77*, p. 1.

20 Mrs Judith Wolters, *Committee Hansard*, 9 March 2016, pp 2-3; Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 7; Ms Donna Darvill, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 8.

21 Public Health Association of Australia, *Submission 172*, p. 10.

> generating negative health consequences, dual use will have much smaller beneficial effects on overall survival compared with quitting smoking completely.[22]

ENDS less harmful than tobacco cigarettes

2.17 Some submitters and witnesses contended that the current research evidence suggests ENDS are significantly less harmful to users than tobacco cigarettes.[23] Mr Clive Bates informed the committee that in the United Kingdom, Public Health England (PHE) has stated this view clearly in a review of the current research.[24] This 2015 review conducted by PHE found that:

> Acknowledging that the evidence base on overall and relative risks of [e-cigarettes] in comparison with smoking was still developing, experts recently identified them as having around [4 per cent] of the relative harm of cigarettes overall (including social harm) and [5 per cent] of the harm to users.[25]

2.18 The PHE review argued that reports ENDS were dangerous had been 'based on misinterpreted research findings' by the media and other outlets.[26] In reviewing the available evidence, it concluded that while vaping may not be 100 per cent safe, 'most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger'.[27]

2.19 Professor Gerry Stimson supported this argument, particularly emphasising the harms of tobacco cigarettes in comparison to ENDS. Professor Stimson stated:

> Smoking tobacco is the most harmful way of delivering nicotine. In excess of 4,000 chemicals are released, a number of which are carcinogenic, along with carbon monoxide… Providing safer ways of delivering nicotine via e-cigarettes and other alternative nicotine delivery systems enables people to continue using nicotine but to avoid the health risks of smoking.[28]

2.20 Submitters further noted that the technical design of ENDS creates less damage to the community at large by reducing or eliminating secondary smoke inhalation, which is produced by tobacco cigarettes. Dr Jim Lemon noted in his

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22 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 6, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016).

23 See, for example: New Nicotine Alliance Australia, *Submission 200*, [p. 2]; Mr Clive Bates, Director, Counterfactual, *Committee Hansard*, 9 March 2016, p. 18.

24 Mr Clive Bates, Director, Counterfactual, *Committee Hansard*, 9 March 2016, p. 18.

25 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, p. 7, https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update (accessed 15 March 2016).

26 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, p. 12.

27 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update p. 7.

28 Professor Gerry Stimson, *Committee Hansard*, 9 March 2016, p. 15.

submission that the vapour emitted from ENDS is 'physiologically inactive' and is not produced when the user is not inhaling, which substantially reduces risk of harm to those in the nearby environment.[29] Some submitters argued that the lack of toxic chemicals in the vapour were at odds with the current regulations restricting the places ENDS can be used in many jurisdictions, and that these restrictions are a breach of personal liberty.[30]

2.21 The WHO's 2014 report into ENDS claimed that the aerosol vapour exhaled by users can expose bystanders to nicotine and other harmful chemicals, although it conceded that the risk is lesser than second-hand smoke from tobacco cigarettes.[31]

2.22 The Australasian Association of Convenience Stores argued in its submission that by allowing ENDS to be sold in a retail setting, it would provide greater choice for consumers seeking to substitute cigarettes with a safer option.[32]

Illegal procurement of ENDS

2.23 The committee was provided with a number of personal stories from witnesses explaining that, under the current law, they were viewed as criminals due to their procurement (through a variety of means) of ENDS and associated equipment.[33] Some of these individuals had provided ENDS for people who did not know where to source them.[34]

2.24 Some witnesses told the committee that they were labelled as criminals because they had given up tobacco cigarette smoking the 'wrong way'.[35] When asked by the committee what the 'right way' was to quit, witnesses advised that smokers were generally directed to use substances such as nicotine replacement therapy, prescribed medication, and over-the-counter products such as gum, lozenges and patches.[36] All of these substances, it was noted, contain nicotine just as ENDS does,

29 Dr Jim Lemon, *Submission 84*, [p. 4].

30 Mr George Gad, *Submission 104*.

31 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, pp 4-5, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016) .

32 Australasian Association of Convenience Stores, *Submission 103*, p. 8.

33 See, for example: Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 1; Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 3, Ms Jennifer Stone, *Committee Hansard*, 9 March 2016, p. 5.

34 Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 3.

35 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 1; Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 3.

36 Ms Jennifer Stone, Mrs Judith Wolters and Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 5.

but the majority of these substances are not subjected to the same restrictions due to their approval by the Therapeutic Goods Administration.[37]

2.25 It was noted that at least two individuals have been prosecuted in Australia for offences relating to ENDS products, and that many users practice civil disobedience to use the devices, risking penalties from fines to a criminal record, in additional to social and personal consequences such as loss of employment and family breakdown due to official sanctions.[38]

Arguments in favour of the current prohibition on ENDS

2.26 Those who argued against changing the current prohibition on ENDS contended that the health risks posed by ENDS were too great in order to allow for widespread use in the Australian community. Furthermore, it was argued that relaxing restrictions on ENDS would substantially change the policy narrative that has been adopted for the past several decades in relation to tobacco cigarette smoking, and that allowing ENDS use would consequently allow tobacco to become socially acceptable once more.

Health risks of ENDS to the individual and the community

2.27 Concerns were raised by some submitters that increasing access to ENDS would lead to health risks for users.[39] The WHO's 2014 report stated that the majority of ENDS have not been independently tested, 'but the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions'.[40] It noted that the health risks posed by ENDS include:

- the variability of the ENDS' delivery of nicotine, depending on technical design, the method of usage, and the concentration of nicotine used in the solution;[41]
- the presence of nicotine, which was described as a 'tumour promotor' as opposed to a direct cause of cancer;

37 Ms Jennifer Stone, *Committee Hansard,* 9 March 2016, pp 5-6; Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard,* 9 March 2016, pp 5-6.

38 Ms Jennifer Stone, *Committee Hansard,* 9 March 2016, p. 6; Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard,* 9 March 2016, p. 6.

39 Public Health Association of Australia, *Submission 172*, p. 10; Australian Health Promotion Association, *Submission 91*, p. 2.

40 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 3 http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016).

41 This concern was also noted in PHE's 2015 report, which found after analysis of multiple brands of ENDS liquid nicotine that there was significant inaccuracies of nicotine content in the solutions as opposed to what was labelled on the product: Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, pp 67-68.

- exposure of nicotine to children, adolescents, pregnant women and women of reproductive age, which can potentially lead to 'long-term consequences for brain development'; and
- nicotine overdose or poisoning, usually by consuming or touching the liquid.[42]

2.28 Deaths due to nicotine poisoning have been a critical concern of the medical community when considering ENDS. The Royal Australasian College of Physicians noted that a dose of liquid nicotine between 6.5 and 13 milligrams per kilogram of body weight is potentially lethal to half of subjects exposed to the quantity.[43] In December 2014, an American toddler died after ingesting liquid nicotine commonly used in an ENDS, although it was unconfirmed whether the liquid was intended to be used for that purpose.[44] Other reports have suggested further cases of children suffering nicotine poisoning or illness after consuming nicotine liquid.[45]

2.29 The claim regarding nicotine's overall toxicity is disputed by the PHE report and some submitters to this inquiry, who suggested that it was extremely difficult to overdose as a result of consumption of nicotine. The PHE report argued that the toxicity of nicotine has been overstated. It stated that nicotine poisoning was limited to a certain level of toxicity due to the fact that even relatively small doses often result in nausea and vomiting, thus preventing users from continuing consumption.[46] Additionally, while suicides using liquid nicotine have been reported, the PHE report stated that it took an extremely high dosage (over 10,000mg of nicotine, compared to up to 360mg of nicotine per bottle of ENDS liquid nicotine) to result in death.[47]

2.30 However, the PHE recognised the risk of accidental poisoning for children, and recommended the use of 'childproof' packaging to ensure children could not accidentally consume the liquid.[48] As less than one teaspoon of liquid nicotine may

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42 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, pp 3-4.The WHO noted that data relating to these incidents is difficult to obtain, as many countries do not record such cases. However, it notes that there have been reports from the United States and the United Kingdom where nicotine overdose or poisoning has occurred.

43 Answers to questions on notice from a public hearing held in Sydney on 9 March 2016, received from the Royal Australasian College of Physicians on 29 March 2016, p. 1.

44 Anthony Rivas, 'E-Cig Liquid Nicotine Linked to 1-Year-Old's Death; Poison Control Centers Say FDA Should Move Forward With Regulations', *Medical Today*, 14 December 2014, http://www.medicaldaily.com/e-cig-liquid-nicotine-linked-1-year-olds-death-poison-control-centers-say-fda-should-314392 (accessed 17 March 2016).

45 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, p. 63 https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update (accessed 15 March 2016).

46 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, p. 63.

47 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, pp 63-64.

48 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, p. 63.

potentially be a lethal dose to a small child, some US jurisdictions have reportedly commenced implementing safety precautions on bottles of nicotine.[49]

Lack of evidence on long-term health risks

2.31 Submitters to the inquiry noted that as ENDS technology is relatively new, very little evidence exists on the long-term health impacts of ENDS use. A common thread running through submissions made by public health organisations was that ENDS should remain heavily regulated until more evidence becomes available. For example, the Australian Health Promotion Association (AHPA) stated:

> While the evidence is rapidly building, there are still many unknowns about E-cigarettes… [D]espite the vested "nanny-state" criticism, long-term evidence is crucial in formulating health promotion responses that protect everyone's right to enjoy a healthy and happy existence. As such, the overall long-term impact of E-cigarettes must be known before they are considered for legalisation (let alone regulation).[50]

2.32 Those supporting the use of ENDS argued strongly against this position. Several submitters argued that the lack of evidence on the long-term effects of ENDS should be weighed against the anticipated long-term effects of tobacco cigarette smoking. According to this contention, evidence already exists regarding the harm that will be caused due to tobacco cigarette smoking, which could be reduced or potentially eliminated by ENDS. Professor Stimson stated:

> I think the precautionary principle here simply does not work. When you apply the precautionary principle you are supposed to look at the consequences of both action and inaction. If you ban something that is much safer than the product that is the market norm and you do that saying, 'Well, we don't know how dangerous it is; we'd better ban it,' the danger is that you just leave people to smoke. It is a kind of reckless precaution: you think you are being responsible and cautious but by denying people an option to move to a product that is much lower risk—because you are not absolutely sure it is lower risk, or you are not paying attention to what we do know but concentrating on what we do not know—you might actually be putting people in greater danger.[51]

2.33 The risk of inaction was therefore strongly argued to outweigh the potential long-term health risks of using ENDS, meaning that smokers should be granted the choice to use ENDS.

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49 Answers to questions on notice from a public hearing held in Sydney on 09 March 2016, received from the Royal Australasian College of Physicians on 29 March 2016, p. 1; Anthony Rivas, 'E-Cig Liquid Nicotine Linked to 1-Year-Old's Death; Poison Control Centers Say FDA Should Move Forward With Regulations', *Medical Today*, 14 December 2014, http://www.medicaldaily.com/e-cig-liquid-nicotine-linked-1-year-olds-death-poison-control-centers-say-fda-should-314392 (accessed 17 March 2016).

50 Australian Health Promotion Association, *Submission 91*, p. 2. See also: Royal Australasian College of Physicians, *Submission 261*, p. 7.

51 Professor Gerry Stimson *Committee Hansard,* 9 March 2016, p. 19.

A 'gateway' product

2.34 Public health organisations argued that the deregulation of ENDS would allow the devices to operate as 'gateway' products, which would introduce users to tobacco cigarettes.[52] The AHPA argued in its submission that the introduction of ENDS may 'normalise' the act of smoking (regardless of whether a person smoked a tobacco cigarette or used an ENDS device), 'thus indirectly encouraging more tobacco smoking overall.'[53] However, the WHO's 2014 report noted that it was difficult to obtain data to validate this theory, and further stated that most ENDS users were either current or former tobacco cigarette smokers.[54]

2.35 The Royal Australasian College of Physicians expressed concern that ending the current ban on ENDS would result in young people taking up the use of these devices, which may in turn lead to experimentation with other forms of nicotine products such as tobacco cigarettes.[55] The WHO report also noted this point, recognising that there was a concern in the medical profession that it was possible that children may start using nicotine by using ENDS, which could then lead to a switch to tobacco cigarette smoking.[56]

2.36 It was further argued that the introduction of ENDS could 'renormalize' tobacco smoking, which would negate many decades' work to reduce it. The WHO report outlined this argument, which states that deregulation of ENDS could 'enhance the attractiveness of smoking itself and perpetuate the smoking epidemic'.[57]

2.37 Many submitters in favour of deregulation rejected the argument that the introduction of ENDS would result in a 'gateway' effect.[58] It was argued that there is evidence to suggest that the overwhelming majority of those who use ENDS are smokers or former-smokers.[59] Additionally, these studies also showed that the proportion of users who were not smokers previously was negligible, and had found no evidence as of yet of a 'gateway effect' taking place in deregulated jurisdictions.[60] Mr Michael Monteney made the point that this argument did not consider that it would offer a different gateway, namely that which would assist tobacco cigarette smokers to quit.[61]

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52 Australian Health Promotion Association, *Submission 91*;

53 Australian Health Promotion Association, *Submission 91*, p. 2.

54 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 6.

55 Royal Australasian College of Physicians, *Submission* 261, p. 7. See also: Australian Health Promotion Association, *Submission 91*, p. 2.

56 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 6.

57 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 7.

58 Mr Michael Monteney, *Submission 29*, pp. 2-3.

59 Professor Riccardo Polosa, *Submission 92*, p. 2.

60 Professor Riccardo Polosa, *Submission 92*, p. 2.

61 Mr Michael Monteney, *Submission 29*, p. 3.

Committee view

2.38 The question of how best to approach the regulation of electronic nicotine delivery systems (ENDS) is a complex one. There are undoubtedly positive benefits to be gained from the broader availability of these devices, particularly in relation to their use as a smoking cessation aid. However, the lack of data on the long-term health effects of ENDS use, as well as concerns about other possible consequences arising from the normalisation of these products highlighted by the WHO and others, mean that a degree of caution is still warranted.

2.39 The committee heard compelling first-hand evidence from individuals who had managed to quit smoking through the use of ENDS devices. It seems clear that for this cohort, the health risks associated with using ENDS devices are significantly lower than continuing to smoke tobacco cigarettes. As such, the committee has no in-principle concerns with ENDS products being made available in Australia for use as a smoking cessation aid, in the same way that other medical quitting aids are available. Ensuring that liquid nicotine and the ENDS devices themselves are available on a prescription-only basis could provide a measure of control over how these products are being used in the community.

2.40 This in-principle support is subject to the caveat that, unlike proven anti-smoking aids like nicotine patches, which have been rigorously assessed by Australia's Therapeutic Goods Administration (TGA) before being approved for use here, no similar assessment of e-cigarettes has been undertaken. The committee notes that any company that wishes to legally market e-cigarettes as an anti-smoking aid in Australia needs to follow the standard process and apply to the TGA with evidence of the safety and efficacy of their product to allow the TGA to consider the product. To date, no company has been prepared to take this step.

2.41 Given that some comparable international jurisdictions have taken a considerably more liberal approach to this issue, the Australian Government should continue to monitor the emerging international evidence around the safety, long-term health effects and efficacy of ENDS in order to appropriately adjust Australia's regulatory response in the future.

Senator Chris Ketter

Committee Chair