

The Senate

Community Affairs
Legislation Committee

Vaporised Nicotine Products Bill 2017

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45th Parliament

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Participating members for this inquiry

Senator David Leyonhjelm	New South Wales, LDP
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ABBREVIATIONS

ADA	Australian Dental Association
Airports Act	<i>Airports Act 1996</i>
AMA	Australian Medical Association
Bill	Vaporised Nicotine Products Bill 2017
Department	Department of Health
ENDS	Electronic Nicotine Delivery System
Health Committee	House of Representatives Standing Committee on Health, Aged Care and Sport
PHAA	Public Health Association Australia
PJCHR	Parliamentary Joint Committee on Human Rights
Poisons Standard	<i>Standard for the Uniform Scheduling of Medicines and Poisons</i>
TAP Act	<i>Tobacco Advertising Prohibition Act 1992</i>
TG Act	<i>Therapeutic Goods Act 1989</i>
TGA	Therapeutic Goods Administration

LIST OF RECOMMENDATIONS

Recommendation 1

2.57 The committee recommends that the Senate does not pass the Bill until further scientific evaluation of the efficacy and safety of e-cigarettes and related products has been undertaken.

Chapter 1

Introduction

Purpose of the Bill

1.1 The Vaporised Nicotine Products Bill 2017 (Bill) is a private senators' bill introduced by Senators Leyonhjelm and Roberts. The Bill seeks to exclude e-cigarettes from regulation by the Therapeutic Goods Administration (TGA) in order to legalise e-cigarettes in Australia.¹

1.2 **Schedule 1** amends three Acts to permit the importation, use and advertisement of e-cigarettes. The Bill amends:

- the *Therapeutic Goods Act 1989* (TG Act), to ensure that nicotine delivered via an electronic nicotine delivery system (ENDS) is subject to the same regulations as other nicotine products under the *Standard for the Uniform Scheduling of Medicines and Poisons*;
- the *Airports Act 1996* (Airports Act), is amended to permit e-cigarettes to be used in airports; and
- the *Tobacco Advertising Prohibition Act 1992* (TAP Act), is amended to permit ENDS products to be advertised by modifying the definition of 'smoking'.²

Background

1.3 The Senate Select Committee on Red Tape, chaired by Senator Leyonhjelm, has previously considered e-cigarettes in the context of its interim report into the effect of red tape on tobacco retail. The majority report noted the inability of some Australians to legally purchase nicotine products and recommended that Commonwealth, state and territory governments develop and implement an appropriate framework for alternative nicotine delivery systems.³

1.4 On 25 May 2017, the Minister for Health, Aged Care and Sport, The Hon Greg Hunt MP, referred an inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia to the House of Representatives Standing Committee on Health, Aged Care and Sport (Health Committee).

1.5 The Health Committee's inquiry will consider the use and marketing of e-cigarettes to assist people to quit smoking, in addition to the health impacts,

1 Explanatory Memorandum, p. 1.

2 Explanatory Memorandum, pp. 2-3.

3 Senate Select Committee on Red Tape, *Interim report into the effect of red tape on tobacco retail*, June 2017, pp. 23-24.

international approaches and appropriate regulatory framework for e-cigarettes and personal vaporisers.⁴

Legislative scrutiny

Scrutiny of Bills Committee

1.6 The Senate Scrutiny of Bills Committee considered the Bill in its *Scrutiny Digest 8 of 2017* and made no comment on the Bill.⁵

Parliamentary Joint Committee on Human Rights

1.7 The Parliamentary Joint Committee on Human Rights (PJCHR) considered that the Bill appeared to give rise to human rights concerns.

1.8 The PJCHR noted that the right to health, protected by article 12(1) of the International Covenant on Economic, Social and Cultural Rights, imposes obligations on Australia with respect to tobacco and other harmful substances. Regarding the risks posed by e-cigarettes, the committee stated that:

it is noted that it is unclear at this stage exactly what the health impacts of nicotine e-cigarettes are. However, it is well established that nicotine is a highly addictive drug, including one that may appeal to and be marketed to children.⁶

1.9 The PJCHR further noted that the Bill's statement of compatibility 'does not acknowledge that the right to health is engaged', and subsequently does not provide details regarding the compatibility of the measures with the right to health.⁷

1.10 The committee recommended that the human rights implications of the Bill be drawn to the attention of the legislation's proponents and the Parliament. It further noted that, subject to the Bill proceeding to further stages of debate, that the PJCHR may request further information from the proponents of the legislation.⁸

Conduct of the inquiry

1.11 The Bill was introduced to the Senate on 19 June 2017. The Senate Selection of Bills Committee referred the Bill to the committee for inquiry and report by 13 September 2017.⁹

4 Terms of Reference, Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, Standing Committee on Health, Aged Care and Sport, http://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Terms_of_Reference, (accessed 24 August 2017).

5 Senate Scrutiny of Bills Committee, *Scrutiny Digest 8 of 2017*, 9 August 2017, p. 42.

6 Parliamentary Joint Committee on Human Rights, *Report 7 of 2017*, 8 August 2017, pp. 34-35.

7 Parliamentary Joint Committee on Human Rights, *Report 7 of 2017*, 8 August 2017, p. 35.

8 Parliamentary Joint Committee on Human Rights, *Report 7 of 2017*, 8 August 2017, p. 35.

9 Senate Selection of Bills Committee, *Selection of Bills Report No 7 of 2017*, 22 June 2017, [p. 3]; *Journals of the Senate*, No. 48, 22 June 2017, pp. 1540–1542.

1.12 The committee advertised the inquiry on its website and wrote to relevant individuals and organisations inviting submissions by 4 August 2017. A list of submissions to the inquiry is available at Appendix 1. The committee decided not to hold a hearing as part of this inquiry.

1.13 The committee received a number of submissions expressing general support for the deregulation of e-cigarettes, including many accounts of personal experiences using e-cigarettes. The committee also received 2023 form letters similarly expressing general support for deregulation of e-cigarettes. An example of these letters is available on the committee website. These expressions of general support have been noted in the committee's consideration of the Bill.

1.14 The committee thanks those submitters who submitted to the inquiry.

Chapter 2

Issues

Introduction

2.1 Submissions to the inquiry generally focused on the merits of the Bill's proposal to remove e-cigarettes from regulation by the Therapeutic Goods Administration (TGA) and the proposed nicotine limit of 20mg/mL. Some submissions also considered the Bill's proposal to exempt e-cigarettes from the current ban on smoking in airports and advertising tobacco products.

Harm caused by e-cigarettes uncertain

2.2 A recurring theme throughout the submissions was that the debate regarding the risk posed by e-cigarettes remains unsettled. This was also highlighted by the Parliamentary Joint Committee on Human Rights (PJCHR) in its analysis of the Bill.¹

2.3 A number of submitters argued that e-cigarettes are less harmful than other forms of nicotine products.² British America Tobacco Australia cited a study funded by Cancer Research UK which supported this view:

...people who swapped smoking regular cigarettes for e-cigarettes or nicotine replacement therapy for at least six months had much lower levels of toxic and cancer causing substances in their body than people who continued to use conventional cigarettes.³

2.4 The Explanatory Memorandum for the Bill states that:

There is evidence to suggest that e-cigarettes are less harmful than cigarettes, and no evidence that e-cigarettes are more harmful than cigarettes.⁴

2.5 The Explanatory Memorandum notes that e-cigarettes have been found to assist as a smoking cessation method, and that 'no evidence' exists to demonstrate that smoking e-cigarettes encourages non-smokers to take up the habit.⁵ The committee also received a significant amount of anecdotal evidence from individuals who

1 Parliamentary Joint Committee on Human Rights, *Report 7 of 2017*, 8 August 2017, pp. 34-35.

2 See, for example: Dr Joe Kosterich, *Submission 11*, p. 2; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 24*, p. 6; Conjoint Associate Professor Colin Mendelsohn, *Submission 42*, pp. 4, 6, 10; Electronic Cigarettes Australia, *Submission 43*, p. 4; Philip Morris Limited, *Submission 64*, pp 5-6.

3 British American Tobacco Australia, *Submission 46*, p. 9.

4 Explanatory Memorandum, p. 1.

5 Explanatory Memorandum, p. 1.

claimed that e-cigarettes had assisted them to quit or reduce smoking conventional cigarettes.⁶

2.6 Conversely, the Australian Dental Association (ADA) pointed out that the Explanatory Memorandum does not provide details of the evidence it refers to. A review of research literature undertaken by the ADA found that further research must be conducted in order to clarify whether the use of e-cigarettes assists people to quit smoking and if it results in further health impacts.⁷

2.7 The Public Health Association Australia (PHAA) acknowledged the argument that e-cigarettes may form part of a harm reduction approach to smoking but considered that both this argument and the Bill were inconsistent with the Australian National Drug Strategy 2017-2026.⁸ The PHAA explained:

...the Australian National Drug Strategy 2017-2026¹ emphasises that to reduce harm a three pillared approach is necessary: supply reduction, demand reduction and harm reduction. The proposed legislation ignores this strategy. Rather than reducing harm, it would facilitate both an increase in supply and an increase in demand and, by doing so, increase harm.⁹

2.8 The Department of Health (department) expressed similar concerns regarding the statements made in the Explanatory Memorandum and the potential harm posed by e-cigarettes. The department noted that there was limited evidence available regarding e-cigarettes' safety and efficacy for smoking cessation or harm reduction.¹⁰

2.9 The department further noted that claims made by stakeholders regarding the safety of e-cigarettes have been contradicted by studies in multiple international medical journals and by experts in the field. Additionally, the department noted these claims are inconsistent with the positions of public health bodies such as the World Health Organisation, US Centres for Disease Control and the European Commission.¹¹ Based on these studies and guidelines, the department stated that 'the relative safety of e-cigarettes compared to tobacco smoking cannot be scientifically established'.¹²

2.10 The department advised the committee in its submission that it has adopted a precautionary approach to e-cigarettes and related products, and continues to monitor

6 See, for example: Name withheld, *Submission 8*; Name withheld, *Submission 16*; Name withheld, *Submission 21*; Name withheld, *Submission 23*; Name withheld, *Submission 26*; Name withheld, *Submission 27*; Name withheld, *Submission 31*.

7 Australian Dental Association, *Submission 56*, p. 2.

8 Public Health Association Australia, *Submission 54*, p. 4.

9 Public Health Association Australia, *Submission 54*, p. 4.

10 Department of Health, *Submission 50*, p. 4.

11 Department of Health, *Submission 50*, p. 5.

12 Department of Health, *Submission 50*, p. 5.

the regulatory framework of these items in the context of scientific evidence of their safety and efficacy as smoking cessation aids.¹³

Proposed amendments to the *Therapeutic Goods Act 1989*

Exclusion of e-cigarettes from regulation by Therapeutic Goods Administration

2.11 The Bill seeks to amend the *Therapeutic Goods Act 1989* (TG Act) to provide that nicotine in electronic nicotine delivery systems and nicotine in tobacco prepared and packaged for heating is excluded from the *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard) in the same way it excludes nicotine in tobacco prepared and packed for smoking conventional cigarettes.¹⁴

2.12 The Explanatory Memorandum states that the effect of the Bill is to exclude e-cigarettes and related products from regulation by the TGA. It notes that this exclusion will make the treatment of e-cigarettes consistent with the existing exclusion of conventional cigarettes from regulation by the TGA.¹⁵ The department noted that, having searched the minutes of the relevant decision-making bodies, the reasoning why nicotine in tobacco was excluded from regulation under the Poisons Standard is undocumented. However, it is likely the decision was made before there was consensus regarding the risks posed by smoking tobacco.¹⁶

2.13 Submitters argued that the current classification of products using vaporised nicotine as a Schedule 7 product under the Poisons Standard appeared to be inconsistent when compared to similar ingestible products that contained nicotine, such as nicotine chewing gum which can be easily purchased in Australia.¹⁷

2.14 Conversely, the department explained that if e-cigarettes are to be considered a smoking cessation method, as many submitters to this inquiry claimed, excluding them from regulation by the TGA would make their regulation inconsistent with other smoking cessation products such as gum, sprays, patches and lozenges which are subject to TGA pre-market assessment and approval.¹⁸

2.15 The department noted in its submission that the proposed amendments to the TG Act would result in nicotine in e-cigarettes being unscheduled. Consequentially, this would result in the TGA being unable to evaluate any nicotine-containing e-cigarette as a therapeutic good.¹⁹ The department further stated that:

13 Department of Health, *Submission 50*, p. 7.

14 Explanatory Memorandum, p. 2.

15 Explanatory Memorandum, p. 1.

16 Department of Health, *Submission 50*, pp. 14-15.

17 Dr David Outridge, *Submission 14*, p. 2.

18 Department of Health, *Submission 50*, p. 3.

19 Department of Health, *Submission 50*, p. 16.

This would also prevent TGA examining any substance contained in an e-cigarette. This would potentially include harmful substances added to the e-cigarette other than nicotine...²⁰

2.16 The department noted that the proposed amendment 'undermines the integrity of the scheduling system' by seeking to schedule a product as opposed to a substance.²¹ It further stated that the proposed amendments were in conflict with the objects of the TG Act, which focus on 'providing a system of controls relating to the quality, safety and efficacy of therapeutic goods used in Australia'.²²

2.17 In addition, the department stated that the proposed amendment would override the safety considerations in section 52E of the TG Act that the Secretary must take into account when amending or replacing the Poisons Standard. The effect of the amendment is that in the future, the Secretary would not be able to take into account new evidence in relation to the safety or effectiveness of e-cigarettes as the amendment requires that nicotine in tobacco prepared for smoking, and nicotine for e-cigarettes, be treated in the same manner.²³

Sale of e-cigarettes in Australia

2.18 The Bill proposes to make the sale of e-cigarettes with two per cent nicotine or less lawful under Commonwealth law. The Explanatory Memorandum states that the proposed amendments made to the TG Act will 'remove a Commonwealth barrier to the sale of e-cigarettes in Australia'.²⁴

2.19 Many submitters were supportive of the intention of the proposed amendments, particularly those operating tobacco-related businesses and current users of e-cigarettes.²⁵ However, some submitters noted that the Bill's interaction with state and territory laws would remain an issue.²⁶

2.20 The department stated in its submission that state and territory legislation regulating the sale of all tobacco products (including e-cigarettes) would 'undermine the potential achievement of this goal', noting that all states and territories outlaw the sale of nicotine for use in e-cigarettes.²⁷

20 Department of Health, *Submission 50*, p. 16.

21 Department of Health, *Submission 50*, p. 17.

22 Department of Health, *Submission 50*, p. 17.

23 Department of Health, *Submission 50*, p. 17.

24 Explanatory Memorandum, p. 1.

25 See, for example: Cignall Specialist Tobacconist Hervey Bay, *Submission 5*; Electronic Cigarettes Australia, *Submission 43*; Australian Vaping Advocacy, Trade and Research Incorporated, *Submission 48*; Vapora, *Submission 53*; New Nicotine Alliance, *Submission 55*.

26 See, for example: Mr Terry Barnes, *Submission 19*, p. 6; British American Tobacco Australia, *Submission 46*, p. 3; The Eros Association, *Submission 47*.

27 Department of Health, *Submission 50*, p. 15.

2.21 The Government of South Australia submitted that the Bill was inconsistent with the approach taken by the government in their state and other jurisdictions and that the Government of South Australia had adopted a 'precautionary approach' which aimed to prevent the uptake of smoking e-cigarettes by young people and minimise the exposure of bystanders to e-cigarettes vapour.²⁸

2.22 The Queensland Department of Health also noted that the Bill is inconsistent with Queensland's legislative approach for the sale, supply and promotion of smoking products which treats e-cigarettes the same as conventional cigarettes.²⁹ The Queensland Department of Health acknowledged that while further research is needed, early evidence suggests that e-cigarettes present a significant health risk to users and bystanders and expressed support to maintain regulatory control of nicotine in order to protect public health.³⁰

2.23 The Western Australian Government raised similar concerns, noting that it is illegal to sell electronic cigarettes containing nicotine in Western Australia and other jurisdictions.³¹ In particular, the Western Australian Government was concerned that if e-cigarettes were removed from regulation by the TGA, that there would be no alternative standards or regulatory schemes which would provide appropriate standards for formulation, packaging, labelling or quality of the products.³²

2.24 The department informed the committee that the Explanatory Memorandum's claim that it is currently legal for Australians to import e-cigarettes for personal use was misleading. The department submitted that:

Importation of nicotine containing e-cigarettes into Australia is only permitted with a valid Australian's doctor's prescription. They cannot be freely imported.³³

2.25 The department clarified that the importation of nicotine-containing e-cigarettes for personal therapeutic use by prescription is exempt from TGA registration requirements only where specific conditions are met.³⁴ The department confirmed that the importation or possession of nicotine-containing electronic cigarettes for recreational use is not covered by the TGA personal importation scheme and such importation would be in breach of state and territory laws.³⁵

28 Government of South Australia, *Submission 58*, p. 2.

29 Department of Health, Queensland Government, *Submission 59*, p. 5.

30 Department of Health, Queensland Government, *Submission 59*, pp. 3, 5.

31 Government of Western Australia, *Submission 62*, p. 2.

32 Government of Western Australia, *Submission 62*, p. 4.

33 Department of Health, *Submission 50*, p. 15.

34 Department of Health, *Submission 50*, pp. 15-16.

35 Department of Health, *Submission 50*, p. 16.

Nicotine content limit

2.26 The Bill proposes to amend the TG Act in order to exempt nicotine in electronic nicotine delivery systems up to a concentration of 20 mg/mL from regulation by the TGA. The Explanatory Memorandum notes that the 20 mg/mL concentration limit corresponds with Directive 2014/40/EU of the European Parliament and Council which allows nicotine-containing liquids where the concentration does not exceed 20 mg/mL.³⁶

2.27 It was indicated in submissions that the proposed limit of 20 mg/mL of nicotine in e-cigarettes was too low for those with long-term nicotine addictions.³⁷ One submitter suggested that the nicotine content limit should be dependent on the product's purpose, for example, 30mg/mL for bottled e-liquid, 60mg/mL for e-liquid in sealed units and 100 mg/mL for entities which supply e-liquid.³⁸

2.28 However, others expressed concern at higher doses of nicotine which could cause harm when used by inexperienced e-cigarette smokers.³⁹ It was also noted that exposure to liquid nicotine in children can be highly toxic and in some cases fatal.⁴⁰

2.29 The Australian Medical Association (AMA) submitted that the Bill failed to recognise that nicotine is widely regarded as a dangerous poison and that this posed a particular risk to children.⁴¹ The AMA outlined the risks associated with nicotine:

Nicotine poisoning can occur through ingestion, and also via inhalation. Nicotine containing solutions that are used in e-cigarettes pose a very real poisoning risk to small children. Sales of e-cigarettes in the United States have been complemented by a substantial increase in the incidence of nicotine poisoning according to reports from the Centre for Disease Control. Nicotine containing solutions are undoubtedly appealing to young children; they are commonly fruit or confectionary flavoured, and are presented in colourful containers that are not required to be childproof.⁴²

2.30 A proposed solution from one submitter suggested that the nicotine concentration not be prescribed in the Act. Limits would instead be placed in regulations for the relevant Minister to decide, taking into consideration expert

36 Explanatory Memorandum, p. 2.

37 See, for example: Name withheld, *Submission 7*, p. 2; Name withheld, *Submission 8*, pp 1-2; Australian Vaping Advocacy, Trade and Research Incorporated, *Submission 48*, p. 2, Name withheld, *Submission 16*, p. 1; Name withheld, *Submission 21*, p. 3, Name withheld, *Submission 25*, pp. 1-2; Mr Clive Bates, *Submission 65*, pp. 7-8.

38 Name withheld, *Submission 12*, p. 1.

39 Name withheld, *Submission 10*, p. 1.

40 Dr David Outridge, *Submission 14*, p. 1.

41 Australian Medical Association, *Submission 57*, p. 3.

42 Australian Medical Association, *Submission 57*, p. 3.

scientific advice and international best practice standards regarding the appropriate level of concentration.⁴³

Proposed amendments to the *Airports Act 1996*

2.31 At present, the *Airports Act 1996* (Airports Act) states that the regulations may make provisions for and in relation to smoking in airports.⁴⁴ The proposed amendments seek to clarify the status of e-cigarettes as exempt from the application of the Airports Act.⁴⁵

2.32 The Australian Drug Law Reform Foundation noted that using an e-cigarette to vaporise liquid was a different process to burning organic material such as tobacco in conventional cigarettes and that the legislation relating to airports should acknowledge this difference.⁴⁶ Aotearoa Vape Community Advocacy supported this view and submitted that disallowing vaping in any public place, including airports, should be a decision of individual companies and organisations.⁴⁷

2.33 Another submitter noted that the Bill could also be broadened to allow the Minister for Transport to make regulations under the *Civil Aviation Act 1988* in order to enable airline operators to have the discretion to allow e-cigarettes or related products on board Australian passenger aircrafts in specific circumstances.⁴⁸

2.34 The department stated that the proposed amendments to the Airports Act had the effect of limiting the Commonwealth's ability to protect people from exposure to tobacco smoke in federally-leased airports. However, the department also noted that the amendments may have limited practical effect as 'in the absence of Commonwealth laws relating to the use of e-cigarettes at federally-leased airports, state or territory laws will apply.'⁴⁹ As noted previously, all states and territories have laws restricting the use and sale of e-cigarettes.

2.35 Additionally, the department noted that the amendments conflict with Australia's obligations under Article 8 of the World Health Organization Framework Convention on Tobacco Control. The department stated that Article 8 required that parties adopt and implement:

effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places.⁵⁰

43 Mr Terry Barnes, *Submission 19*, p. 4.

44 *Airports Act 1996* (Cth) s. 174.

45 Explanatory Memorandum, p. 2.

46 Australian Drug Law Reform Foundation, *Submission 15*, p. 2.

47 Aotearoa Vape Community Advocacy, *Submission 13*, p. 2.

48 Mr Terry Barnes, *Submission 19*, p. 5.

49 Department of Health, *Submission 50*, pp. 13-14; *Airports Act 1996*, s. 177.

50 Department of Health, *Submission 50*, p. 13.

Proposed amendments to the *Tobacco Advertising Prohibition Act 1992*

2.36 It is currently unclear whether e-cigarettes fall within the definition of 'smoking a tobacco product' under the *Tobacco Advertising Prohibition Act 1992* (TAP Act).⁵¹ The Bill proposes to amend the TAP Act to change the definition to 'smoking a tobacco product using a combustion process' in order to clarify that e-cigarettes do not fall within the definition of smoking.

2.37 Some submitters to the inquiry were supportive of the proposed amendment to the TAP Act which would allow the advertising of e-cigarettes.⁵² Electronic Cigarettes Australia noted that the proposed amendment would enable the advertising of the benefits of e-cigarettes which may assist in reducing rates of traditional cigarette smoking.⁵³

2.38 Another submitted argued that the definition should be amended further to ensure it also excluded smokeless products such as the Swedish tobacco product 'snus' and emerging heat-not-burn tobacco products.⁵⁴

2.39 The department stated that the proposed amendments to the TAP Act would be damaging to the Australian community and be in conflict with the Australian Government's efforts in tobacco control. The department explained this position with reference to Item 4 of the Bill, which provides that prohibitions on advertising and promotion of smoking do not apply to e-cigarettes or related products. The department stated that this proposed amendment could have the unintended consequence of re-normalising smoking behaviour among the Australian population, in particular young people and children.⁵⁵ It stated:

This would directly conflict with the objects of the TAPA Act [*Tobacco Advertising Prohibition Act 1992*] and undermine the public health benefits which have been achieved through several Commonwealth, state and territory tobacco control measures and laws.⁵⁶

2.40 The department noted that e-cigarettes and related products may not be encapsulated by the TAP Act, as it contains no tobacco and thus may not be considered a 'tobacco product' for the purposes of the Act. However, it noted that the physical appearance and action of using an e-cigarette resembles a traditional cigarette, and may re-normalise smoking in young people.⁵⁷

51 Department of Health, *Submission 50*, p. 18.

52 See, for example: Electronic Cigarettes Australia, *Submission 43*; British American Tobacco Australia, *Submission 46*; Australian Taxpayers Alliance, *Submission 49*; End Smoking NZ, *Submission 52*; Mr Clive Bates, *Submission 65*.

53 Electronic Cigarettes Australia, *Submission 43*, p. 2.

54 Mr Terry Barnes, *Submission 19*, p. 5.

55 Department of Health, *Submission 50*, p. 18.

56 Department of Health, *Submission 50*, p. 18.

57 Department of Health, *Submission 50*, p. 18.

2.41 A submitter argued that the proposed amendment to the TAP Act was insufficient to effectively permit the advertising of e-cigarettes and related products. Mr Terry Barnes stated that the TAP Act was an 'inappropriate place' to regulate the advertising of e-cigarettes.⁵⁸ Mr Barnes further stated that, were the TAP Act to be amended to exclude e-cigarettes and related products from the Act's application, a system of regulation to monitor the marketing and advertising would need to be established.⁵⁹

Committee view

Evidentiary basis of the Bill

2.42 The committee recognises that this Bill is attempting to assist smokers in accessing e-cigarettes as an alternative to combustible cigarettes. The Explanatory Memorandum cites the importance of reducing smokers' reliance on combustible cigarettes and encouraging alternative means of reducing their addiction.⁶⁰ To this end, the committee supports the good intentions underpinning this Bill as far as they extend to promoting the reduction or cessation of smoking.

2.43 However, the committee holds serious concerns regarding the evidentiary basis supporting the Bill, particularly in relation to the safety of e-cigarettes. The committee notes the issues raised by the department and the PJCHR regarding the uncertain state of evidence about the safety and efficacy of e-cigarettes and related products as smoking cessation devices. The committee notes it is not clear what the long-term effects of e-cigarettes are or the level of risk posed by the products to consumers or public health.

2.44 The committee supports the Australian Government's current harm reduction approach, and supports the department's undertaking to monitor the situation closely and review the tobacco control framework as needed while ensuring consistency with Australia's international obligations.

2.45 The committee notes the general support of the deregulation of e-cigarettes expressed by submitters. It recognises that e-cigarettes and related products have assisted some people in addressing their nicotine addiction. However, the committee believes that it is critical that legislation supporting this path be supported by a strong evidentiary basis.

Proposed amendments to the TG Act

2.46 The committee accepts the department's statement that the proposed amendment would have little practical effect due to the application of relevant state and territory laws which would continue to prevent the sale of nicotine for e-cigarettes.

58 Mr Terry Barnes, *Submission 19*, p. 6.

59 Mr Terry Barnes, *Submission 19*, p. 6.

60 Explanatory Memorandum, p. 1.

2.47 The committee notes the significant concerns raised by the department and the PJCHR regarding the potential breach of Australia's obligations under international treaties and agreements. Given the long-standing work that has been conducted by Australian governments over recent decades in relation to tobacco control, changes to the regulatory system are not to be taken lightly or without consideration of the full scope of evidence available.

2.48 The committee concurs with the view expressed by the PJCHR that the Bill requires additional evidence supporting the safety of e-cigarettes if the Bill were to progress further in the legislative process. However, as the committee notes above, the uncertain state of the evidentiary basis for these claims does not commend the Bill to the committee.

2.49 The committee is particularly concerned by the department's advice that the proposed amendments would result in nicotine packaged for e-cigarettes being unscheduled, meaning that the TGA could not evaluate any nicotine-containing e-cigarettes for their quality, safety and efficacy as a therapeutic good. The committee believes that the TGA should maintain its ability to evaluate the quality, safety and efficacy of e-cigarettes.

2.50 Given the lack of a strong evidentiary basis surrounding e-cigarettes, the committee supports the department's precautionary approach, which is based on the need to consider the overall impact that e-cigarettes may have on population health, including smokers and non-smokers.

Proposed amendments to the Airports Act

2.51 The committee notes the view that this Bill seeks to address the lack of clarity as to whether e-cigarettes fall within the scope of the Airports Act. The Bill would provide that e-cigarettes are exempt from the Airports Act.

2.52 The committee accepts the explanation provided by the department that international obligations prevent the insertion of this clause. The committee further accepts the department's statement that the proposed amendment would have limited practical effect due to the application of relevant state and territory laws which would continue to regulate the use of e-cigarettes in federally-leased airports.

Proposed amendments to the TAP Act

2.53 The committee holds significant concerns regarding the proposed advertising of e-cigarettes which may lead to the re-normalisation of smoking in Australia and undermine Australia's previous efforts to reduce smoking.

2.54 The committee shares the department's concern that young people are likely to be susceptible to the advertising techniques and new technology associated with e-cigarettes which glamorise and promotes smoking to young people. The committee is particularly concerned given the lack of evidence examining the long term health impacts of e-cigarettes.

House of Representatives Standing Committee on Health, Aged Care and Sports inquiry

2.55 The committee notes that the House of Representatives Standing Committee on Health, Aged Care and Sport (Health Committee) is conducting an inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia. The Health Committee has included in its terms of reference to consider, among other matters, 'the appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia'.⁶¹

2.56 The committee anticipates that the Health Committee's inquiry may assist in identifying an appropriate framework for the regulation of e-cigarettes. The committee considers that any decisions regarding the regulatory framework for e-cigarettes should take into account the findings of that inquiry.

Recommendation 1

2.57 The committee recommends that the Senate does not pass the Bill until further scientific evaluation of the efficacy and safety of e-cigarettes and related products has been undertaken.

Senator Slade Brockman

Chair

61 Terms of Reference, Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, Standing Committee on Health, Aged Care and Sport, http://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Terms_of_Reference, (accessed 24 August 2017).

Australian Labor Party Senators' Additional Comments

1.1 Labor Senators note that the Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC) have reviewed the evidence around e-cigarettes in recent months, and recommended against changes to their regulation.

1.2 Labor Senators are alarmed that both Senator Leyonhjelm (via this bill) and the Minister for Health (via the House Health Committee) are attempting to subvert these recommendations. 15,000 Australians a year still die from smoking-related disease, and anything that reduces tobacco regulation or re-normalises smoking would add to this tragic toll.

1.3 Labor will continue to follow the advice of the independent experts at the TGA and NHMRC on this issue.

Senator the Hon Lisa Singh

Senator Murray Watt

Liberal Democratic Party Dissenting Report

1.1 Reducing smoking saves lives.

1.2 Notwithstanding plain packaging and the highest rates of tobacco taxation in the world, and contrary to the long term trend of declining smoking rates in Australia over previous decades, the rate of smoking in Australia has plateaued.

1.3 In contrast, the rate of smoking continues to decline in other countries, the UK and USA included, where plain packaging and such high taxation are not found.

1.4 The key difference between these countries and Australia is the availability of nicotine alternatives, in particular e-cigarettes.

1.5 While e-cigarettes are a relatively recent innovation, the effect on smoking rates of an acceptable nicotine alternative can be seen in Sweden, where the rate is just 5% (compared to 14% in Australia). This is attributed to the longstanding availability of snus, a form of powdered tobacco from which nicotine is absorbed orally.

1.6 Australia's prohibition policy towards e-cigarettes prevents Australian smokers from accessing a means of quitting smoking which is proving effective in other countries.

1.7 Anecdotal evidence from Australians who are privately importing e-cigarettes and liquid nicotine indicates the same success would be seen in Australia if they were widely available.

1.8 Private imports are denying Australian retailers an opportunity to generate sales, and the Australia government an opportunity to collect tax revenue.

1.9 New Zealand has recently decided to legalise the sale of e-cigarettes. Australia's continuation of a prohibition policy will be impossible to enforce.

1.10 The prohibition policy is costing lives; lives would be saved if e-cigarettes were widely available.

Recommendation 1

1.11 The Bill should be passed.

Senator David Leyonhjelm

APPENDIX 1

Submissions and additional information received by the Committee

Submissions

- 1** Name Withheld
- 2** Name Withheld
- 3** Name Withheld
- 4** Name Withheld
- 5** Cignall Specialist Tobacconist Hervey Bay
- 6** Name Withheld
- 7** Name Withheld
- 8** Name Withheld
- 9** Name Withheld
- 10** Name Withheld
- 11** Dr Joe Kosterich
- 12** Name Withheld
- 13** Aotearoa Vape Community Advocacy
- 14** Dr David Outridge
- 15** Australian Drug Law Reform Foundation
- 16** Name Withheld
- 17** Associate Professor Renee Bittoun
- 18** Fact Asia Consultants Ltd

- 19 Mr Terry Barnes
- 20 Name Withheld
- 21 Name Withheld
- 22 Name Withheld
- 23 Name Withheld
- 24 Professor Wayne Hall and Associate Professor Coral Gartner
- 25 Name Withheld
- 26 Name Withheld
- 27 Name Withheld
- 28 Name Withheld (plus an attachment)
- 29 Professor Neal Benowitz
- 30 Name Withheld
- 31 Name Withheld
- 32 Name Withheld
- 33 Emeritus Professor Ian Webster AO
- 34 Ms Jeannie Cameron
- 35 Name Withheld
- 36 Mr Joel Nitzkin
- 37 Name Withheld
- 38 Name Withheld
- 39 Professor Richard Day
- 40 Professor Riccardo Polosa

-
- 41 Dr Stephen Elsom
- 42 Conjoint Associate Professor Colin Mendelsohn
- 43 Electronic Cigarettes Australia
- 44 Name Withheld
- 45 Dr Michael Lowy
- 46 British American Tobacco Australia
- 47 The Eros Association
- 48 Australian Vaping Advocacy, Trade and Research Incorporated
- 49 Australian Taxpayers' Alliance
- 50 Department of Health
- 51 Pfizer Australia
- 52 End Smoking NZ
- 53 Vapora
- 54 Public Health Association Australia
- 55 New Nicotine Alliance
- 56 Australian Dental Association
- 57 Australian Medical Association
- 58 Government of South Australia (plus an attachment)
- 59 Department of Health, Queensland Government
- 60 Consumer Advocates for Smoke-Free Alternatives Association
- 61 Name Withheld
- 62 Government of Western Australia

- 63** The Royal Australian and New Zealand College of Psychiatrists
- 64** Philip Morris Limited (plus four attachments)
- 65** Mr Clive Bates
- 66** Dr Catherine Silsbury
- 67** Name Withheld

Additional Information

- 1** Nicotine without smoke, Tobacco harm reduction, A report by the Tobacco Advisory Group of the Royal College of Physicians, April 2016, from Royal College of Physicians, received 2 August 2017

Form Letters

- 1** The committee received correspondence from 2023 individuals in relation to this inquiry.