Doing Nothing Is Not An Option

Supplementary Submission to

The Standing Committee on Health, Aged Care and Sport inquiry into the use and marketing of electronic cigarettes (E-cigarettes) and personal vaporisers in Australia

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The author has no commercial or other interest in any electronic cigarette or tobacco company.

Inquiry submissions

Professional submissions

The following table summarises the 100 submissions to the inquiry that are from professionals working in the areas of tobacco and e-cigarettes.

In the table below:

(a) Type: *Evidence* are submissions that refer to a significant number of publications in professional journals. *Other* are submissions that rely on less evidence (the distinction was made fairly arbitrarily). *E + O* is the total of the *Evidence* and *Other* submissions. And *Australian* are submissions by Australian medical and health authorities (such as the AMA and the NHMRC) and Australian government health departments.

(b) Response: *Pro* are submissions that advocate for the largely unrestricted advertising and sale of e-cigarettes (with or without nicotine), and so would require the Federal Government to legislate to this purpose. *Anti* are submissions that request a total ban on all e-cigarettes, again requiring the Federal Government to legislate. And *Restrict* are submissions that advocate for a limited sale subject to strict conditions.

	Evidence	*Other*	*E + O*	*Australian*
Pro	31 (77.5%)	35 (83.3%)	66 (80.5%)	2 (11.1%)
Anti	0 (0.0%)	2 (4.8%)	2 (2.4%)	3 (16.7%)
Restrict	9 (22.5%)	5 (11.9%)	14 (17.1%)	13 (72.2%)
Anti + Restrict	9 (22.5%)	7 (16.7%)	16 (19.5%)	16 (88.9%)

(In addition, there were 1,695 form-letter submissions supporting the legalization of e-cigarettes with nicotine. I assume these are the submissions prompted by an email circular from a tobacco company and, as they do not provide substantive arguments, I have ignored them.)

Most of the *Restrict* category of submissions are effectively total bans and the *Anti* and *Restrict* categories can be merged. This is because the majority of the *Restrict* submissions advocate for e-cigarettes to be limited to those approved by the TGA as therapeutic goods. However:

(a) *Every single good* (and every modification of a good) has to receive a separate approval from the TGA.[1]

Submitting goods to be approved is a long, costly process and, although I do not have information for the TGA, the estimated costs for US FDA approval are between $200,000 and $2 million for each item.[2] Such costs restrict approvals to goods manufactured by large international companies for large markets. It is very unlikely that an e-cigarette or liquid manufacturer would bother.

(b) Although e-cigarette liquid containing nicotine could be regarded as a therapeutic good, it is unlikely that this classification could be applied to e-cigarette liquid that does not contain nicotine. More importantly, the hardware of an e-cigarette (battery holder, battery, electronics, liquid tank, heating coils and wicks, etc.) is in no sense a therapeutic good and probably would never be approved by the TGA.[3]

1 For example, https://tga-search.clients.funnelback.com/s/search.html?query=nicotine&collection=tga-artg listing 116 nicotine replacement therapies, and https://tga-search.clients.funnelback.com/s/search.html?query=vitamin&collection=tga-artg listing 684 separate authorisations for vitamins.

2 Inquiry submission 321, page 11

3 The TGA does approve "hardware", such as inhalers, but these are specifically designed for use with a specific therapeutic good. In contrast, e-cigarette hardware can be used for non-therapeutic purposes.

(c) On the basis of the reasons that the TGA gave for rejecting an application to exclude e-cigarette liquid from the poisons schedule,[4] it seems very unlikely that the TGA would approve any application.

The two submissions that support e-cigarette use are:

(a) The Royal Australian and New Zealand College of Psychiatrists:[5] This group's concern stems from the fact that about 70% of schizophrenic and 61% of bipolar people smoke, catastrophically high compared with the national average. It is also clear that addiction to smoking involves more than just addiction to nicotine, and it appears that this psychological addiction has not been studied properly.

(b) Australian Drug Law Reform Foundation (Inquiry submission 317): Not surprisingly, this group advocates allowing e-cigarettes containing nicotine to be freely available as a consumer good, in line with its other harm reduction policies.

Anecdotal submissions

As of 10 August there have been 333 submissions, of which 9 are confidential and 1 is irrelevant (about hearing). Of the remaining 323 submissions:

(a) 221 submissions provide anecdotal evidence that e-cigarettes are being used successfully to quit tobacco smoking. As some submissions refer to multiple people, particularly because of the influence submitters had on smokers around them, the number of successful quits is much greater than 221.

(b) At least 179 submissions (81.0%) state that quitting is total and there is no parallel use of both e-cigarettes and tobacco cigarettes.

(c) 152 submissions definitely (68.8%), and 42 submissions possibly (19.0%), state that e-cigarettes were used successfully after attempts to quit using other methods failed. The most prominent other method was nicotine replacement therapy (NRT, patches etc), but several also failed to quit using drugs that often had unacceptable side-effects.

(d) At least 41 submissions (18.6%) cited sourcing e-liquid with nicotine as a major problem.

In addition, there were 2 form-letter submissions from people who had quit tobacco smoking successfully that are not included in the above.

Open Warfare?

Science or opinion?

My education was in science and mathematics, including statistics. And over the years I developed the idea that medicine and public health were based on these disciplines. But apparently I am wrong.

How can the submissions to this inquiry be explained? In particular, about 89% of *Australian* (professional and government) submissions want e-cigarettes to be banned, but about 81% of the other submissions want them legalised. Why? Surely if both groups rely on the same scientific and statistical evidence they should come to similar conclusions?

4 Inquiry submission 220, page 20, and https://www.tga.gov.au/sites/default/files/scheduling-delegates-final-decisions-23-march-2017.pdf

5 Inquiry submission 294

More importantly, how can this committee make recommendations to government?

You can agree with *Australian* authorities and impose a de facto ban on e-cigarettes, even though this goes against science. Or you can agree with the international research and regulate e-cigarettes as consumer goods, even though this will invoke the ire of the Australian authorities. Or you can do nothing and allow the "dog's breakfast" of state and territory laws to continue.

Two inquiry submissions suggest that the difference between *Australian* authorities and the rest of the submissions is due to personal interests rather than science:

> *The Committee needs to be aware of the influence wielded by a very small group of determined Australian public health professionals on the issue of e-cigarettes. The views of this determined group are out-of-step with public health colleagues in Australia and elsewhere in the world. The divergence of opinion between so called "Australian tobacco experts", and international tobacco experts has led to an extraordinarily aggressive, sometimes abusive level of dialogue and correspondence on issues around e-cigarettes. ... This abusive discourse indicates that the differences of opinion are related to matters other than the scientific evidence, which is usually discussed in more dispassionate terms.*[6]
>
> *Someone is right and someone is wrong. Why should the Australian medical and health establishment be right, and similarly competent international organisations be wrong?*[7]
>
> *... I have never been involved with an issue that has generated such personal vitriol, anger, ad hominem attacks and complete disrespect for professional integrity and reputations as e-cigarettes and vaping.*[8]
>
> *In comparison to the UK and the EU, the prevailing approach of the Australian public health establishment, and Commonwealth, state and territory officials is to:*
>
> *• Treat ENDS with suspicion and outright hostility as an apparent threat to progress made in reducing smoking rates over recent decades.*
>
> *• With some exceptions, adopting a "ban first and ask questions later" regulatory philosophy.*[9]

The last point provides a more useful view of the *Australian* submissions. That is:

Australian medical and health authorities work within a culture based on fundamentalism. That is, a strict adherence to a total cessation and zero harm approach to tobacco control.

Thus these organisations support prohibition, a policy derived from the US:

> *The dominant social and health policy in the US, as it relates to substance-related problems, and other issues such as birth control, centres on an absolutist approach whereas European countries, and Australia, have a pragmatic approach based on minimising risks and harms, a paradigm that sits in company with the traditions of Australian medical practice. The unhappy consequences of the US approach can be seen in their high rates of drug problems (a now escalating opioid epidemic), rates of mental illness and imprisonment.*[10]

But the *pragmatic approach based on minimising risks* is not applied to e-cigarettes.

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6 Inquiry submission 296, page 2.
7 Inquiry submission 296, page 11.
8 Inquiry submission 330, page 1.
9 Inquiry submission 330, page 9.
10 Inquiry submission 65, page 2.

The result of absolutist policies

This has led to what can only be described as a bizarre situation.

First, in Queensland nicotine in e-cigarettes is banned and:

> *To report the sale or possession of electronic cigarettes containing liquid nicotine, call 13 QGOV (13 74 68).*[11]

Although this approach might be expected in a dictatorship, its use in Australia should be vigorously condemned.

Second, in Western Australia:

> *Owners/managers **may choose** to implement a policy applying to their premises which prohibits the use of e-cigarettes wherever smoking is prohibited.*[12] (My emphasis.)

So apparently a hotel bar might allow e-cigarette use. But:

> *... products that resemble tobacco products, regardless of whether they contain nicotine or not, cannot be sold in WA and it is an offence under the Tobacco Products Control Act to sell these products.*[12]

So you might be able to use an e-cigarette in some pubs, but you will be arrested or fined!

I am not a constitutional lawyer, but the constitution allows for free trade between states and territories. Certainly some restrictions can be appropriate; for example, people who enter Tasmania cannot bring fruit or plants in order to protect the state from diseases and pests. However, if I travel from Tasmania to Queensland or Western Australia I can be arrested or fined for having and using an e-cigarette that is legal in my home state. So do I take a risk or do I smoke tobacco while I am away and resume using my e-cigarette when I get home?

Is this a sensible restriction of commerce and movement between states?

Finally, prohibition has never worked, is not working now and will not work. A graphic illustration of this was a news report, on Monday 7 August, regarding the alcohol ban on Mornington Island that the residents want lifted:

> *A remote far north Queensland island community struggling with a home-brew epidemic wants its state imposed alcohol ban lifted, saying alcohol abuse has gotten worse since it was brought in.*[13]

The present policy on tobacco cigarettes, although not a total ban, has serious problems:[14]

Year	2013	2016	Difference	Difference %
Population	23,120,000	24,130,000		
Daily smokers %	12.8	12.2		
Daily smokers number	2,959,360	2,943,860	15,500	0.06%
Occasional smokers %	3.0	2.7		
Occasional smokers number	693,600	651,510	42,090	0.17%

Allowing for population growth, although the percentage of daily smokers has dropped by 0.6%, the actual number of daily smokers has only dropped by 0.06%. Most of the decrease in

11 https://www.qld.gov.au/health/staying-healthy/atods/smoking/devices

12 http://ww2.health.wa.gov.au/Articles/A_E/Electronic-cigarettes-in-Western-Australia

13 http://www.abc.net.au/news/2017-08-07/mornington-island-homebrew-queensland-alcohol-management-plan/8763484

14 Data from http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/

smoking is in the occasional (weekly or less than weekly) smokers. These differences are not statistically significant.

That is, sadistically whipping smokers into submission is no longer working. And at the same time it appears that the traditional nicotine replacement therapies and prescription medicines are no longer effective. So current policy just makes the poor, mentally ill and criminals poorer, and just makes illegal tobacco use increase. There is no benefit.

However, in the area of tobacco control governments continue to deliberately hurt people, as is happening in Risdon Prison:

> *The inmates unfurled a banner demanding "basic human rights" while prison authorities said they were calling for the phased out nicotine replacement program to return.*
>
> *Acting Corrections Minister Guy Barnett said this morning the program was being reviewed. Correctional officers have told the Mercury that the nicotine patches became a black market currency in the prison with inmates being bashed and stood over for the patches.*
>
> *"It can be misused and abused and it has been in the past," he said.*[15]

And this must be seen on the context of:

> *... in prisons, where no downward trend is apparent and the rate remains stubbornly high at around 84%. High rates of community smoking persist in groups over-represented in the criminal justice system — the mentally ill (32% of current smokers had a 12-month mental disorder, compared with 16% of non-smokers), Indigenous people (44% of Indigenous v 16% of non-Indigenous Australians) and illicit drug users (37%).*[16]

As I have previously pointed out, such bans achieve absolutely nothing other than creating stress, anger and alienation.[17]

Conflicting views

May cause harm

Australian submissions are littered with statements like "insufficient evidence", "may expose users", and "may also contain". I will restrict my comments to three statements.

First:

> *Claims that e-cigarettes are "95% safer" than tobacco smoke, however, are unfounded and devoid of any scientific basis. Their propagation is redolent of the misleading claims of harm-reduction made about tobacco products over many years – claims that would be unlawful if e-cigarettes were approved for use in Australia as a therapeutic good.*[18]

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15 http://www.themercury.com.au/news/scales-of-justice/lockdowns-spark-inmate-protest-at-hobarts-risdon-prison/news-story/413eaf341c4ccb84f225b2e2b868ddf0, August 10, 2017.

16 *Smoking bans in prison: time for a breather?* Available from https://www.mja.com.au/system/files/issues/203_08/10.5694mja15.00688.pdf

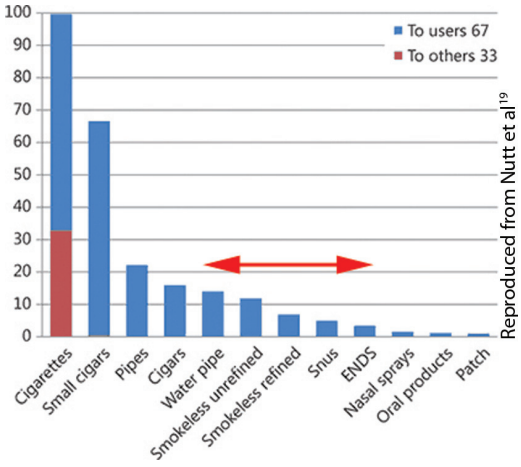
17 Inquiry submission 220, pages 2-3.

18 Inquiry submission 295, page 5.

Unlike other inquiry submissions, this picturesque complaint does not refer to the original article but, like the others, it takes the tobacco cigarette/e-cigarette comparison out of context.[19]

In fact the article compares cigarettes with 11 other nicotine sources: Cigars, Little and small cigars, Pipes, Water pipes, Smokeless refined tobacco, Smokeless unrefined tobacco, Snus, ENDS, Oral products, Patches, and Nasal sprays. The majority of these sources have been researched and their relative harm investigated. The article looked at

> *... 14 harm criteria. Seven criteria represented harms to the user* (such as death, illness and loss of tangibles)*, and the other seven indicated harms to others* (such as injury, environmental damage and economic cost).



The 12 products were then rated on these criteria with tobacco cigarettes given a score of 100%. It is clear that some products definitely cause more harm than e-cigarettes and, *in context*, the harm from e-cigarettes is probably less than about 12%, the score given to smokeless unrefined tobacco (tobacco products used orally, including chewing tobacco and dry snuff). This is based on the available evidence that there have been no reports of significant harm from e-cigarettes after about 7 years of research.

Chapman et al,[20] quoting other research, state that:

> *preliminary evidence . . . suggests that the effect of vaping on four . . . inflammatory markers of likely relevance to cardiovascular disease (CVD) and respiratory disease* ***may be*** *at least half that of tobacco smoking ... the results for cancer-related toxicants* ***were variable****, with most studies reporting between 14% and 23%* (my emphasis)

And:

> *Vaping advocates urge smokers to switch to ENDS. Those who fully switch are likely to experience reduced risk of premature death from smoking caused diseases, but the magnitude of that risk* ***remains entirely speculative****, in the absence of any large longitudinal population studies.* (My emphasis.)

As the original article investigated many criteria, not just the two cited above, a score of 15% or less is reasonable.

Second, Chapman et al[21] provide a survey of articles showing that nicotine can cause harm; other submissions also refer to the possible harm caused by nicotine. But, as Australian authorities want zero harm, the TGA approved nicotine replacement therapies, especially inhalers, must cause the same harm and should be banned.

The most obvious example of a conflict of interest is QuickMist.[22] This TGA approved NRT contains, in addition to nicotine:

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19 David J. Nutt, Lawrence D. Phillips, David Balfour, H. Valerie Curran, Martin Dockrell, Jonathan Foulds, Karl Fagerstrom, Kgosi Letlape, Anders Milton, Riccardo Polosa, John Ramsey, David Sweanor, "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach", available from https://www.karger.com/Article/FullText/360220

20 Inquiry submission 313, pages 27-28.

21 Inquiry submission 313, pages 66-73.

22 http://www.medicines.org.au/files/pcpnicqm.pdf

> ***propylene glycol**, anhydrous ethanol, trometamol (used for acidosis.), poloxamer 407 (a non-ionic detergent causing liver damage[23]) **glycerol**, sodium hydrogen carbonate, levomenthol (used for coughs, pain, sore throats, occasional minor irritation, sore mouth and other conditions), **mint flavour**, **cooling flavour**, sucralose (an artificial sweetener), acesulfame potassium (an artificial sweetener that contains a carcinogen[24]), hydrochloric acid and purified water.* (My emphasis.)

That is, it contains *the same ingredients as e-cigarettes* and other ingredients that are known to cause harm. Certainly QuickMist is not meant to be swallowed (actually unavoidable) or inhaled, but both are likely. Also "NICORETTE® QuickMist can be safely used while smoking." This statement is probably included because the company, unlike the Australian authorities, recognise that some people can only cut down and not quit immediately.

Finally, with regard to QuickMist:

> *A total of 479 smokers motivated to quit were enrolled in a multicenter, randomized, double blind, placebo-controlled, 52-week smoking cessation study.[22]*

I presume Chapman et al (and others) would reject this research as hopelessly inadequate and, to be consistent, require large longitudinal population studies *before* QuickMist can be deemed an acceptable product.

Third, anecdotal evidence is generally considered unreliable and is ignored by professionals. For example, Chapman et al state:

> *No one respectful of evidence gives any credibility to such personal testimony ... We should hold claims about the efficacy of ENDS in cessation to the same standards. Those who quit smoking after using ENDS understandably attribute their smoking cessation to ENDS. ... However, those who have tried and failed to quit using ENDS i.e. the substantial majority are far less likely to be as enthusiastic and evangelical. Positive personal testimonies represent flagrant self-selection bias about success and cannot be given any credibility when it comes to making generalisations about the success or otherwise of a cessation method.[25]*

This is absurd. The same submission (page 9) cites a study:

> *At 6 months, ... abstinence was 7.3% with nicotine e-cigarettes, 5.8% with patches, and 4.1% with placebo e-cigarettes ...*

That is, e-cigarettes with nicotine are about as effective as NRT. So an equally valid statement is:

> *We should hold claims about the efficacy of NRT in cessation to the same standards. Those who quit smoking after using NRT understandably attribute their smoking cessation to NRT. ... However, those who have tried and failed to quit using NRT i.e. the substantial majority are far less likely to be as enthusiastic and evangelical.*

Certainly the anecdotal evidence provides no information about people who have tried to quit using e-cigarettes and failed (although the claim that these are *the substantial majority* is not explained). However:

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23 http://journals.sagepub.com/doi/full/10.1177/0192623310394212

24 http://www.medicinenet.com/artificial_sweeteners/article.htm#acesulfame_k_what_are_the_cons: "The problems surrounding acesulfame K are based on the improper testing and lack of long-term studies. Acesulfame K contains the carcinogen methylene chloride. Long-term exposure to methylene chloride can cause headaches, depression, nausea, mental confusion, liver effects, kidney effects, visual disturbances, and cancer in humans. There has been a great deal of opposition to the use of acesulfame K without further testing, but at this time, the FDA has not required that these tests be done."

25 Inquiry submission 313, page 13.

(a) From the anecdotal evidence submitted to this inquiry there is absolutely no doubt that some people successfully quit using e-cigarettes.

(b) Australian data, consistent with data in other countries, show that only a small number of e-cigarette users are non-smokers.[26]

That is, the evidence supports the claim that e-cigarettes are being used successfully to quit tobacco smoking.

As an aside, I suspect none of the authors of the *Australian* submissions have ever used an e-cigarette, and it is likely that they have never smoked a tobacco cigarette. That is, their opinions are based on a strictly academic view and fail to recognise the real world facts regarding quitting, as explained by the Royal Australian and New Zealand College of Psychiatrists.

Black or white market?

There are concerns about the quality of e-cigarettes and liquids imported into Australia from China, and some people refer to these as *black market* products.

A large quantity of consumer items are imported from China without any problems: TVs, cars, mobile phones, fresh produce (such as garlic), packaged foods (such as chocolates and biscuits) and frozen foods. The quality of these goods is assessed by Australian consumer law and food regulations. That is, China has a large, reliable *white market* industry.

However, at present there is no oversight of e-cigarettes and liquids.

Liquid

Not all e-cigarette liquids are low quality. For example Dekang BW[27] manufactures high standard liquids and also has a plant in the EU to supply the European market.[28]

Applying regulations, like those used for imported foods, would ensure that liquids would meet Australian standards.

Hardware

E-cigarette hardware, in particular batteries, pose a regulatory problem, best handled by Australian consumer law that already has standards for electronics, batteries and other goods.

Batteries pose a serious problem, because there have been instances of them exploding and causing serious injuries and fires. Information, unfortunately vague, about 240 lithium e-cigarette battery explosions is available.[29] Unfortunately, lithium battery technology inherently has a risk of overheating and explosion and there are many instances of batteries in other consumer goods exploding.

Of the e-cigarette cases:

(a) 35% occurred while charging a battery, and many of these definitely involved incorrect chargers.

Lithium batteries *must* be charged with the correct, reliable charger and many of these instances could be avoided by providing warning information and education.

26 http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/
27 http://www.dekangbio.com/ and http://www.dekangbio.com/company/faq
28 http://www.dekangbio.com/company/dekang-europe
29 http://ecigone.com/featured/e-cigarette-explosions-comprehensive-list/

(b) 18.3% occurred with loose batteries carried in a pocket or purse.

These instances refer to *mods*, e-cigarettes that use separate batteries (like ordinary cylindrical batteries). The mod consists of a box, into which the batteries are inserted, and to which tanks, atomisers and mouth-pieces are attached. Other e-cigarettes, like the eGo design, have the battery permanently encased in a metal tube.

I am not sure if this group should be classed as ignorance or stupidity. A loose battery with exposed terminals can short if coins or keys close a circuit between the terminals. Again, batteries should be sold with warnings and with containers to store them in.[30]

(c) 7.5% occurred when the e-cigarette was carried in a pocket or purse and the firing button (the button that turns on the power) was depressed by other things pressing against it.

These were presumably old or inferior e-cigarettes. Modern e-cigarettes include electronic safety devices; they can be turned off to prevent accidental firing, and automatically turn off if the firing button is depressed for more than 10 seconds. New mods include software that can be updated.

(d) A few cases were probably due to human error. For example, putting atomisers on mods when they were not suitable, and inserting a battery the wrong way round.

(e) In addition to these 60.8% cases, 31.2% of occurrences had an unknown cause. Some of these may fit into the above categories, but many have no explanation.

The actual number of battery failures would be higher. So, even though they represent only a very small proportion of lithium batteries that have been manufactured (hundreds of millions), they are of concern, and it is clear that consumer education and quality control is necessary. Australian consumer law provides the framework to do this, as has successfully done with huge numbers of other consumer goods. Indeed, lithium battery models 18650 and 26650, commonly used in e-cigarettes, are available in Australia from retailers such as Jaycar.[31]

30 For example https://www.heavengifts.com/product/Plastic-Storage-Case-for-18650-Battery.html

31 https://www.jaycar.com.au/18650-rechargeable-li-ion-battery-2600mah-3-7v/p/SB2308 and https://www.jaycar.com.au/26650-rechargeable-li-ion-battery-3400mah-3-7v-nipple/p/SB2315