

Submission to Senate Standing Committees on Economics;

Inquiry into measures introduced to restrict personal choice 'for the individual's own good', the economic and social impact of legislation, policies and Commonwealth guidelines, with particular reference to: nicotine products, and e-cigarettes, including impacts on the health, enjoyment and finances of users and non-users.

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Submission on behalf of the New Nicotine Alliance, Australia

The New Nicotine Alliance (AU) is a group formed by Australian consumers of reduced risk nicotine products, health professionals, public health practitioners and scientists with strong links to the UK based group of the same name.

We recognise the immense harm of tobacco smoking comes from the inhalation of smoke, not from the nicotine.

We are established as a not-for-profit entity, financially independent of industry and refuse unequivocally to receive any payment, either monetarily or in kind, from any tobacco company, electronic cigarette company or pharmaceutical company.

We represent the views of consumers of safer nicotine products, going by the principle "nothing about us, without us".

We are committed to health-driven, evidence-based policies, supporting appropriate and proportionate regulation for nicotine and other related products.

I am a vaper myself. I was one of the most hardened smokers I ever met, being a daily smoker from the age of 11; but I gave up smoking 2 years ago by using vapourised nicotine products when nothing else worked. I am also a full time General Practitioner and I have seen many of the most hardened smokers give up using these. I am also an advisor to Professor Ron Borland on an upcoming Australian NHMRC funded trial on e-cigarettes. I was also a plenary speaker recently at the world's foremost scientific and public health conference on safer nicotine products, the Global Forum on Nicotine 2015 in Warsaw earlier this year, I have met personally and

am in ongoing contact with the world's top scientists and doctors in this field. I do not accept any payment for my work, and I am passionate about the potential for this game changing technology to make smoking obsolete with perhaps a billion potential lives to be saved. On returning from Warsaw I established the New Nicotine Alliance Australia, along with other vapers and public health professionals including two Associate Professors, nurses and a lawyer. I receive no payment for my work in this.

I would be grateful for the opportunity to present evidence to the Senate Committee and policy advisors in person and to answer any questions Members might have.

Current laws in regard to e-cigarettes to restrict choice for 'the individual's own good'.

Nicotine e-liquid for use in e-cigarettes/personal vapourisers, no matter how low the concentration, is currently listed as a Schedule 7 poison across Australia and therefore illegal to sell, supply or possess without a licence unless it is in tobacco for smoking or a pharmaceutical product. It is legal to import, possess and use nicotine e-liquid in electronic cigarettes for the purposes of smoking cessation under the TGA's Personal Importation Scheme if prescribed by a medical doctor (1) but most 'vapers' (e-cigarette users) in Australia are currently importing and using nicotine e-liquid illegally, with penalties in some states similar to the penalties for the possession of heroin.

The most effective electronic cigarettes that help people cease smoking look nothing like cigarettes, are sold by independent manufacturers with no connection to Big Tobacco companies and are generally sold without any e-liquid in them as they are designed to be refillable (otherwise known as 2nd, 3rd and 4th generation electronic cigarettes/personal vapourisers). (2) Currently it is legal to purchase these devices throughout Australia, with the exception of Western Australia, but not the nicotine e-liquid which makes them work. The first randomised controlled trial on 2nd generation e-cigarettes on smokers **unwilling** to quit showed an unprecedented 37% success rate, which is the first study to show such a high rate of success in people not even trying to quit and is a glimpse of their potential. (3)

No scientist, even the most skeptical, credibly disputes the idea that electronic cigarettes are far less harmful than combustible cigarettes as explained in the most comprehensive scientific review on their toxicology so far. (4) It has been long recognised that nicotine away from smoke is fairly benign and this is reflected in the rational widespread availability of pharmaceutical nicotine products in many stores and supermarkets which are available for purchase by anyone, even children. Clinical studies on e-cigarettes also confirm they are far safer than smoking. A recent study shows that quitting smoking via e-cigarettes leads to harm reversal, with clinical indicators of lung function significantly improving (5) and effects on the heart not being detectable compared with the clear detrimental effects of cigarette smoking. (6) It is clear that smokers who switch to these products are improving their health and many also enjoy the choice that they have in no longer giving any more money to 'Big Tobacco' companies.

To those of us who consider personal vapourisers to be nothing less than a miracle, allowing us to give up smoking when nothing else has worked, it is deeply puzzling that the majority of tobacco control and public health groups in Australia have put extremely strenuous efforts into achieving further bans even though the laws in Australia are already far more draconian than in most other countries. They seem to be extremely worried that increasing numbers of ordinary Australians are flouting the law to give up smoking by accessing products online and through a growing black market. They seem to be putting more effort into stopping e-cigarettes than on reducing smoking. They have generous access to policy makers and politicians so that only one side of the story has been given to them so far. Even tobacco companies have more access to politicians and advisors. Until now, consumers of these products have not had a voice and as the New Nicotine Alliance we are grateful for what is the first opportunity for ordinary people who have given up smoking 'the wrong way' to present our side of the story.

Toxic, combustible cigarettes are at present available everywhere. Only a very few dedicated vape shops exist in Australia due to the prohibitionist regulatory environment, and they can only sell the hardware, they cannot sell the 'software', that is e-liquid containing nicotine. Many smokers who are predominantly from lower SE backgrounds or have mental health issues who cannot navigate the online world or the black market simply want to go to a vape shop to buy everything they need and get advice on how they can use e-cigarettes to quit smoking. Current laws forbid these smokers from accessing this way of quitting.

These are hardly laws for 'the person's own good', they act as laws that keep people in smoking. Instead of harm reduction, these laws are harm increasing; these laws kill.

Advanced generation electronic cigarettes, almost exclusively not from tobacco companies but sold through dedicated vaping shops, are associated with very high verified smoking cessation rates of 40-66% (7) (8). Dedicated independent small business vaping shops therefore behave as de-facto 'stop smoking' centres, with a financial interest in helping people transition completely and with success rates equal to or greater than standard smoking cessation clinics. They achieve this at no cost to the taxpayer, indeed they have a net positive economic impact by creating an industry and jobs. They appeal to people who would never access standard smoking cessation clinics and therefore are additive to cessation success in a population.

Some call for regulations that only tobacconists should sell e-cigarettes. Tobacconists generally sell weaker 1st generation 'cigalike' e-cigarettes, often tobacco company products which are less likely to help people quit smoking.(9) Unlike in vape shops, where dedicated owners and staff help smokers to transition to a far safer alternative, there is no incentive within a tobacconist to help transition people off smoking. Certainly tobacconists should be allowed to sell e-cigarettes (and there are calls in the UK to force them to sell e-cigarettes) but to restrict sales to them alone will eliminate the most ethical and dedicated vape shops which actually help people to stop smoking.

The most recent data we have shows that at least 7% of Australian smokers and recent quitters regularly use e-cigarettes, many of whom have quit smoking by using them.(10) This data is almost 2 years out of date, and in that time the use of e-cigarettes has increased, so the number of regular users right now is almost certainly much higher. For thousands of Australians, continued access to e-cigarettes is life saving, as without them they would relapse to smoking.

Regulating e-cigarettes more strictly than tobacco cigarettes (as they currently are in relation to nicotine) gives the unspoken message that toxic combustible tobacco cigarettes are safer and more approved by the Australian Government. Already much of the anti-e-cigarette sentiment negligently expressed by many powerful organisations has led to a situation where close to half the public in many countries have a false perception that smoked cigarettes are just as safe or even safer than using e-cigarettes. (11) Smokers who might have switched therefore continue to smoke and to die.

Many public health workers and scientists, while accepting that switching entirely to vaping would benefit the individual smoker, are concerned about population effects of the wider availability of electronic cigarettes. (12) They cite the fact that the majority of e-cigarette users smoke cigarettes as well and that this dual use might maintain a smoking habit amongst people that would otherwise have quit entirely, that flavoured e-cigarettes might be 'training wheels' for smoking behaviour in children and addict them to nicotine (where this is available) and that they then might transition to combustible cigarettes (the gateway effect), that overall nicotine use and addiction might increase in a population and that unanticipated harms might result from widespread e-cigarette use in the long term.

The evidence we have from the United Kingdom, the most mature e-cigarette market in the world with easy availability and only light consumer regulation of these products, overwhelmingly refutes all of these claims. The data from the UK shows increasing e-cigarette use and a decreasing proportion of dual users as consumers move to more advanced e-cigarette models with 400,000 people quitting smoking via e-cigs in the last year alone. (13) Smoking rates are declining at an increasing rate, possibly faster than in Australia as vaping displaces smoking and total nicotine use in the population is declining. (13) Due to the growing evidence and experience, **increased** e-cigarette use is an official goal of the UK Government as recommended by the recent groundbreaking Public Health England report. (14)

What about the Children?

Experimental (monthly) youth e-cigarette use has increased in the US, coinciding with youth smoking rates plunging to the lowest rates ever. From some states where the data is available daily smoking rates amongst youth in the US are now lower than Australia's 3.4%, suggesting that e-cigarettes are displacing smoking in this most important population. (15) (16) The data from the Hawaiian study (15) is particularly compelling as it showed a daily smoking rate of less than 1%, which is the level associated with a society transitioning to an end to smoking altogether and puts Australia's supposed success in reducing youth smoking to shame. This was associated with a very high rate of experimental e-cigarette use but only 2% daily e-

cigarette use (15, table 2). Data on whether the e-cigarettes contained nicotine was not available but when 'never smokers' experiment with e-cigarette use it is often if not predominantly with non-nicotine e-cigarettes. (17)

Recent data from the UK shows that regular e-cigarette use in youth is confined almost entirely to smokers and previous smokers. (18) With almost no 'never smoking' youth taking up regular (as opposed to experimental) e-cigarette use there is very little possibility of a gateway effect.

It raises the controversial possibility that widespread availability of e-cigarettes could act as a powerful diversion from smoking in youth and accelerate the end of smoking, with the massive public health benefits that this would represent. If a risk taking youth wishes to experiment with a smoking type behaviour and they access an e-cigarette without nicotine, they satisfy the urge to perform the behaviour without any risk of addiction. Even if there is nicotine in the e-cigarettes, nicotine alone, without burnt tobacco, has much less addictive potential than cigarettes. (19) Conversely even a few standard cigarettes in childhood can induce life-long smoking addiction (20).

The Consumer Viewpoint.

Finally, there will be some that are convinced that allowing e-cigarettes is possibly tolerable as long as it is within a strictly regulated medical model. There are grave flaws in this idea.

The e-cigarette/personal vapouriser phenomenon is successful in the UK precisely because it is an alternative **enjoyable, recreational** nicotine device. The pace of innovation and improvement is staggering, every month new exciting devices and liquids are coming out that attract more and more smokers away from smoking. It is a genuine consumer led movement amplified by massive interaction on social media. Almost every innovation so far in the personal vapouriser market has occurred through the mass distributed intelligence of consumers tinkering with new ideas which are then taken up by small to medium sized manufacturers. It started with flashlight hobbyists helping vapers to modify the early e-cigarette devices by making them more powerful (hence the name 'mods'). A recent example is the use of cotton instead of silica as a wicking material. Hobbyists posted their experiments on the Internet and collaboratively refined them and in recent months the manufacturers have followed suit by coming out with organic cotton wicking atomisers. The pace is far too hot for tobacco companies, whose model is to spend millions of dollars and many years of research and development leading to products such as 'heat not burn' that fail anyway being a 'top down' distrusted approach without any involvement of consumers.

If we simply allow current consumer led improvements and innovations to continue within a lightly regulated consumer market, we have the profound prospect of having personal vapourisers and liquids that are so much better in every way for every smoker that smoking simply becomes obsolete. An alcoholic would not drink methylated spirits if fine wine was cheaper and more available. A smoker would not smoke anymore if

there was a vapour device/liquid that was so much better and enjoyable than any form of smoking.

Obsessions about safety are about reducing the harm of an already far safer product by a fraction of a percent. But a perfectly safe product that no-one wants to use is useless.

Ironically, burdensome regulations and rules and medicalisation will likely cost so many millions of dollars that only tobacco companies will have the resources to comply. Tobacco companies **want** more regulations to eliminate the consumer led competition.

(21) We see an unholy alliance between Big Tobacco and Tobacco Control developing regulations to destroy this revolution of nicotine of the people, by the people and for the people. Over-regulated, control of recreational nicotine will go back to Big Tobacco who, perhaps intentionally, are producing ineffective products that are not satisfying enough for smokers to switch entirely and therefore allowing them to maintain their market for their most profitable product; deadly, combustible cigarettes.

It would be quite simple to make safe nicotine eliquid legal and available in Australia for sale through dedicated vaping shops. This one simple Commonwealth legislative step would put us into line with the UK and the USA where more and more smokers are enjoying the choice to have a far safer method of recreational nicotine. It would be a boon for public health in reducing smoking rates and would be an important measure for human rights, for people to be able to take control of their own health through making better choices. It is to simply add one line, (d) in the Commonwealth Poison Standard, (SUSMP) which all the States are bound by as follows under Schedule 7 as follows:

Proposed Schedule 7 amendment

NICOTINE **except**:

- a) when included in Schedule 6;
- b) in preparations for human therapeutic use; or
- c) in tobacco prepared and packed for smoking.

add d) in preparations containing 7.2% or less of nicotine when labeled and packed for use in electronic cigarettes (personal vapourisers).

(7.2% nicotine is chosen to bring us into line with UK laws and has a low enough toxicity but allows adequate strength for practical use.)

Final Words

There is a huge disconnect in Australia where we see e-cigarettes as such a massive threat to health that it requires heroin level penalties and strident campaigns by huge organisations backed by millions of public dollars to stop them. This is perhaps the first time in history that people seeking to access a safer alternative have to become criminals and buy on the black market to do so. Elsewhere in the world nations like the

UK are seeing the benefits of liberalised regulation of e-cigarettes and are increasingly actively encouraging their use at an official level.

The advent of this consumer led revolution in e-cigarette use has the real potential to accelerate the end of smoking at a much faster rate than has ever seemed possible before. There is no evidence of any negative population effects in mature e-cigarette markets elsewhere in the world. There is growing evidence of beneficial effects in the increase of smoking cessation overall and a reduced incidence of youth uptake of smoking. To ban and restrict these products to make it hard or impossible for smokers to switch, without good evidence based reasons, could in time be seen as a negligent or even criminal act against human rights, causing untold death and misery by the maintenance of smoking.

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(1) <https://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes>

(2) [Nicotine Tob Res.](#) 2015 Apr 20. pii: ntv078. [Epub ahead of print]

Associations Between E-Cigarette Type, Frequency of Use, and Quitting Smoking: Findings From a Longitudinal Online Panel Survey in Great Britain.

[Hitchman SC](#)¹, [Brose LS](#)², [Brown J](#)³, [Robson D](#)², [McNeill A](#)².

<http://www.ncbi.nlm.nih.gov/pubmed/25896067>

(3) [Int J Environ Res Public Health.](#) 2014 Oct 29;11(11):11220-48. doi: 10.3390/ijerph111111220.

[Effectiveness of the electronic cigarette: An eight-week Flemish study with six-month follow-up on smoking reduction, craving and experienced benefits and complaints.](#)

[Adriaens K](#)¹, [Van Gucht D](#)², [Declerck P](#)³, [Baeyens F](#)⁴.

(4) [Ther Adv Drug Saf.](#) 2014 Apr;5(2):67-86. doi: 10.1177/2042098614524430.

Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review.

[Farsalinos KE](#)¹, [Polosa R](#)².

(5) [BMC Med.](#) 2015 Mar 18;13:54. doi: 10.1186/s12916-015-0298-3.

Electronic cigarette use and harm reversal: emerging evidence in the lung.

[Polosa R](#).

(6) [BMC Cardiovasc Disord.](#) 2014 Jun 23;14:78. doi: 10.1186/1471-2261-14-78.

Acute effects of using an electronic nicotine-delivery device (electronic cigarette) on myocardial function: comparison with the effects of regular cigarettes.

[Farsalinos KE](#)¹, [Tsiapras D](#), [Kyrzopoulos S](#), [Savvopoulou M](#), [Voudris V](#).)

(7) [Addiction.](#) 2015 May;110(5):868-74. doi: 10.1111/add.12878.

Biochemically verified smoking cessation and vaping beliefs among vape store customers.

Tackett AP¹, Lechner WV, Meier E, Grant DM, Driskill LM, Tahirkheli NN, Wagener TL.
<http://www.ncbi.nlm.nih.gov/pubmed/25675943>

(8)[Int J Environ Res Public Health](#). 2015 Mar 24;12(4):3428-38. doi: 10.3390/ijerph120403428.
Quit and smoking reduction rates in vape shop consumers: a prospective 12-month survey.
[Polosa R](#)^{1,2}, [Caponnetto P](#)^{3,4}, [Cibella F](#)⁵, [Le-Houezec J](#)^{6,7}.
<http://www.ncbi.nlm.nih.gov/pubmed/25811767>

(9)*Nicotine Tob Res*. 2015 Apr 20. pii: ntv078. [Epub ahead of print]

Associations Between E-Cigarette Type, Frequency of Use, and Quitting Smoking: Findings From a Longitudinal Online Panel Survey in Great Britain.

Hitchman SC, Brose LS, Brown J, Robson D, McNeill A.

(10) Gravely, Shannon et al.

Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project.

Ed. Paul B. Tchounwou. *International Journal of Environmental Research and Public Health* 11.11 (2014): 11691–11704. *PMC*. Web. 15 July 2015.

(11) Kiviniemi MT, Kozlowski LT.

Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey.

Harm Reduct J. 2015 Jul 2;12(1):21. doi: 10.1186/s12954-015-0055-0.

(12)Pisinger C.

Why public health people are more worried than excited over e-cigarettes.

BMC Med. 2014 Dec 9;12:226. doi: 10.1186/s12916-014-0226-y.

(13) West,R,

Smoking toolkit study

accessed from <http://www.smokinginengland.info/>

(14) Public Health England, **E-cigarettes: a new foundation for evidence-based policy and practice.**

Accessed from

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf

(15)[Wills TA](#)¹, [Knight R](#)², [Williams RJ](#)³, [Pagano I](#)², [Sargent JD](#)⁴.

Risk factors for exclusive e-cigarette use and dual e-cigarette use and tobacco use in adolescents.

ref Table 2 in [Pediatrics](#). 2015 Jan;135(1):e43-51. doi: 10.1542/peds.2014-0760. Epub 2014 Dec 15.

Table 2 data in this study accessed from

<http://pediatrics.aappublications.org/content/135/1/e43/T2.expansion.html>

(16) Florida Youth Tobacco Survey 2014, accessed from http://www.floridahealth.gov/statistics-and-data/survey-data/fl-youth-tobacco-survey/_documents/2014-state/_documents/fs1-cigarette.pdf

(17) [Hamilton HA](#)¹, [Ferrence R](#)², [Boak A](#)³, [Schwartz R](#)², [Mann RE](#)⁴, [O'Connor S](#)⁵, [Adlaf EM](#)⁴
Ever Use of Nicotine and Nonnicotine Electronic Cigarettes Among High School Students in Ontario, Canada..

[Nicotine Tob Res.](#) 2014 Oct 30. pii: ntu234. [Epub ahead of print]

(18) Youth Tobacco Policy Survey, 2014, Cancer Research UK accessed from <http://www.cruk.cam.ac.uk/news/latest-news/research-shows-most-children-do-not-regularly-use-e-cigarettes>

(19) [Neuropsychopharmacology](#). 2014 Jul;39(8):1843-51. doi:10.1038/npp.2014.31. Epub 2014 Feb 11.

Comparison of the reinforcing properties of nicotine and cigarette smoke extract in rats.

[Costello MR](#)¹, [Reynaga DD](#)¹, [Mojica CY](#)¹, [Zaveri NT](#)², [Belluzzi JD](#)¹, [Leslie FM](#)¹.

(20) [Arch Pediatr Adolesc Med.](#) 2007 Jul;161(7):704-10.

Symptoms of tobacco dependence after brief intermittent use: the Development and Assessment of Nicotine Dependence in Youth-2 study.[DiFranza JR](#)¹, [Savageau JA](#), [Fletcher K](#), [O'Loughlin J](#), [Pbert L](#), [Ockene JK](#), [McNeill AD](#), [Hazelton J](#), [Friedman K](#), [Dussault G](#), [Wood C](#), [Wellman RJ](#).

(21) Special Report: When it comes to e-cigs, Big Tobacco is concerned for your health.

Reuters March 23rd 2015

<http://www.reuters.com/article/2015/03/23/us-ecigarettes-regulations-specialreport-idUSKBN0MJ0GN20150323>