

Committee Secretary
Senate Economics Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

25 August 2015

Dear Dr Thompson

Please find below a contribution to the Committee's inquiry into personal choice. We are restricting our remarks to the first theme in the terms of reference with specific emphasis on e-cigarettes:

The economic and social impact of legislation, policies or Commonwealth guidelines, with particular reference to: the sale and use of tobacco, tobacco products, nicotine products, and e-cigarettes, including any impact on the health, enjoyment and finances of users and non-users;

Clive Bates is a UK-based public health advocate supporting tobacco harm reduction as a strategy for public health. He runs the Counterfactual website (www.clivebates.com)

Ron Borland is an Australian behavioural scientist with over 40 years experience in behaviour change and has published around 350 peer-reviewed papers, mostly on aspects of tobacco control and smoking cessation, and recently a book-length exposition of an integrated theory of behaviour and behaviour change. Professor Borland holds honorary appointments at University of Melbourne, University of Queensland and Monash University and a Visiting Professorship at Harvard University.

Lynn Kozlowski is a U.S.-based professor of community health and health behavior and former dean of a school of public health and health professions. He has published research on tobacco and nicotine issues since 1975 and contributed to Reports of the U.S. Surgeon General and to U.S. National Cancer Institute Monographs.

David Swenor is a Canadian professor of law, and has been a long-standing tobacco control and public health advocate.

We have no competing interests with respect to tobacco, nicotine or pharmaceuticals industries. The views expressed are those of the authors and do not necessarily represent the views of host institutions. If we can be of further assistance, please do let us know.

Yours sincerely

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Summary

- The policy framework for e-cigarettes in Australia violates almost all of Australia’s principles for good policy making. These principles include: showing net benefits, justifying regulation, minimising costs and burdens, making reasoning transparent, consultation with affected parties and acting with “common sense, empathy and respect”.

Ten principles for Australian Government policy makers

1. Regulation should not be the default option for policy makers: the policy option offering the greatest net benefit should always be the recommended option.
2. Regulation should be imposed only when it can be shown to offer an overall net benefit.
3. The cost burden of new regulation must be fully offset by reductions in existing regulatory burden.
4. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.
5. Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals.
6. Policy makers must consult with each other to avoid creating cumulative or overlapping regulatory burdens.
7. The information upon which policy makers base their decisions must be published at the earliest opportunity.
8. Regulators must implement regulation with common sense, empathy and respect.
9. All regulation must be periodically reviewed to test its continuing relevance.
10. Policy makers must work closely with their portfolio Deregulation Units throughout the policy making process.

Source: The Australian Government Guide to Regulation¹

- There is no case for the *de facto* prohibition of e-cigarettes in Australia through misclassification of consumer products as poisons or medicines. E-cigarettes pose at least 95% lower risks than smoking (and probably negligible risk of serious disease) and provide significant individual benefits to those who switch. There is no precedent or scientific and ethical case to restrict consumer choice in any market to only the most dangerous products. We are witnessing is a rapid shift away from simple acceptance of state paternalism to a world of greater demand for informed choice backed by adequately safe but enjoyable technology-rich consumer products.
- Several arguments have been advanced to justify *de facto* prohibition: harm to users, renormalisation of smoking, undermining tobacco control, gateway effects, precautionary principle, reduced quitting and so on. These arguments have no basis in evidence or reality. In most cases, evidence supports the opposite argument: that prohibition of e-cigarettes is an unjustifiable infringement of individual rights and harmful at population level.
- There is no case to apply the force of law to banning vaping in public places or workplaces. Given there is no evidence or prospect of material harm to bystanders, a robustly principled position is to let owners or managers to decide vaping policy, not to override their choices.
- The bureaucratic harassment and near-bankrupting of an e-cigarette vendor using law that prohibits sale of products that *look like* cigarettes is self-evidently absurd and abusive given that the far more dangerous product, cigarettes, is widely available. These laws were designed to prevent candy cigarettes, not to bully e-cigarette vendors.

1. De facto prohibition of e-cigarettes in Australia

The interaction of poisons and medicines regulation applied to e-cigarette in Australia has created a *de facto* prohibition, with Australian vapers having to access foreign internet sites or illicit trade². Instead of being prohibited, e-cigarettes should be a legitimate and highly valued low-risk alternative to smoking. Both the misclassification as poisons and medicines and the resulting prohibition are harmful and unethical. When e-cigarettes are proving popular and without any significant issues in other countries, what is the case for denying the Australian smoker the option to use products that are at least 95% lower risk than smoking? Even if there are uncertainties in the science of e-cigarettes, they are concentrated in a range of risk two orders of magnitude lower than the risks of smoking (is the reduction in risk 95% or 99.8%?). There is no logical or ethical basis, including arising from residual scientific uncertainty, to restrict consumer choice to only those products known to be very harmful, primarily cigarettes. The gains to health arise from the following:

- Smokers who switch to e-cigarettes completely will avoid almost all (at least 95%)³ of the incremental risk of serious disease of continued smoking and experience a range of other health, wellbeing and economic benefits.
- Smokers who cut down smoking will reduce risks of most diseases for which there is a linear dose-risk relationship.
- Young people who have risk factors for smoking (parental smoking, peer group pressure, poor educational attainment, delinquency, etc) may avoid starting to smoke if they switch to vaping. It is likely, though cannot be shown definitively, that this effect has contributed to significant declines in youth smoking in the UK, France and United States.
- Young smokers have options to switch to vaping at a later stage. Most of the risk of serious disease does not begin to accumulate in smokers until after age 35-40. Smokers who quit before this age avoid almost all of the risk of serious disease⁴.
- Smokers with existing chronic conditions (COPD, asthma etc) can experience relief of symptoms⁵.
- Ex-smokers who are at risk of relapse to smoking may be able to avoid starting to smoke again.
- For particular groups prone to high dependency (suffers of psychosis for example), it is likely that harm reduction strategies involving alternative sources of nicotine offer the best approach.

The legal and policy approach in Australia actively obstructs these routes to better health for nicotine users, on the assumption that they should quit instead – an approach we know as “quit or die”. In setting up this policy framework, the regulators are denying people access to life-saving alternatives that are proving effective elsewhere. In the UK, there are now 2.6 million e-cigarette users, of which some 1 million are ex-smokers⁶, but there is minimal use among never-smokers and use among adolescents is concentrated in smokers⁷.

Understanding the experience of vapers and behaviour change

It is also important to listen carefully to testimony of users, and not to discount their experience as mere anecdote – there are thousands of ‘anecdotes’ that build up a valuable picture of the lived experience of vaping as a personal and public health strategy.

A modest effort to look for testimonies of e-cigarette users' experience would confirm this, for example from Australian⁸, UK⁹ and US sources¹⁰. Any public health professional should be capable of reading these and feeling great empathy and respect for the personal triumphs described. Here are three of many testimonials from Australia's AussieVapers forum, expressed in their own words:

1. **Example 1.** *Well folks, today's the day! It's been 12 months since I had a tobacco cigarette and I still can't believe it! A whole Year without a smoke!! In my wildest dreams I never, ever thought I'd be able to give up smoking after having smoked for over 52 years. I'm still in awe! Even though I've been Vaping for around 2.5 years, it took me a fair while, around 14 months of 'dual using' (smoking & vaping), before I became Smoke free. Even though once I started vaping, I did cut down enormously on the ciggies, I still just had to have a smoke. I was a VERY heavy smoker. We are all different. Some people stop smoking immediately, as soon as they start Vaping, (good on them!). Others take longer. It doesn't matter how long it takes you, as long as you get there in the end). And, the BEST thing of all is, I did it EASILY, much easier than I ever expected. I think it's because I've never felt deprived. In my brain, I feel like I'm still smoking, so I'm not looking for a ciggie. I've had a few 'life dramas' (as we all do), over the past year and never once thought, 'oh, I need ciggie'. I just grabbed my vape and was completely content. Amazing!! Health wise, I feel FANTASTIC and no more stressing out about how I'm going to find all the money for my smokes. Wonderful feeling now that I don't have to worry about that anymore ! I don't need accolades. I fought this battle for ME and I am just so Happy and Content now and I wanted to share this so it may give hope to anyone NEW to vaping and show that it does work, no matter what age you are OR how heavy a smoker you are/were OR how long it takes. MIRACULOUS!!! THANK YOU ALL FOR YOUR HELP!!! One HAPPY lady here.*
2. **Example 2.** *Was a confirmed smoker with over 40 years on the smokes. Habit of around 60 a day with all that entails - burn marks on clothes, on bedding, and on the floor. Constant cough was getting a bit much to deal with, as was the increasing cost of the smokes. I remember saying that I would give up when the cost reached \$2 a pack. When I started you could get a pack of 20 for \$0.42. With the price increase of December 2013 my packs were up to \$36 for a pack of 50. Yep, a confirmed smoker. I "knew" I couldn't give up the smokes, so started looking for cheaper alternatives. I had tried nicotine gum and patches (really weird nightmares on the patches) in the past with no success. Met someone who was using e-cigs and was interested enough to try the brand he was getting from USA. Had been on them for about 4 weeks when I realized that I had, technically, given up smoking. Tried 2 smokes in the last 13 months and hated the taste. The hacking cough went after 2 weeks. I can now walk the dogs without using their leads as a tow rope on hills. Apparently (according to co-workers) I don't "reek" anymore. I don't have to burp the computer keyboard to get the ash out of it, and I haven't melted any more keys on it either. Will never go back to the smokes. Vaping has literally been a life-changing experience for me. Apart from all the health benefits, I can now afford to do more around my home, plus have the energy (and lungs) to do it. Feeling generally motivated to live a healthier and more productive life. I figure that if I can give up the smokes after so long, nothing is impossible*
3. **Example 3.** *It's really had to believe it's been a year. Never in my wildest dreams did I think that I could really quit smoking and make it last this long. I figured my addiction would kill me one day. Now, I am in great health, have managed to slim down to what I weighed in my 20's, and am fitter than I have been in years. I've tried to convert many people, but so far have only succeeded with one friend. I hope to continue to pay forward the time that the Brisbane lady gave me at the airport one year ago and will chat to anyone in the street about vaping.*

The purpose or effect of Australian Government policy appears to be to prevent or obstruct this sort of experience among Australian citizens, but without any defined countervailing benefits other than vaguely theoretical mitigation of hypothetical and implausible risks.

It is not appropriate to see the people at risk from smoking-related diseases as ‘patients’ or ‘subjects’ for experimentation with ‘interventions’. While this may work for infectious diseases, it is far too simplistic for influencing the behavioural determinants of non-communicable diseases, in which it is important to recognise the individual’s own agency, self-determination, preferences and rights – and to respect the choices they make. E-cigarettes provide a new value proposition to smokers who wish to use the mildly psychoactive drug nicotine, but do not wish to die prematurely as a result. The reason it works, as these testimonials show, is that it empowers smokers and enables them to make better choices *as they see the choices themselves*.

As the Royal College of Physicians of London explained in its landmark report, *Harm reduction in nicotine addiction*¹¹:

This report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.

Use of e-cigarettes in Australia

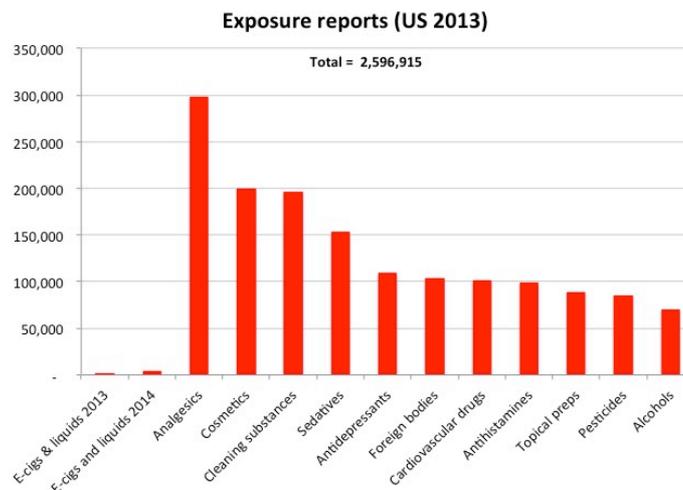
Fortunately, many Australians do circumvent the government’s rules and are experiencing these benefits, albeit through unregulated cross-border or illicit trade. A synthesis of 10 country surveys¹² identified widespread use in many countries, including substantial use in Australia despite the *de facto* ban. According to this survey, 7% of Australian smokers and former smokers were current users of e-cigarettes in 2013 - and the total is likely to have increased since. This is likely to be a contributor to declines in smoking in Australia. However, unlike Britain, where there is routine surveillance of the marketplace for all nicotine products, there is no systematic survey of e-cigarette use and user attitudes in Australia to our knowledge.

The inappropriate classification as poison

Under Schedule 7 of the Commonwealth Poison Standard, nicotine liquids are classed a ‘Dangerous Poison’ and a permit is required to trade in such poisons in every state and territory – such permits are not forthcoming. In contrast, Europe and the United States have vibrant markets in e-cigarettes and have not found it necessary to classify nicotine liquids as poisons at the concentrations widely on sale to consumers - though all jurisdictions do classify nicotine as poisons at higher levels (for example above 7% nicotine or 70mg/ml in the UK). There is a clear case to revisit the “dangerous poison” classification below 3-4%.

Poisoning risks have been greatly overstated in media reports. Recent analysis shows nicotine toxicity is perhaps 20 times lower than widely assumed and huge doses have been ingested without serious consequences¹³. There have been a small number of incidents of people or pets swallowing nicotine liquids and some have tried to characterise this risk by reference to the number of calls to poison centres.

Much international publicity has arisen from data on calls to US poison centers. The calls to US poisons centres are rising in line with growth and public awareness of e-cigarettes and liquids, they represent a tiny fraction of the calls arising from medicines, cosmetics, domestic cleaning products etc^{14 15}



Source: 2013 Annual Report of the American Association of Poison Control Centers ' National Poison Data System

There is a simple protective measure available: to insist on child resistant packaging, for which there is an ISO standard¹⁶.

The inappropriate application of medicines regulation

If poisons regulation does not change, the only route to market for e-cigarettes in Australia would be to apply for a Therapeutic Goods Administration license and to classify the e-cigarette as a medicine. Plans to regulate e-cigarettes as medicines were abandoned in the European Union on 8 October 2013 during the legislative process for developing the Tobacco Products Directive. The two primary reasons were: (1) that legislators were convinced that these products are not medicines (unless therapeutic claims are made for them) and that this mode of regulation is not fit for purpose legally or practically¹⁷; (2) that regulation would be so burdensome that it would either amount to a *de facto* prohibition, or create such regulatory barriers to entry that the current diverse and innovative market would be replaced by small number of major tobacco companies selling commodity products designed for compliance with unnecessary regulation rather than meeting consumers' needs for effective alternatives to smoking¹⁸.

2. Arguments used to justify a prohibitionist approach to e-cigarettes

Harms arising from vapour emissions

Studies of liquids and vapour chemistry reveal traces of contaminants and thermal breakdown products that are potentially harmful, but at levels unlikely to pose a material threat. Critics of e-cigarettes routinely cite studies suggesting presence of harmful substances, but risk is determined by *exposure*, not merely by the presence of a hazardous substance – which are present in just about everything we consume at low levels. The most comprehensive literature review so far concluded¹⁹:

Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. ... Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

Population effects

The opponents of e-cigarettes try to argue that a much safer product is more dangerous because of the way it affects the 'population'. They argue that the availability of a low risk alternative may have increase smoking above what would have happened in the absence of these products. Before examining the evidence, it is important to note just how strange this idea is. There is no other aspect of life in which we ban much safer products because we worry that it will change the way that far more dangerous products are used. The safest, most rational assumption is that people will use low-risk products to reduce their risk, unless there is evidence to the contrary. *But there is no evidence to the contrary and the burden of proof should rest with those making these claims.*

Undermining tobacco control

There is no basis for believing that the availability of alternatives to smoking will somehow undermine tobacco control efforts. The reality is the opposite: e-cigarettes provide very low risk options that allow consumers, especially those who cannot or choose not to quit nicotine use, to respond to tobacco control policies such as high taxes, pack warnings, smoke-free places and motivational campaigns. They offer a rival value proposition, designed to take market share from the cigarette trade. Tobacco control establishes a number of incentives to stop using cigarettes – many of which are punitive or coercive. The credibility of such policies is improved by giving citizens options to respond. The UK's foremost experts in smoking cessation who also manage the surveillance of the market in nicotine products in England concluded²⁰:

Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking

Whether this is the case in Australia remains unknown for the simple reason that the surveillance and necessary assessments are not done. Having an adequate evidence base for policy making is a prerequisite for good policy, and necessary to comply with the second, fourth, seventh and ninth of Australia's ten principles for good policymaking listed on page two above.

Precautionary approach?

It is sometimes argued that because future population effects are unknown, there is a case for acting on a precautionary principle. The problem with this is that the population effects are at least as likely, and more plausibly, to be highly positive. Restrictive precautionary action could therefore have a detrimental impact on health, and although 'precautionary' sounds responsible, it would in this case be reckless. We have experience in Europe of inappropriate interventions to prohibit low risk nicotine products on a 'precautionary' basis. The case of 'snus' provides strong proof of concept that alternative sources of nicotine can radically reduce smoking and related disease - and this is an opportunity that should not be wasted with badly designed legislation. In Europe, Sweden stands out as having by far the lowest smoking rate, 11% in Sweden compared to the EU average of 26%.²¹ The reason for this is the high use of smokeless tobacco instead of smoking. This has led to very substantial reductions in disease in Sweden²² that cannot be even partly replicated in the rest of the EU because snus has been banned in the EU other than Sweden since 1991 on 'precautionary' grounds, and with the support of a number of Australian activists. We believe that a rigorous understanding of the Swedish experience with snus is a test of the credibility of those activists or officials opposing better access to e-cigarettes.

Reduced quitting

Where this has been studied properly and the results interpreted correctly, there is no sign of e-cigarettes reducing quitting, and nor would a neutral observer expect one²³. The most thorough survey in the world, the Smoking Toolkit Survey for England²⁴, concluded in January 2015, that:

Rates of quitting smoking are higher than in previous years. E-cigarettes may have helped approximately 20,000 smokers to stop last year who would not have stopped otherwise.

Gateway effects

Many activists and some public officials have pointed to rising e-cigarette use among adolescents and claimed they could be a 'gateway' risk to smoking. *There is no evidence supporting this hypothesis anywhere.* In its review of e-cigarette science²⁵, Public Health England said:

"The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field. Whilst never smokers are experimenting with EC [e-cigarettes], the vast majority of youth who regularly use EC are smokers. Regular EC use in youth is rare."

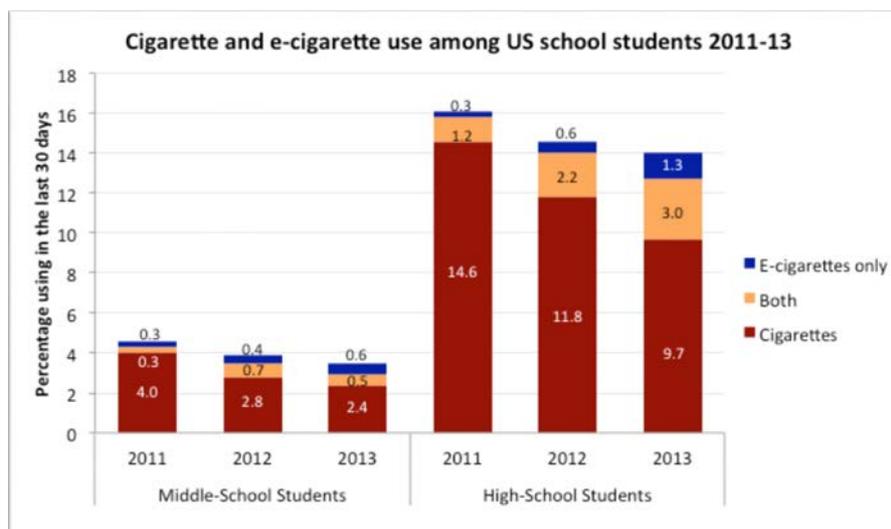
In fact e-cigarettes appeal primarily to existing smokers and the 'value proposition' they offer is strongest among existing smokers with mounting concern about the health and other costs. This expectation is confirmed by data. For example, the UK Office for National Statistics states²⁶:

E-cigarettes are used almost exclusively by smokers and ex-smokers. Almost none of those who had never smoked cigarettes were e-cigarette users.

However, this has not stopped activists making wild misinterpretations of data. For example in 2013, much media coverage was created in the United States over National Youth Tobacco Survey Data showing a rise in e-cigarette use²⁷. According to a top public health official:

This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes.

The data do not support a gateway effect and actually provide reassurance that e-cigarettes may be displacing smoking, as we would expect. The relevant CDC data are shown in the chart below:



Source: raw data from CDC National Youth Tobacco Surveys (NYTS). Data analysis and graphic by Brad Rodu

In reality, US teenage smoking prevalence fell sharply as e-cigarette use increased and e-cigarette use was highly concentrated among existing smokers²⁸. These observations do not confirm that e-cigarettes are causing the decline in cigarette use, but neither do they suggest that e-cigarettes are causing cigarette smoking to increase.

Similar effects were found in France²⁹ and confirmed for the United States in the Monitoring the Future survey, which showed a rise in e-cigarette use, but also found record low rates and record annual declines for “daily” and “past 30 day” cigarette smoking by teens from 2013 to 2014³⁰. In essence we are seeing e-cigarette use rise in line with growth in use among adults, but cigarette smoking falling sharply. These are reasons to be positive, not to conclude that e-cigarettes a problem.

3. Banning e-cigarette use in public places and workplaces

Many health organisations are calling for vaping to be banned by law in public places and workplaces. There is no case to *use the law to mandate vaping bans*. It is important to start by examining the appropriate role of the state in proscribing behaviours and in restricting the choices of citizens and property owners. The use of the law should be confined to those situations where it is imperative that the law overrides the preferences of the owners or managers of public spaces or workplaces (which are often privately owned). That would be where there is clear evidence or reasonable expectation that one person’s behaviour causes or can cause material harm to another – the so-called harm principle famously articulated by John Stuart Mill³¹

That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.

Otherwise, it should be a matter for the owner or manager to decide. There is no evidence that e-cigarette vapour poses any material risk to bystanders. It is completely different chemically and physically to second hand cigarette smoke. The most authoritative reviews of vapour toxicity show no basis for concern about hazards of ‘secondhand’ vapour. It is primarily an issue of etiquette, which forms one part of a wider judgement about commercial and welfare interests.

It is important to recognise the potentially harmful impact of mandatory bans on indoor vaping that are mandated by law. These include:

- Degrading the attractiveness of e-cigarettes as an alternative to smoking and so protecting the cigarette trade through reduced switching or increased relapse to smoking;
- The harmful effects of forcing vapers to join smokers to use e-cigarettes – discouraging switching and promoting relapse;
- The invasion of commercial freedoms and consumer choice together with loss of welfare to e-cigarette users and no concomitant gain for anyone else.

It is unlikely that owners and operators would take a *laissez faire* approach to allowing e-cigarette use and many owners or managers in workplaces and public places are likely to restrict it by their own choice. But if an office wants to have a vaping area, a bar wants a vape room or vaping night, a coffee shop chooses to cater for vapers, or an airport wishes to allow vaping in its terminals, then why should the state intervene with the force of law to prevent them?

4. Harassment of e-cigarette vendors through cigarette look-a-like prohibition

The policy of banning e-cigarettes because they look somewhat like cigarettes is absurd and abusive, and provides a regulatory protection to the cigarette trade by banning much safer products because they look similar. The bureaucratic harassment by health officials of an e-cigarette vendor in Western Australia for selling e-cigarettes on the basis that they violate laws designed to stop toy cigarettes that appeal to children is truly shocking in a modern liberal democracy.

The case of Mr van Heerden deserves some debate as his prosecution has almost destroyed his business and family finances³². Under Section 106 of the Western Australia Tobacco Products Control Act³³, products resembling tobacco products are banned (tobacco products are not banned)

106 .Products resembling tobacco products etc. not to be sold

A person must not sell any food, toy or other product that is not a tobacco product but is —

(a) designed to resemble a tobacco product or a package; or

(b) in packaging that is designed to resemble a tobacco product or a package.

The much safer product is banned and its vendor has been prosecuted under a law intended for a different purpose, yet the far more dangerous product remains on widespread sale. The officials involved in this prosecution chose to take enforcement action and to apply the law in a way that was never intended or envisaged when it was drafted.

Though this is a matter for states or territories, the Commonwealth should provide constitutional protections against such administrative bullying and arbitrary abuse of powers.

Conclusion

We would like to finish with the words of Dr Derek Yach, the former World Health Organisation Director for tobacco policy who led the effort to bring the global Framework Convention on Tobacco Control into being³⁴:

At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.

The approach that has been adopted in Australia has several malign effects

- a denial of individual rights to access a much safer alternative to a widely available legal but hazardous product;
- a likely long term negative impact on population health of Australian citizens;
- a wholly unjustified protection of the cigarette trade from competition from an emerging disruptive category;
- the impact of misinformation from public bodies and activists used to justify the approach;
- the risk that Australia will serve as an example of bad regulatory practice to others.

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- ³² See Mr Van Heerden's account of the case at the site he uses for raising funds for his defence; Ecigs. Our right not to smoke Tobacco [\[link\]](#)
- ³³ Western Australia, Current Acts. Tobacco Products Control Act 2006 [\[link\]](#)
- ³⁴ Yach D. E-cigarettes save lives. Commentary in *The Spectator*. February 2015 [\[link\]](#)