A critical review of an Australian anti-vaping polemic



John Maynard Keynes: "when the facts change, I change my mind. What do you do sir?"

Normally, I just ignore anything written by Professor Emeritus Simon Chapman, a retired academic and noisy tobacco control activist from Australia. It's usually just too error-laden and irritating to bother with and, on the 'bullshit asymmetry principle', one could spend a whole life correcting his endless misunderstandings and mistakes. But because the Australian parliament is considering these issues, I have made an exception for his latest piece of irresponsible anti-vaping propaganda.

This was published in the Sydney Morning Herald: <u>Keep TGA control of ecigarettes or risk repeating the smoking health disaster</u> 20 June, 2017. I hope the SMH will give some space to a credible Australian to provide its readers with a more realistic perspective. In the meantime, here is a critique of the article, with extracts of the original in quotation blocks and a commentary below each block.

Keep TGA control of e-cigarettes or risk repeating the smoking health disaster

Simon Chapman

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There is not a shred of evidence anywhere in the world that e-cigarettes could risk repeating the 'smoking health disaster' under any conceivable regulatory regime, including under no regime at all. This is reckless hype that sets the tone for the rest of the article. Even academics with no scientific background should be capable of understanding that almost all the of the harms caused by smoking arise from products of combustion of tobacco. With e-cigarettes there is no combustion, and so no products or combustion. Indeed the main toxicants of concern are either not detectable in e-cigarette vapour or are detectable at levels far below those found in cigarette smoke. There is plenty of evidence of greatly reduced risk (e.g. a sample here: link link) for those willing to acknowledge it. To overcome these inconvenient realities, an implausibly elaborate theory would be necessary to claim that e-cigarettes could be as dangerous as smoking. No such theory exists, other than in the raving imagination of anti-vaping fanatics.

Following intense lobbying from the tobacco and electronic cigarette industries and their supporters, the Minister for Health, Greg Hunt, has established a parliamentary committee to report on the regulation of nicotine vapourisers or e-cigarettes as they are widely known.

Sadly but predictably, Professor Chapman goes directly into innuendo about those who disagree with him, implying they are lobbyists, unwitting or otherwise, on behalf of industrial interests. But they just aren't. Look at the names lined up behind the position that opposes him and you will find they are academics and experts with a rich and diverse intellectual pedigree and great experience in tobacco control science, policy and practice. For example see <u>Submission to TGA by 40 experts</u> (Sept 2016) and <u>136 signatories</u> to a <u>letter to federal MPs</u> (May 2017) calling for action to correct Australia's perverse policy.

This move follows Australia's peak health and medical agencies, the Therapeutic Goods Administration and the National Health and Medical Research Council, recently conducting an inquiry and a publishing a statement on nicotine used in e-cigarettes.

Their decisions and conclusions angered e-cigarette lobbyists who argue that the nicotine liquid for use in e-cigarettes should be subject to "light touch" regulation, including removal from control of the TGA, which currently

schedules nicotine in anything but cigarettes and tobacco as a poison. This would open the way for e-cigarettes to be sold openly alongside groceries and confectionary; the door opened to what are now over 8000 flavouring chemicals, many with beguiling kid-friendly names; low tax to encourage use; advertising allowed to adults (some magic barrier prevents such advertising also being seen by children); and vaping permitted in any place where smoking has long been banned.

The quality of reasoning by the 'peak agencies' in reaching their decision was incredibly poor. The main argument against the current regulatory regime in Australia is that it means, in practice, that the only form of consumer nicotine product allowed on the Australian market is the most dangerous, namely "tobacco prepared and packed for smoking" i.e. a free ride for cigarettes, which are exempted from the poisons schedule that governs nicotine. The astonishing absurdity of allowing the most dangerous but banning the least dangerous alternative shouldn't require a complex explanation. However, detailed criticisms of the TGA's wholly inadequate reasoning were provided by many experts (example). E-cigarettes are widely available in Europe and the United States, where smoking has been falling rapidly – and among both adults and adolescents. There are millions of happy adult users and the sky hasn't fallen in.

The two core claims made about e-cigarettes are that in the 10 or so years since their debut, they have proved highly effective in stopping smoking and that they are "95 per cent safer than cigarettes".

Both of these have been strongly contested. The world's leading assessor evidence of therapeutic effectiveness, the Cochrane Collaboration, described the quality of the evidence about smoking cessation with e-cigarettes as "low" or "very low", because of imprecision due to the small number of trials.

Professor Chapman avoids stating where the claim 'highly effective in stopping smoking' comes from. It is not made by the manufacturers of these products, so they are not required to do studies necessary to prove a therapeutic argument they don't make. It is that simple. There is, however, <u>evidence</u> that:

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes

than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum.

Though Professor Chapman uses the <u>Cochrane Review</u> to dismiss evidence of any beneficial impact, Cochrane does find a benefit in electronic cigarettes (EC):

Combined results from two studies, involving 662 people, showed that using an EC containing nicotine increased the chances of stopping smoking in the long term compared to using an EC without nicotine.

The fundamental evidence issue is probably too subtle to debate with Professor Chapman, but it relates to the appropriateness of using randomised controlled trials (RCTs) to measure the impact of e-cigarettes. The impact of these products on smoking is determined by hundreds of factors other than just the product itself. RCTs are a poor way of characterising a technology disruption in a rapidly evolving marketplace governed by a complex network of behavioural influences for which it is impossible to control. Policies like tax, vaping bans and advertising restrictions have an effect. Scaremongering by irresponsible academics can shift perceptions of harm and cause people to give up vaping and revert to smoking, or never to try in the first place. In some countries, people find it hard to access reliable advice because, as in Australia, the products are banned or the government's aim is to suppress them. The impact may depend on a user journey through many types of device, liquids and vaping topography and may depend on influences from social media to a nearby friendly vape shop. None of the above lends itself to the kind of neat pharma studies that Professor Chapman is demanding.

There is a large number of smokers who could benefit from e-cigarettes in Australia but do not because they are *de facto* banned and difficult to access. It also is quite possible that Australia's effort to prohibit vaping products even harms those who do manage to access the products. One survey showed that e-cigarettes were less effective as alternatives to smoking in Australia than in the UK and USA because of the more restrictive policy environment: Yong HH et al Does the regulatory environment for e-cigarettes influence the effectiveness of e-cigarettes for smoking cessation?, NTR, 2017. Those are the questions that really demand research answers.

It is working well elsewhere. We have in the UK a large population of vaping ex-

smokers:

For the first time there are more ex-smokers (1.5 million) who use e-cigarettes than current smokers (1.3 million). Over half (52%) of e-cigarette users are now ex-smokers and 45% are smokers."

Alongside this we have rapidly falling smoking prevalence [ONS], and in England, adult smoking prevalence at 15.5% (ONS Adult Smoking Habits in Britain 2016) has now fallen slightly below Australia at 15.7% (NDSHS 2016 Data tables Table 3 cell S14) because declines in recent years have been more rapid than in Australia. People are freely choosing to use these products and finding them beneficial as alternatives to smoking. The point is that Professor Chapman wants to stop Australians having these products: the burden of proof this rests with him to justify this intrusive and abusive intervention, knowing it works well in other countries.

The "95 per cent safer" claim is nothing more than guesswork by a small handpicked group, convened with the support of a Swiss-based agency with ties to the tobacco industry. It cannot refer to any real-world health data because ecigarettes have only been used for a few years.

This is continuing a long-running misrepresentation of the provenance of this figure, which in slightly different forms is backed by two main sources: (1) the experts who worked for Public Health England on its <u>E-cigarette evidence update</u> (and explained in more detail for anyone who cares to look <u>here</u>) and; (2) the Royal College of Physicians in its extensive evidence review and report <u>Nicotine</u> <u>without smoke</u>: tobacco harm reduction April 2016.

Neither of these organisations or their expert groups have any involvement with the tobacco industry, and both reports would make good reading for anyone considering Australia's position on these issues. In both cases, the experts reviewed what is known of chemical and physical processes involved, the toxicology and biomarker data. They concluded that, on the basis of what <u>is</u> known, that they could justify a carefully worded conservative statement to inform perceptions of relative risk, useful to policy-makers and practitioners. For example the RCP said:

Although it is not possible to precisely quantify the long-term health risks

associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure". (Section 5.5 page 87)

The RCP and PHE experts are distinct and independent from the study Professor Chapman refers to. However, the organiser of that study says: "For the avoidance of doubt, I wish to confirm there was no tobacco company involvement in the funding or execution of the Nutt study." The embarrassingly desperate efforts to discredit Public Health England by reference to the tobacco industry, of which Professor Chapman's polemic is merely the most recent, are described here: Smears or science? The BMJ attack on Public Health England and its ecigarettes evidence review.

Smoking skyrocketed when cheap, affordable cigarettes first appeared early in the 20th century with the invention of mechanised rolling machines. Over the next 20 years, lung cancer remained an uncommon, even rare disease. It then began to rapidly increase but it was not until 1950 that definitive evidence was published that long-term smoking caused lung cancer, by far the most common form of fatal cancer today. Knowledge about other diseases followed.

If any scientist had declared in 1920 that cigarette smoking was all but harmless, history would have judged their call as dangerously incorrect. But this is the reckless call e-cigarette spruikers are making today, after just 10 years.

That's just a ridiculous exercise in hyperbolic analogy. A couple of things about modernity are worth noting: we have had 100 years of advancement in science since the early 20th Century, in particular in the detailed study of toxicology, cancer, cardiovascular disease and respiratory illness, and especially as caused by inhaling toxic cigarette smoke but also in occupational exposures. If one follows the logic of this "we just don't know" argument to its stupefyingly absurd conclusion, authorities would never permit any innovation in anything. It is important to recognise the most rudimentary fact of all: that we know the highly lethal properties of cigarette smoke exposure with great certainty. But tobacco control activists are trying to stop e-cigarettes entering the market because there might be uncertainty about exactly how much less risky than smoking they are. The ship is sinking fast but no-one can find the safety certificate for the lifeboat.

So let's all stay on board and drown instead!

The typical e-cigarette user inhales a vapourised mixture of propylene glycol, nicotine and flavouring chemicals deep into their lungs 200 times a day. Some inhale as many as 600 times a day. The heating of these ingredients changes their chemistry. A recent report in the Journal of the American Medical Association found that vapour released from a new "heat not burn" tobacco product produced volatile organic compounds like acrolein, formaldehyde and benzaldehyde in significant amounts.

E-cigarette vapour comprises micro- and nano-particles. There's little to no understanding of what the health consequences will be of deep inhaling these thousands of times a year across many years.

Yes, these effects are quite well understood. But all of these effects have to be compared with exposures arising from smoking. That's the key point, given that's what users buy them for. Even though e-cigarettes are quite different to 'heat-not-burn' products, the exposures to users are *much lower* compared to cigarettes for both heat-not-burn and e-cigarettes. Professor Chapman's phrase "in significant amounts" is not a recognisable construct in toxicology without reference to "compared to what?". If you would like to read a devastating critique of the methods, interpretation and spin in the <u>Auer paper</u> cited here by Professor Chapman by the manufacturer of the product in question, it is <u>here</u>.

The reference to particles is once again something that could confuse the reader: the vapour 'particles' in questions are liquid aerosol droplets and easily absorbed when inhaled – they are *very different* chemically and physically to the particles found in cigarette smoke or, for example, in diesel fumes. [For more see: Scientific sleight of hand: constructing concern about 'particulates' from ecigarettes]. After many years of use, there is little sign these products are causing any material problems and plenty that they are relieving symptoms of chronic diseases in smokers, for example here and here. If problems that are currently "unknown-unknowns" did somehow start to emerge, it would be more straightforward to address them because the chemistry of vapour is much simpler than that of cigarette smoke.

E-cigarette advocates argue that even if vapers don't quit smoking, many reduce how much they smoke. And surely, it's self-evident that halving what

you smoke must reduce harm? Unfortunately for commonsense, several very large longitudinal studies which have followed reducers over many years show that this is not the case. Only stopping confers significantly reduced smoking-caused disease.

First a clarification: most public health experts and practitioners who are supportive of e-cigarettes are not 'e-cigarette advocates'. They are focussed on 'harm reduction' as a public health strategy. This approach is well established in many other areas (drugs, alcohol, sexual health etc) but often opposed by 'abstinence-only' activists, so it is unsurprising to find resistance in the field of nicotine too. Supporters of harm reduction are not backing a particular technology, but a broad strategy to reduce risk to smokers and to continuing nicotine users – it is about trying to meet people where they are, not where bossy academics think they should be forced to go.

Now to the substantive point in this section. So-called "dual-use" is more complicated than Professor Chapman's simplistic made-for-media argument as presented in his polemic. Here are things to bear in mind about dual use:

- 1. Cutting down with an alternative nicotine source is different to cutting down without. This is because consumers are generally seeking a desired dose of nicotine and adjust their smoking behaviour accordingly. It is possible to cut down number of cigarettes and not actually reduce *exposure* because of a compensatory effect of smoking more intensively. Such an effect is less likely if there is an alternative nicotine source. It is impossible to generalise anything from the studies without alternative nicotine to situations where there is alternative nicotine, for example from e-cigarettes.
- 2. Dual use can be many different things nearly always vaping and occasional smoking, or the opposite. These are *completely* different behaviours and it is obvious that cutting down from smoking a pack a day to two cigarettes a week will make a significant difference to health.
- 3. Vapers who continue to smoke may be undergoing a longer-term transition from smoking to non-smoking the system is 'dynamic' and users may be moving through different stages that are not evident in a snapshot survey.
- 4. Almost everyone who quits smoking by any method carries on smoking for

months or years while they do it - this is because success rates are so low with all established methods including NRT, prescription drugs, behavioural support and 'cold turkey'. People will quit and relapse back to smoking multiple times before they finally quit, if they ever do.

5. Unless a product was 100% immediately successful, and nothing is, then some sort of dual use or continued smoking is inevitable – so an artificial and unrealistic expectation has been fabricated to imply some kind of inadequacy in these products – a straw man – given it applies equally to everything else done in tobacco control.

None of this real-world complexity features in his polemic.

Australia introduced drug regulation in 1963 following the thalidomide tragedy. The TGA and its predecessors have had responsibility for the evaluation, regulation and scheduling of any product where therapeutic claims are made.

Ah yes, do I detect a sly little smear-by-association? The TGA is protecting Australia's smokers from risks like those arising from powerful immunotherapeutics that happen to have iconic teratogenic effects. Nice effort, but I see what you did there.

Quack claims about cures for deadly and common diseases like cancers, HIV/AIDS and asthma have long been with us. But we don't allow those with an alleged cancer cure to by-pass the TGA assessment process and sell and promote a substance as cancer-curing simply on the strength of "this is so important" emotional rhetoric designed to put it above regulatory, consumer-protecting red tape.

Vaping advocates walk on both sides of the regulatory street. When it suits, they highlight claims about the therapeutic value of e-cigarettes in quitting. But when they are asked for high- quality evidence, they deny e-cigarettes are therapeutic and switch to premature "less harmful than cigarettes" arguments.

Quack claims? He just seems unable to discuss the issue without throwing around petulant insults. Does he really think the Royal College of Physicians are 'quacks'? This is what their experts <u>say</u>:

E-cigarettes are marketed as consumer products and are proving much more

popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.

His argument is just sophistry – using evidential hurdles to keep people from having what they think would work for them. There are other forms of regulation than the system operating in Australia, which misclassifies these products as medicines or poisons. The 'less harmful than cigarettes' argument may not appeal to Professor Chapman, but to my knowledge he isn't a smoker or one of those at greatest personal risk, so perhaps from his position of comfort and safety, he doesn't give as much weight to 'less harmful than cigarettes' as they do?

There is something not quite believable about all this apparent concern for the health and wellbeing of vapers and smokers, and Professor Chapman's determination to 'protect' them from what they say they want. If he cared, wouldn't he listen first to them on the *nothing about us without us* principle? It would be a surprise if he was acting in their interests as vapers and smokers perceive them, given he was co-author of the The Worst Letter of 2014 and countless other examples of *ad hominem* attacks on vapers too dire to repeat here. Perhaps he has other objectives, such as 'defeating industry', whatever that now is? It is not uncommon for leaders in tobacco control to be confused about what they are trying to do or to have unsurfaced objectives, see: Who or what is the WHO at war with?

They argue that if e-cigarettes makers had to convince the TGA on safety and effectiveness, only Big Pharma and Tobacco could afford to conduct the research to the standards required. This may well be true. But the alternative — to allow any backyard "kitchen chemist" maker of vaping equipment and ingredients to sell and promote their products without TGA regulation – is an outrageous proposal that would set a very dangerous precedent.

Having read this statement, it's unclear to me whose interests Professor Chapman holds dearest, those of Big Pharma or Big Tobacco. It is certainly true that both industries have prospered through huge regulatory barriers to entry of the form favoured by Professor Chapman. But it is surprising that he believes the only alternative to these behemoths is a kitchen-based industry. A minute of research

would have informed him that is not the case.

Barely a day passes without a new reports of e-cigarette explosions causing serious burns. Nearly all airlines ban e-cigarettes because of the potential disaster that could follow such an explosion and fire on board. Without regulation of this cowboy industry, it is only time before this occurs.

Yes, there are a few rare sensationalised reports of e-cigarette accidents and naturally Professor Chapman avoids quantification other than "barely a day passes" (updated: see MJ McFadden comment on the truth in this claim). Not mentioned in the article is the carnage of smoking related fires. This data from the United States, for example [link], shows the scale of the problem and suggests vaping may also function as a harm reduction approach to smoking-related fires and injuries. (I don't have data for Australia):

In 2011, U.S. fire departments responded to an estimated 90,000 smoking-material fires in the U.S., largely unchanged from 90,800 in 2010. These fires resulted in an estimated 540 civilian deaths, 1,640 civilian injuries and \$621 million in direct property damage; deaths were down substantially from the year before.

Almost all harm reduction advocates want a sensibly regulated industry, not laissez faire. Beyond his lazy insult, there is nothing to suggest that Professor Chapman is right to describe it as 'a cowboy industry'. As in any industry, there

will be a few cowboy *firms*, but it is the purpose of sound regulation deal with them.

Every major tobacco company has invested in e-cigarettes and made statements urging smokers to migrate to e-cigarettes. Only those with weapons-grade naivety swallow their nonsense. Their statements are empty public relations gestures because all these companies continue to aggressively oppose any tobacco-control policy like excise tax and plain packaging with proven ability to reduce smoking. They want people to smoke and vape, not vape instead of smoking.

When in doubt (or in this case, in desperation) invoke Big Tobacco and get back to that most comfortable of comfort zones for tobacco controllers. Look at the technique here: chest-beating and crowd-pleasing rhetoric is used to fend off any critical thinking and to evoke the familiar Manichean struggle that has driven them on for decades. Those who suggest something different is happening in the market are dismissed as naïve, making it hard to see how Professor Chapman would notice if something different was actually happening in the nicotine market. But it is Professor Chapman who is the naïf. He seems to know next to nothing about the functioning of markets and competition. If he did, he would understand that tobacco companies can't get people to vape and smoke, even if they wanted to (explained here: Pariahs, Predators or Players). If you'd like to see Professor Chapman being flayed by someone who really does understand markets and the companies, see these polite but devastating takedowns by investor and analyst, Jon Fell link link.

Australia's smoking rates have never been lower in both adults and children. Our achievements place us in the frontline of nations reducing smoking. Tobacco control is the crown jewel of successful chronic disease reduction. To remove nicotine regulation from the TGA would be to learn nothing from the historic failure to regulate cigarettes. The argument being made is "cigarettes are an unregulated disaster and are freely available. Let's take the same route with e-cigarettes."

No, the argument is that just under 16%, or 1 in 7 of Australian adults still smoke, so let them have access to products that will do them far less harm and that many would choose to use if Professor Chapman and others weren't blocking their way.

Vaping is about expanding the range of options available to stop smoking. Again, it is absurd and reckless to make claims of equivalence between smoking and vaping.

Professor Chapman hasn't mentioned that progress in Australia has slowed and rates of decline in smoking have been more rapid in the UK and USA since the emergence of vaping products in those countries. And this has happened despite Australia's adoption of Professor Chapman's preferred policies of plain packaging and very high taxes. Australia's much-vaunted 'leadership' is slipping away as technology, innovation and consumer choice are taking over from coercion and punishment.

Australia's successful efforts to reduce smoking have had multi-party support for 40 years. All parties must affirm the regulatory expertise and authority of the TGA and encourage manufacturers of vapourisers to submit their evidence-based applications for TGA approval, as manufacturers of any product making therapeutic claims must do. If these products are as effective and safe as claimed, they will have nothing to fear.

It seems a strange political gambit to remain stuck in the past. Why is it that "all must parties reaffirm" that they are backward-looking and determined to carry on doing what has been done for 40 years even when things are quite different now? None of this can divert from the fundamentals – Australia allows cigarettes onto the market wholly untroubled by the TGA. The TGA's medical regulatory framework provides huge barriers to entry to much safer vaping products, even though these products are not medicines, the manufacturers do not make therapeutic claims and they used by people who do not consider themselves in treatment. This is 'anti-proportionate' regulation and harming Australians by denying them the right to make reasonable choices that can control their own health risks. All parties would be better off ignoring Professor Chapman and giving priority to the health and wellbeing of Australian citizens.

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Retired academic, Professor Simon Chapman should take more of his free time to think carefully about what he is doing and consider the consequences – and more

importantly the lethal unintended consequences – of trying to impede smokers' access to much safer products than cigarettes through excessive and inappropriate regulation. The approach is anti-scientific and unethical. It protects the cigarette trade and harms public health.

Let me finish with the <u>cautionary words</u> of the Royal College of Physicians, explaining how easy it is for the likes of Professor Chapman to cause harm through their actions:

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.

However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. (Section 12.10 page 187)