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Standing Committee on Health, Aged Care & Sport
House of Representatives
PO Box 6021
Parliament House
Canberra ACT 2600
Australia

Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

Please accept this submission to the Inquiry:

Credentials to Comment

This submission is personal and represents my own views as Managing Director of JCIC International Ltd, a London based management consultancy advising both public and private sector on public policy issues primarily in the areas of international regulation, tobacco harm reduction, supply chain security, anti-illicit trade and sports integrity. Additionally, I co-chair an OECD Committee relating to security and international public private partnerships. I am also a regular commentator and presenter on tobacco regulatory issues.

My credentials to comment on the subject matter of this Committee inquiry come primarily from the writing of a LLM Dissertation in 2007 at Kings College University of London titled: *Emerging International Public Health Issues – Human Rights, Harm Reduction and the Framework Convention on Tobacco Control (FCTC)*. Additionally, I held the roles of International Regulatory Affairs Manager and International Health Affairs Manager during ten years at British American Tobacco London between 2001 & 2011 responsible for advising the company on the development of the global tobacco control treaty (FCTC). Also, I worked for entrepreneur Dick Smith with ASH Australia on the *Truth-in-Ad Campaign* against tobacco industry advertising in the late 1980s. I have 20 years of tobacco and nicotine policy and regulatory experience at the international level.

Other relevant personal experience comes from time spent in the Executive as an Assistant Director in International Legal Section of the Australian Department of the Prime Minister & Cabinet including working in various multilateral policy forums, attending the World Summit for Social Development with PM Paul Keating; and latterly working directly with Bob Hawke on a post-ministerial international project. Also I spent time in the Legislature as Chief of Staff to Senators Richard Alston and Jocelyn Newman in various portfolios; as well as Chief of Staff to Kate Carnell as Leader of the Opposition in the ACT, and to Gary Humphries Attorney-General. I am Australian but I

have lived outside of Australia for 20 years. I visit Australia from time-to-time and I am responsible for bringing various reduced risk tobacco products to Australia to help my recently heavy-smoking brothers to stop smoking - due to the unavailability of alternative products in Australia.

SUMMARY OF KEY POINTS

- Australia needs to recognise and address the fact that its policy thinking on tobacco and nicotine is outdated, unscientific and detrimental to public health. Australia currently permits only the most harmful of tobacco products to be freely sold – cigarettes. Scientific evidence demonstrates unequivocally that the harm from smoking cigarettes comes from the tobacco smoke and not from nicotine, and that it is essential therefore that smoke-free alternatives be available for sale in Australia.

- From a policy and regulatory perspective create two categories of product:

    - Category 1) **smoke producing (combustible) products** [cigarettes, cigars, cigarillos, pipe tobacco, roll-your-own] recognising that combustion causes the smoke which is what causes the harm; and

    - Category 2) **smoke-free (non-combustible) products** – vapour producing products [nicotine vapour (e-cigarettes); tobacco vapour products (heat-not-burn), Swedish Snus (smokeless tobacco products) and other novel tobacco and nicotine products] recognising these different alternative reduced risk products will appeal differently to different consumers and it would be wrong to enable only one choice.

      Each category may have in due course its own spectrum of risk, once science and research establishes clear evidence. However, until that granularity can be established, all smoke-free alternative products should be considered as being much safer than smoking.

- Ensure that in any legislation/regulation that the definition of a harm reduction or reduced risk product is not so narrow as to favour any particular product or category, or which may have the effect of stifling innovation or development of new novel products; or that would prevent consumers from making a free choice of which product works best for them as an alternative to smoking.

- Ensure that any regulation of tobacco and nicotine products, does not favour one industry and its products over another. This recognises that different products work for different consumers and one-size-does-not-fit-all in shifting consumers from cigarettes to smoke-free alternatives.

- Aim to achieve a smoke-free Australia by 2030 by enabling smoke-free alternatives to cigarettes as soon as possible, regulated and legislated at the Federal level.

- Regulate reduced risk tobacco and nicotine products as consumer products which meet acceptable standards rather than medicinal products, which follows the UK example. Remove nicotine e-liquid from the category 7 poisons list as soon as possible.

- In order to shift smokers to reduced harm alternatives as fast as possible enable reasonable communication and marketing of reduced harm alternatives and ensure taxation policy is considered so as to drive consumers to reduced risk alternatives.

- Ensure that all policy decisions in relation to tobacco and nicotine are made on the basis of evidence, science and consumer insight of what works to quit or reduce consumption. Australia

should look to international example, particularly the UK Royal College of Physicians, Public Health England, ASH UK etc.

- Australia needs to enable its medical and scientific institutions to carry out nicotine and tobacco research more freely than is currently possible. The current limited approach stifles innovation and potential scientific and medical breakthroughs.

- Lift the ban on oral Swedish snus smokeless tobacco - deemed by almost every eminent and respected scientific and health body globally to be the least harmful of all products after more than 50 years of epidemiological scientific evidence. Swedish snus is endorsed as a recommended harm reduction product by the Royal Australasian College of Physicians (RACP) and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) in their "*Tobacco Policy - Using evidence for better outcomes*" 2005 publication.

- Australia must recognise the principle of harm reduction with respect to smoking (as it does with drugs with safe-needles, seat-belts, condoms to prevent AIDs etc., by accepting that not all smokers can quit or want to quit; and that these people have a right to information about and access to less harmful alternatives to smoking. This recognises the right that all people (including the mentally ill, indigenous and low-income persons) which have a statistically higher propensity to smoke) to achieve the highest attainable standards of physical and mental health in line with international treaty obligations ratified by Australia.

COMMENTS ON COMMITTEE INQUIRY TERMS OF REFERENCE

My comments focus on two sections of the Committee Inquiry:

- Section 3 - **International approaches to legislating and regulating** the use of E-cigarettes and personal vaporisers; and

- Section 4 - **The appropriate regulatory framework** for E-cigarettes and personal vaporisers in Australia;

Section 3 - International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers; and

In considering international approaches to legislating and regulation the use of e-cigarettes and personal vaporises, it is important to outline for the Committee the international tobacco control regulation from which global tobacco policy is drawn. This will demonstrate the harm reduction principles contained within it, including the human rights principles, with which all Parties to the international law, including Australia, should be implementing national regulation to meet their international obligations. It is also important to then to look to how other countries are meeting these provisions in the context of national policy and regulation. My comments are structured under the following three areas:

1. International Regulation and Australia's Treaty Obligations
2. Human Rights and the FCTC
3. Lessons from the UK

1. International Regulation and Australia's Treaty Obligations

In setting an appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia, it is essential that the Committee consider Australia's international obligations under the first health

treaty negotiated under the auspices of the World Health Organisation - the Framework Convention on Tobacco Control 2005 (FCTC). Australia took part in negotiating the FCTC between 2000 and 2003, signed it on 5th December 2003, and ratified it on 27th October 2004 thereby indicating its intention to transpose the treaty provisions into national law. The FCTC entered into force as international law for Australia on 27th February 2005 and it currently has 180 Parties including Australia.

As a Party to the FCTC, Australia is required to implement national tobacco control measures to meet its treaty obligations. To date Australia has taken a leading role in FCTC implementation, including measures to implement FCTC Article 8 regarding public smoking bans; and has been a global leader in implementing FCTC Article 11 packaging and labelling obligations, with its introduction of plain packaging measures. However, on the FCTC requirements to implement harm reduction strategies as part of national tobacco control measures [FCTC Article 1 (d)] Australia has been silent and appears to ignore the requirement.

FCTC Article 1(d) defines what is meant by "tobacco control". The definition includes harm reduction strategies. Recognising that the harm from tobacco products comes from the combustion or the smoke and not the nicotine, most scientific experts concur that the harm reduced product category generally includes all smoke-free alternatives including nicotine vapour (known as e-cigarettes) and tobacco vapour products (known as heat-not-burn) as well as Swedish Snus (pasteurised oral smokeless tobacco).

FCTC Article 1

Use of terms

For the purposes of this Convention:

(d) **"tobacco control"** means a range of supply, demand and **harm reduction strategies** that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;

By not permitting any smoke-free alternatives to cigarette smoking at present, Australia does not appear to recognise the concept of harm reduction in its tobacco control laws and regulations, and there is nothing in Australian legislation or regulation that encourages harm reduction alternatives. Instead Australia permits only the most lethal option – cigarette smoking.

It is also apparent that Australia's current regulatory situation is not aligned with the FCTC treaty's objective which requires that Parties provide a **national framework of tobacco control measures** so as to reduce tobacco related harm. Given that "tobacco control" includes harm reduction strategies, Australia should not be denying Australians the right to information about and access to reduced harm smoke free products, such as nicotine and tobacco vapour products as well as smokeless tobacco products.

FCTC Article 3

Objective

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing **a framework for tobacco control measures** to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

It is important also to note in the FCTC objective the word "reduce" in the context of the framework of tobacco control measures as this also infers a concept of reduction which is at odds with those that seek to interpret the FCTC as having a cessation only approach. The Committee has the opportunity to recognise both these elements by recommending that Australia's future regulatory framework takes into consideration the need for reduced harm products including nicotine and tobacco vapour products so as to meet its international obligations and to ensure the future public health of Australians.

In addition, the FCTC treaty provides for Parties in Preamble recital 21 to change course and promote new methods of tobacco control on the basis of time, scientific development and innovation; and makes clear that considerations that were current and relevant when the FCTC was created – in 2000 to 2003 – 17 years ago are no longer current or relevant today.

> ***Preamble***
>
> The Parties to this Convention,
>
> **(21)** *Determined* to promote measures of **tobacco control** based on current and relevant scientific, technical and economic considerations,

As well, the FCTC requires Parties in Preamble recital 22 to learn from each other and to cooperate in the fields of scientific, technical and legal experience in order to implement the objectives of the treaty - and yet Australia remains behind many of the leading governments in accepting scientific developments and accepting and implementing the principles of harm reduction in the protection of public health. The FCTC makes very clear that implementation requires of a strong legislative foundation to protect from exposure to tobacco smoke.

> ***Article 22***
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> *Cooperation in the scientific, technical, and legal fields and provision of related expertise*
>
> 1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and Parties with economies in transition. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, **to establish and strengthen national tobacco control strategies, plans and programmes aiming at, *inter alia*:**
>
> (a) facilitation of the development, transfer and acquisition of technology, knowledge, skills, capacity and expertise related to tobacco control;
>
> (b) provision of technical, scientific, legal and other expertise to **establish and strengthen national tobacco control strategies, plans and programmes, aiming at implementation of the Convention through, *inter* *alia***:
>
> (i) assisting, upon request, in the development of a strong legislative foundation as well as technical programmes, including those on prevention of initiation, promotion of cessation and **protection from exposure to tobacco smoke**;

The effect of the non-recognition of harm reduction by Australia has been not only the denial of the right to choose alternative products or the right to information on which to base choice, but the right for research to be done to advance scientific knowledge to develop the information on which to understand and base risk decisions.

2. Human Rights and the FCTC

In taking part in the three years of negotiations to create the FCTC, as well as signing and ratifying the treaty at its conclusion, Australia took on the requirements to meet the human rights obligations contained within it. These are delineated in the FCTC's Preamble, the area of a treaty used to outline a treaty's overriding principles. Recitals 1, 19 and 20 of the Preamble are very clear about the human rights that the Parties accept and must protect in relation to tobacco control and public health. It is significant that the FCTC Treaty opens with the right to protect public health and that this is a determined priority of the Parties. If this is the case, why does the Australian government not permit reduced risk alternative tobacco and nicotine products?

The FCTC recalls the rights of Parties under Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) which Australia ratified on 10th December 1975. This obliges Australia in both the International Covenant and the FCTC to protect the "right of everyone" (including smokers) to the highest attainable standard of physical and mental health. If smokers can't or don't wish to quit smoking, is it not their right to have information about and access to reduced risk alternatives as a means of enabling them the highest attainable standard of health? In

Australia, upwards of 70% of the mentally ill community smoke cigarettes, and for this group nicotine is an essential and beneficial part of daily life. Yet Australia's mentally ill in institutional care are not permitted to smoke in public buildings or outdoor areas, and this adds great stress and anxiety not only to mentally ill patients but also to carers.

Australia is a member of the World Health Organisation and agreed to its constitution on 2nd February 1948, accepting that the highest attainable standard of public health is a fundamental right of every human being. Australia is denying its human rights obligations in this area though its inability to accept the tobacco harm reduction concept and permitting Australians only to access the most harmful tobacco product – cigarettes. The Committee should therefore, ensure that these obligations are taken into consideration in its deliberations regarding a new regulatory framework for tobacco and nicotine products, and ensure that it really is determined to give priority to the right to protect public health.

FCTC Preamble

The Parties to this Convention,

(1) Determined to give priority to their **right to protect public health,**

FCTC Preamble

The Parties to this Convention,

(19) Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the **right of everyone** to the enjoyment of the **highest attainable standard of physical and mental health**,

FCTC Preamble

The Parties to this Convention,

(20) Recalling also the preamble to the Constitution of the World Health Organization, which states that the **enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being** without distinction of race, religion, political belief, economic or social condition

FCTC Preamble

The Parties to this Convention,

(10) Deeply concerned about the high levels of smoking and other forms of tobacco consumption by **indigenous peoples**,

When the FCTC preamble recalls the International Covenant on Economic, Social and Cultural Rights, which provides for *'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*', and the preamble to the WHO Constitution, which states that *'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being…*' did it really mean to deny rights to smokers, including mentally ill and indigenous smokers by omitting the whole issue of harm reduction? No, it didn't and this must be rectified. They could still be consuming cigarettes, or could be consuming other forms of tobacco and nicotine in substantially safer forms that could dramatically reduce their risks for premature death and disease.

If Australian consumer health advocates and tobacco policy makers are, as they have stated, genuine in wanting to secure a right to health for everyone, then it is anomalous to premise all regulation on the highly improbable goal of complete cessation instead of a combination of cessation and the provision of the least risky options. The FCTC itself already provides the legal framework for the inclusion of tobacco harm reduction, all that is required is political will. In summary:

1. The promotion of reduced harm tobacco and nicotine products constitutes tobacco control.
2. Parties to the FCTC (currently 180 governments) have an obligation to implement national harm reduction measures.
3. It is the duty of governments, (public health), to promote any and all strategies that are necessary for, or incrementally conducive to (however small) , the "highest attainable

standard of health" , which includes any harm reduction strategy that aims to improve health by reducing consumption and /or exposure.

4. There is an obligation on FCTC parties to not only allow reduced risk products, but to actively promote them as part of implementing their tobacco control policies.
5. Cooperation in scientific and technical fields is essential.
6. The tobacco control framework referenced in the FCTC objective, should include all products that are deemed to reduce risk. This would therefore include vapour products (nicotine and tobacco), Swedish snus, and other new nicotine products yet to emerge – to reduce the collective harm from tobacco smoke.

3. Lessons from the UK

The United Kingdome (UK) leads the world in acceptance of tobacco harm reduction as policy. The government, the tobacco control NGOs, the public health advocates, the e-cigarette industry, the tobacco industry, the consumers, the academics, the scientists and the politicians all appear to work closely together or are at least on the same page. I don't believe that it was planned, but when all stakeholders are in pursuit of the same outcomes positive things happen.

The UK has regulated vapour products as lifestyle consumer products rather than as medicinal products. This enables products to be developed from any size commercial manufacturers, start-ups to big-tobacco companies – anyone who meets the standards. If the UK had chosen the medicinal pharmaceutical regulatory route it would have limited the market to only those large companies with enough resources to be able to spend the required money to fund clinical trials. Australia should do the same as the UK has done. The e-cigarette industry was built on small start-up consumer driven companies, which continue to play a dominant role despite the entry of tobacco companies into the market. It appears that there is room for all as consumers make choice from a wide variety of products.

The UK was instrumental at the last FCTC Conference of the Parties (COP7) of ensuring that e-cigarettes were not banned in WHO FCTC recommendations. Many of the WHO member States were seeking to ban e-cigarettes (one may argue for trade protection reasons rather than public health reasons) but regardless of that the UK, its NGOs and academics collectively did their best to educate the Parties of the benefits of e-cigarettes and reduced risk with a positive outcome. In effect, the world owes the UK for its efforts.

At the Global Forum on Nicotine 2017, which took place in Warsaw in June it was announced that between 2010 and 2016 UK prevalence of smoking had dropped from 20% to 15.8%. In the USA, it had dropped from 19% to 15.1%, but in Australia in spite of plain packaging and the highest cigarette prices in the world, Australia's prevalence had slowed showing 18.9% to 15.8%. And that in the last three years where the UK has been continuing to drop, based on switiching to alternatives, Australia has plateaued.

The UK permits both nicotine and tobacco vaping. There are numerous vape stores around the country and a flagship IQOS store in London. Doctors and the medical community are encouraged to recommend alternative products as a backup to cessation. The debate is healthy. Swedish Snus is not yet legally permitted, however, there is currently a case before the European Court of Justice brought be the UK regarding the legality of banning Swedish snus whilst permitting e-cigarettes in the context of a European Directive banning snus and allowing e-cigarettes and cigarettes. Many believe, therefore it may only be a matter of time.

The UK is adhering to a rational template of health regulation by offering cigarette smokers a viable alternative to total nicotine abstinence. My strong view is that the Australian Committee or some of its members should undertake a fact-finding mission to the UK. The benefit of having first hand insight from the UK regulators, the NGOs, the academics, public health, and other relevant

stakeholders would be of immense value to the Committee in making its deliberations and recommendations.

Section 4 - The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia;

In setting an appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia, it is important that the Committee fully consider the concept of tobacco harm reduction and its value to the future protection of public health in Australia. Secondly, the Committee should also take in to consideration all currently available alternative products that may reduce risk rather than limiting the scope, and thirdly it should consider the policy framework of the UK which is demonstrating international leadership in the area of tobacco harm reduction.

In general terms, a harm reduction policy or approach seeks pragmatic rather than absolutist solutions such as free condoms and needles to help prevent the spread of AIDS – an alternative option to reduce the harm from the given activity. According to Robert Wallace in his Institute of Medicine testimony to the US House of Representatives (2003) '*Tobacco harm reduction refers to decreasing the burden of death and disease without completely eliminating nicotine and tobacco use*.'

1. Reduced Risk & Product Categories

From a regulatory perspective, I believe there are two primary categories:

- Category 1) **smoke producing (combustible) products** [cigarettes, cigars, cigarillos, pipe tobacco, roll-your-own] recognising that combustion causes the smoke which is what causes the harm, and:

- Category 2) **smoke-free (non-combustible) products** – a) vapour producing products [nicotine vapour (e-cigarettes); b) tobacco vapour products (heat-not-burn), c) Swedish Snus (smokeless tobacco products) and d) other novel tobacco and nicotine products] recognising these different alternative reduced risk products will appeal differently to different consumers and it would be wrong to enable only one choice.

Each category may have in due course its own spectrum of risk, once science and research establishes clear evidence. However, until that granularity can be established, all smoke-free alternative products should be considered as being much safer than smoking. To paraphrase what leading Canadian tobacco control activist, Professor David Sweanor, says: we can all assume that jumping out of a plane with a parachute is safer than jumping out of a plane without a parachute - we don't need clinical trials to tell us that. Similarly, we know that it is the smoke that causes the harm, so it ought to be intuitive that using tobacco and nicotine without smoke is going to reduce harm.

With this principle in mind, it is therefore important to ensure that any regulatory framework that may define a harm reduction product or a reduced risk product is not so narrow as to favour any particular product or category, or which may have the effect of stifling innovation or development of new novel products; or that would prevent consumers from making a free choice of which product works best for them as an alternative to smoking. The following smoke-free alternative products should all be made legally available in Australia as soon as possible:

a) Vapour Products [e-cigarettes]: Vapour released from a battery-operated device used to heat a mixture of nicotine liquid, propylene glycol and flavour. The nicotine in nicotine liquid is derived from the leaf of a tobacco plant, although more expensive synthetic mixtures can be made. E-cigarettes can be disposable or consist of a refillable tank as part of a device which is the most

common choice. It is against the principles of harm reduction and Australia's FCTC obligations for Australia to continue to regulate nicotine e-liquid as a category 7 poison. The UK Royal College of Physicians concluded and advised in its 2016 report: **Nicotine without smoke: tobacco harm reduction**, that "*e-cigarettes are likely to be beneficial to UK public health. Smokers can therefore be reassured and encouraged to use them, and the public can be reassured that e-cigarettes are much safer than smoking."* There is consensus among the UK public health community including ASH UK and Public Health England, that e-cigarettes are less harmful than smoking and that they should actively be promoted.

b) Vapour Products [Heat-not-Burn]: Vapour released from a battery-operated device used to heat , but not burn, mini tobacco sticks containing sheets of prefabricated tobacco inserted into the high-tech device. The nicotine in heated tobacco comes from the natural tobacco itself. IQOS the most common heat-not-burn product was launched in Japan in 2016 where e-cigarettes are not permitted. In less than a year approximately 10% of the Japanese tobacco market has switched to IQOS. IQOS is not available in Australia, however, I took my long-term smoking brothers one each from the UK IQOS store early this year. Both stopped smoking within a month - one used IQOS to cut down and quit and the other uses IQOS 100%. If I don't post him IQOS tobacco sticks from the UK he would return to smoking.

It is apparent that both kinds of smoke-free vapour products can be successful in switching smokers and both should be available in Australia as alternatives to smoking.

c) Swedish Snus [Pasteurised Smokeless Tobacco]

Swedish snus is a unique product that is different from any other form of smokeless tobacco product such as the oral tobacco products found in the USA and India. Swedish snus is pasteurised (heated) during the manufacturing process which reduces the harmful tobacco nitrosamines found in other forms of oral tobacco. Snus is packed into a tiny "teabag" which a consumer puts into his/her mouth under the gum and nicotine is received buccally without any smoke or vapour. Snus is a tobacco product where epidemiological evidence shows unequivocally that it not harmful when compared with smoking according to many scientific studies over more than 50 years including the UK Royal College of Physicians. Sweden has the lowest death rate from tobacco related disease in Europe by a significant margin because Snus is legal and widely used in Sweden compared to other European countries where only cigarettes are permitted.

Indeed, the Royal Australasian College of Physicians (RACP) and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) state in the harm reduction section of their ***"Tobacco Policy - Using evidence for better outcomes***" publication 2005 that: *"…relapse could also be prevented if satisfying forms of non-cigarette nicotine were available. Such measures are complementary parts of a comprehensive smoking tobacco control program. Oral tobacco is much less dangerous than cigarette smoking. When sourced from Sweden ('snus'), oral tobacco is less toxic than when sourced from South Asia.Currently, commercial import from any country is prohibited in both Australia and New Zealand. Both countries are well-placed to permit only the importation of 'snus'. Oral tobacco carries a reduced mortality risk (10 per cent) compared with cigarette smoking*.

Professor Simon Chapman is a significant Australian public health advocate at the School of Public Health, University of Sydney. His 2007 book titled: *Public Health Advocacy – Making Smoking History*, contains a chapter on harm reduction and product regulation. Although the book is now ten years old, Simon was ahead of his time in promoting the benefits of a harm reduction approach (although some of his recent commentary appears to have abandonded his earlier published views). On page 77 he says: *"For many years, I counted my role in the ban (of snus) as one of my most tangible achievements in public health. But today in 2006, I ask myself whether I was wrong…"* Significantly Dr Chapman goes on to say: "*In my view, the strongest argument advanced by LNST (low nitrosamine smokeless tobacco) advocates is the argument for consumer sovereignty in having the right to be informed about the potential of reduced risk from LNST, and being able to exercise*

choice on the basis of that information. As Kozlowski and colleagues sum it up: 'Individuals who do use or who are thinking of using cigarettes have a right to know that smokeless products are safer than cigarettes."

In considering a regulatory framework for reduced risk alternative products Australia should lift its ban on Swedish snus as it would not be justifiable to permit vapour products without it.

d) Novel nicotine and tobacco products

The development of innovation nicotine delivery devices, science and technology are moving at a rapid pace and in an environment that enables innovation and scientific research, novel products will emerge. I am aware of a number of small companies that have tried or would like to develop products in the novel nicotine area but cannot get investment due to the uncertainty of the regulations – which results means only large companies with significant resources are able to get products into the market. Australia needs to enable its medical and scientific institutions to carry out nicotine and tobacco research more freely than is currently possible. The current limited approach stifles innovation and potential scientific and medical breakthroughs.

2. Policies to Shift Smokers from Cigarettes to Reduced Risk Alternatives

A regulatory framework will need to ensure that policy drives smokers to use less harmful alternatives in order to achieve Australia's public health objectives, but in an environment where advertising is banned and the population has little information or knowledge about tobacco alternatives or tobacco harm reduction (the public and the medical community) this will be difficult and policy will need to address it. It may be that the government carries out its own public awareness raising campaign, or commercial enterprises can advertise openly within clear guidelines, or that dedicated vape and alternative product shops (where no children are present) can educate consumers, or a government communication campaign to raise awareness among GPs and the medical and psychiatric community and for them to communicate to consumers may be appropriate.

Dr Simon Chapman raises this issue in earlier referenced book in Chapter 4 on tobacco harm reduction in the section on page 98 titled: **How will consumers be informed about the new less dangerous products?** He says:*" Under the model of influencing consumer demand, the core concern would be that there would be little point in developing reduced-harm products if consumers could not somehow be informed about their existence and the characteristics that justified their claims to harm reduction.*" It will be important for new Australian policy to take account of this.

Also, it will be important for policy not to close off access to flavours for nicotine liquid. Many vapers advise that certain flavours are or were helpful to making the switch from smoking, while others advise that the natural tobacco flavour of an IQOS or a snus made the switch easier as it was more like what they were used to. Different consumers will find different flavours helpful and these choices should not be regulated so as to prevent reasonable choice.

Taxation is another important issue that a regulatory framework must consider. Clearly the treasury will need to collect tax and ensure transition from lucrative cigarette taxation to alternatives but the level should not be set at a rate that may prohibit smokers from financially making the switch. Excise tax is applied to cigarettes in Australia at approximately 70-75% and together with GST this is a significant revenue for the government. Australia will need to ensure that the taxation applied to reduced risk products encourages smokers to make the transition, rather than hinder them.

FINAL COMMENTS

Australia has the potential to jump directly from having arguably the developed world's most detrimental policy on tobacco harm reduction, to being a leader in harm reduction policy as it has been in drugs harm reduction, if it were to apply the same thinking to tobacco and nicotine and permit cigarette alternatives as consumer products. Australia could take leadership role, not just in packaging but with the product itself if it were to aim to be truly smoke-free by 2030, and put in place the appropriate policy and regulation to achieve it.

Unfortunately, the Australian health department appears to be invested in the well-rehearsed arguments against tobacco being harmful in any form, and that introducing qualifications into the regulatory picture is viewed as politically incorrect. The Department of Health is responsible as the lead government agency to implement all Australia's FCTC obligations, not to pick and choose those that it doesn't like. It appears not to want to countenance opening up a potential door for the commercial exploitation in Australia of any new tobacco product alternatives – even ones that are up to 95% less risky to consumers than smoking. The Australian Heath Department unfortunately appears to believe that cessation and complete de-normalisation of tobacco and nicotine is the easiest and safest regulatory approach. But this view is challenged by significant global commentators in the public health and tobacco control community.

Known as the 'architect of the FCTC', and former head of the World Health Organisation's Tobacco Free Initiative, South African epidemiologist Dr Derek Yach said **"***In 20 years, if we are lucky, only 20% of the world's population will still be smokers – equivalent to 1.3 billion smokers. And what is to be done with them? What is crucial here is getting them to use less harmful products than they do today…In the future it must be possible for companies to develop and market products which are demonstrably less harmful than the products of today. This is why regulation requires plenty of thought.'*[1]

And, Canadian Professor of Law and Public Health, Professor David Sweanor said: *"We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for the nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.'*[2]

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6 July 2017

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[1] *MondagMorgen* Denmark: The world's true state of health is shocking 2006:

[2] Tobacco Harm Reduction: how rational public policy could transform a pandemic International Journal of Drug Policy 2007 David Sweanor, Faculties of Law and Medicine, University of Ottawa,