CAPHRA
Coalition of Asia-Pacific Tobacco Harm Reduction Advocates

17 October 2020

Committee Secretary
Select Committee on Tobacco Harm Reduction
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600
AUSTRALIA

I am writing to you on behalf of the Coalition of Asia Pacific Tobacco Harm Reduction Advocates (CAPHRA). We submit this white paper to specifically address the issues presented in the terms of reference by the Select Committee for Tobacco Harm Reduction formed by the Australian Parliament.

Items covered by this submission are:

1. Youth Vaping and the Gateway Theory
2. Cardiovascular health effects of Vaping
3. Secondhand Exposure to Vape Aerosol
4. Evidence of Harm Reduction in Safer Nicotine Products
5. Concerns around nicotine and its' effects in people under the age of 25.
6. The call to ban all flavours in nicotine e liquid to remove appeal to youth.

We finish our submission with the case for Risk Proportionate Regulation – utilizing New Zealand as an example.

If you have any questions or concerns, please do not hesitate to contact us. Thank you again for the opportunity to make this submission

Kind Regards,

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Issues Presented:

In the following sections, we address the concerns of the Minister of Health with the presentation of evidence based information and scientific guidance to address the main concerns presented by the minister and the TGA with regards to the risk proportional regulation of Safer Nicotine Products that is currently being discussed.

1. Youth Vaping and the "Gateway Effect" the presumption that youth who vape will go on to using combustible tobacco.

According to Dr. Linda Bauld, who is the lead researcher for the Cancer Research Council and Public Health England on the use of electronic cigarettes in youth and by pregnant women, the data do now show that youth vaping is an "epidemic" as has been touted in the media. Also, **youth who vape are coming to vaping FROM smoking**, not the other way around.[5] Dr Bauld has stated - repeatedly - that **youth and pregnant women are more inclined to switch to vaping from smoking and not the other way around.** There is no evidence that youth are using vaping as a gateway to smoking. **There is no evidence that the nicotine in electronic cigarettes has the same detrimental effect on pregnant mothers and their children as does smoking during pregnancy**.

Another study, done in the US entitled "Adolescents and e-cigarettes: Objects of concern may appear larger than they are" by Kozlowski and Warner stated unequivocally that "The role of e-cigarettes in the future of youth smoking has yet to be definitively assessed.

2. Cardiovascular/Cerebral Health Harms (Heart Attack/Stroke) from Vaping. Recently there was a study on electronic cigarette users to determine their risk for heart attack and stroke. *"Daily e-cigarette use, adjusted for smoking conventional cigarettes as well as other risk factors, is associated with increased risk of myocardial infarction."*. In the media, coverage of the conference abstract mentions: *"E-cigarettes linked to higher risk of stroke, heart attack, diseased arteries."* This study published by the University of Southern California had major flaws in methodology and reporting.

Action on Smoking and Health UK even commented on the problems with the study and conclusions stating "This study does not establish a causal relationship between heart attacks and the use of e-cigarettes. Rather it shows that at the point they were surveyed people who smoked and/or vaped were more likely to have had a heart attack in their lifetime. The study was not able to determine when the heart attack took place, whether it followed or preceded use of an e-cigarette. It is therefore inaccurate to say this research shows that vaping leads to an increased risk of a heart attack. The link between tobacco smoking and heart attacks is well established."

According to Dr. Konstantinos Farsalinos, a cardiologist and researcher from Greece, "Increasing the risk" means that someone is FIRST exposed to a condition (in this case, exposed to e-cigarette use) and THEN, BECAUSE OF THIS EXPOSURE, he/she develops disease. **Both studies CANNOT provide any of this information to substantiate an increased risk.** Both are cross-sectional surveys, meaning that they asked participants if they have heart disease and if they use e-cigarettes.

The studies provide no information on whether e-cigarette use was initiated before (and how long before) or after the development of disease. What if participants used e-cigarettes after they developed the disease to quit smoking?

"In conclusion, both studies provide no information about any risk associated with the use of e-cigarettes. **They do not prove an increased risk and of course they do not prove that no such risk exists.** They simply cannot address the question of whether e-cigarettes increase the risk for heart disease or not. I am confident that the authors of the published study and the American Heart Association, which released the press statement for the conference abstract, are very aware of these basic epidemiological principles. This is simple, basic knowledge for a medical student, let alone for acknowledged scientists. And they know that the statements about "increased risk" are wrong."

A five-year study done by Dr. Riccardo Polosa, in Italy found that non-smokers who vaped, had **no increases in markers of cardiovascular risk, lung function and or symptoms of respiratory disease.**[9]

Another study done by Dr. Polosa in smokers suggested that E-cigarette (EC) use may **ameliorate objective and subjective COPD outcomes and that the benefits gained may persist long-term. EC use may reverse some of the harm resulting from tobacco smoking in COPD patients.** These include **reduced blood pressure, fewer exacerbations of chronic obstructive pulmonary disease (COPD) and improvements in asthma symptoms.**

In the United States, the National Academy of Sciences, Engineering and Medicine published their own report entitled "Public Health Consequences of E-Cigarettes"[11] where they stated clearly that ***"There is insufficient evidence that e-cigarette use is associated with long-term changes in heart rate, blood pressure, and cardiac geometry and function."***

Experts: Konstantinos Farsalinos, MD (Greece) & Riccardo Polosa, MD (Italy)

3. Concerns around Effects of Second/Third Hand Exposure of Vapor/Aerosol. According to experts at the US Department of Health and Human Services, there are no quantifiable harms from second/third hand vapor/there is no additional harm from vaping in those who have been exposed. This has been studied extensively by a few different researchers in different projects.

The first presented is that done by the US Department of Health and Human Services entitled
"Evaluation of Chemical Exposures at a Vape Shop" The work involved "Our primary objective
was to evaluate employees' potential exposures to chemicals associated with vaping in the shop. Our work involved (1) sampling air for specific flavoring chemicals associated with respiratory disease; (2)sampling air for nicotine, propylene glycol, formaldehyde, and other VOCs; (3)sampling work surfaces for metals and nicotine; and (4) observing work practices." The conclusion from the study states "Employees were exposed to detectable levels of diacetyl and 2,3-pentanedione in the air while working in the vape shop. Although the measured concentrations were below all applicable OELs…"

Expert: US Department of Health and Human Services (USA)

4. Evidence of Harm Reduction in users of Safer Nicotine Products. Evidence of Harm Reduction has been scientifically proven, most notably those done and reviewed Public Health England - the National Health Service, the Royal College of Physicians[14] (United Kingdom) and University College and King's College London[15].

Both studies done by University College and King's College London and the Royal College of Physicians have shown a 95-98% reduction in the harm compared to that of combustible tobacco. As Michael Russell said over 30 years ago, it is the TAR that kills, not the nicotine. Alternative nicotine products do not involve combustion, which is what creates TAR.

These studies have been followed up and reviewed regularly by Public Health England, in 2015, 2016 and most recently in 2018. This is the basis for the National Health Service promoting the use of Alternative Nicotine Products in lieu of smoking on hospital grounds in various locations throughout the country, the promotion and use of Alternative Nicotine products within their smoking cessation programs and also the provision of these products in prisons to alleviate the currency of tobacco, as well as the health harms of smoking, to the prisoners and staff.

Expert: Royal College of Physicians, United Kingdom, UK Centre for Tobacco and Alcohol Studies (UK)

5. Concerns that nicotine contained in Alternative Nicotine Products is detrimental to those under the age of 25. As far back as 2003, researchers were studying and evaluating the effects of nicotine on the adolescent brain and its effects on development. These studies were carried out on adolescents who obtained nicotine via the use of combustible tobacco. **The method of delivery has a distinct effect on the addictiveness of nicotine in both adults and youth, as the chemical constituents of the additives in commercially available combustible tobacco products potentate the addictive qualities of nicotine**[16].

This is why, in many countries, including the United States, United Kingdom, Canada and New Zealand, the age for prescribing Nicotine Replacement Treatment begins as early as 12 years old, based on a recommendation from the American Cancer Society, in 2010, that stated **"that youth (ages 12-18) be included in smoking cessation initiatives, recognizing that support and encouragement are important for this age group in particular"**

It needs to be noted that in the Australia the age to prescribe NRT is 12. NRT is also readily available over the counter in the entire country and there is no requirement for age verification.

Therefore, two main features are at play here with regards to the claim that nicotine is dangerous to the developing brain - the first is that nicotine, as delivered through combustible tobacco, is potentiated by the additives and processing of combustible tobacco products and that the combustion itself is what is detrimental to this method of delivery; secondly, the provision of Nicotine Replacement Therapy to adolescents has been shown to NOT be detrimental to the developing adolescent brain, hence the recommendation to prescribe NRT to youth smokers.

Lastly, the age of adolescence, in the global medical field, is from the age of 12-18. If combustible tobacco products are available to adults 18 and over, there is no reason why the harm-reduced alternatives of nicotine consumption should be restricted differently.

Expert: Royal Society of Physicians (UK), National Cancer Society (United States)

6. The call to ban all flavours outside of Tobacco in E Liquid to restrict appeal to Youth.

A study done by Farsalinos, et al. showed that **flavours are necessary for adult smokers to find vaping a sufficient substitute to combustible smoking**. "*A major characteristic of the electronic cigarette (EC) market is the availability of a large number of different flavours. This has been criticised by the public health authorities, some of whom believe that diverse flavours will attract young users and that ECs are a gateway to smoking. At the same time, several reports in the news media mention that the main purpose of flavour marketing is to attract youngsters. The importance of flavourings and their patterns of use by EC consumers have not been adequately evaluated, therefore, the purpose of this survey was to examine and understand the impact of flavourings in the EC experience of dedicated users.*" The findings of this study concluded that "*The results of this survey of dedicated users indicate* ***that flavours are marketed to satisfy vapers' demand. They appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking****. Due to the fact that adoption of ECs by youngsters is currently minimal, it seems that implementing regulatory restrictions to flavours could cause harm to current vapers while no public health benefits would be observed in youngsters. Therefore,* ***flavours variability should be maintained; any potential future risk for youngsters being attracted to ECs can be sufficiently minimized by strictly prohibiting EC sales in this population group.***"

Expert: Konstantinos Farsalinos, MD (Greece)

The Case for Risk Proportionate/Pragmatic Regulation - New Zealand

We take this opportunity to first present to you the example of Aotearoa/New Zealand. They are currently in process of implementing risk proportionate regulation that addresses the same concerns that the current Australian Minister of Health, the officials at the Therapeutic Goods Administration and the Royal Australasian College of Practitioners hold with regards to harm reduced products such as youth uptake, cardiovascular/respiratory harm, second and third hand aerosol exposure and the effects of nicotine on the brains of those younger than 25 years of age.

In a white paper[2] written by the former head of ASH NZ, Professor Robert Beaglehole et al, addressed how to reach the government's goal of SmokeFree Aotearoa by 2025 addressing these contentious issues using statistical and scientific facts. What makes this paper so groundbreaking is that all the authors are experts in Public Health, Tobacco Control and most have affiliations with and were architects of the FCTC treaty.

The underlying theme of the paper is that the harm reduction concept is endorsed in Article 1 of the World Health Organization Framework Convention on Tobacco Control (FCTC) and is supported by many scientists and policy experts world-wide. They remind the reader, and the New Zealand government, that harm reduction is a complement, not an alternative, to established tobacco control approaches and works by giving smokers additional and more appealing options to quit smoking.

“We advocate a surge strategy based on driving down smoking by facilitating smokers to switch to smoke free alternatives such as vaping products, heated tobacco and smokeless tobacco products. These smoke free alternatives present much lower health risks compared to cigarettes and with the right tax structure can ease financial pressures on smoking households, mitigating both health and economic inequities.”

Furthermore, they state “The concept of a public health surge is drawn from management of disasters and emergencies where a rapid increase in capability is essential to meet immediate demands. We argue that the concept can be applied to long-running chronic emergencies where a rapid change relative to business-as-usual is necessary – in this case to meet a target that will otherwise be missed.”

The concepts presenting in this paper are very appropriate to the situation in Australia, as the harms from combustible tobacco are higher than compared to New Zealand (economies of scale population wise).

It needs to be noted that New Zealand's Ministry of Health also took into serious consideration the testimony and concerns of the former smokers who are now consumers of these products in New Zealand as part of the development of the regulations currently under consideration.

The Ministry of Health made a conscious effort to engage with and seriously consider the effects that punitive regulation would have on the people of New Zealand who had chosen to move away from combustibles. They wanted to learn and know how the use of these products have benefitted the consumers and their families. They also took into consideration the importance of choice - for flavours and multiple nicotine strengths, access and availability issues, in order to understand how these choices had assisted these adult smokers successfully switch to the less harmful alternatives available to them.

Then, the MoH called for statistical and scientific evidence to back up what the consumers had told them of their experiences and effects to their physical health. And the FACTS were then confirmed officially by the experts they had called upon.

As noted above, the New Zealand government is currently devising the regulatory framework for consumer nicotine products. It has the opportunity to introduce world best-practice by developing a framework for risk-proportionate regulation for smoke free alternative nicotine products.

Key features of the new framework include some of the following:

- Differentiation between smoked and smokefree products. A comprehensive framework would cover all forms of consumer nicotine products. The key differentiator for policy purposes is whether the product is for smoking. Combustion is far more important than the distinction between tobacco and non-tobacco products. Smokefree tobacco and nicotine products can displace smoking and greatly reduce health burdens. It follows that they should be treated differently to smoked products – reflecting opportunity as well as risk.

- Recognising that flavours play an important role. Flavours are integral to the appeal of smokefree alternatives and an essential part of the proposition to smokers to try switching and remain smokefree. They also raise concerns about attracting non-smoking youth. We recommend focussing controls on marketing, branding, and flavour descriptors rather than on banning particular flavour chemicals or categories (except where there are safety concerns).

- Warning and packaging labels should convey accurate information including messages that explain relative risk. Warnings should not be misused to scare users out of trying products that could be lifesaving for them. They should be focussed on helping smokers make better-informed decisions by communicating relevant risk information, including

risks relative to smoking, ideally using a range of statements authorised by health officials.

- Public health agencies will provide well-crafted communications to help smokers make informed choices. Public health communicators should engage all relevant stakeholders in communicating risk and the case to switch from smoking to smokefree products.

None of the foregoing could have been accomplished had the main stakeholders, the consumers, not been an equal and integral part of the development of the regulatory framework, along with public health officials, scientists, and other stakeholders.

CONCLUSION:

In conclusion, we implore all the involved public health officials and government ministers to consider the scientific evidence and facts when making the decision to regulate Safer Nicotine Products. We remind them that their mandated responsibility is to promote the health and wellbeing of all the citizens of Australia. Lastly, we offer our assistance to them, to provide information, expert advice, and guidance in developing regulation, which it is hoped will be risk proportionate and progressive. Please find an addendum with statements regarding the issues presented from Internationally respected authorities on the issues presented herein.

ADDENDUM:

American Cancer Society, February 15, 2018

"*Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes, but the health effects of long-term use are not known.*"
"*Many smokers choose to quit smoking without the assistance of a clinician and some opt to use e-cigarettes to accomplish this goal. The ACS recommends that clinicians support all attempts to quit the use of combustible tobacco and work with smokers to eventually stop using any tobacco product, including e-cigarettes. Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible, switching to the exclusive use of e-cigarettes are preferable to continuing to smoke combustible products.*" Link:
https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html

American Heart Association, 24 August 2014

"*If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt.*" Link:
https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000107

American Association of Public Health Physicians, 2 April 2010

"*AAPHP favors a permissive approach to E-cigarettes because the possibility exists to save the lives of four million of the eight million current adult American smokers who will otherwise die of a tobacco-related illness over the next twenty years.*" "*E-cigarettes can and should be marketed as a substitute for conventional cigarettes for smokers unable or unwilling to quit.*" Link:
https://www.aaphp.org/special/joelstobac/2010/harmredcnupdatejuly2010.html

National Academies of Sciences, Engineering and Medicine, 2018

"*E-cigarette aerosol contains fewer numbers and lower levels of most toxicants than does smoke from combustible tobacco cigarettes.*"
"*Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.*"
Link: https://www.nap.edu/read/24952/chapter/2

Public Health England, 6 February 2018

"*Risks of cancer, cardiovascular disease, and respiratory diseases due to ECs are expected to be reduced compared with smoking because toxicants and carcinogens present in cigarette smoke are absent or present at much lower concentrations in EC aerosols.4,16 Although not without risk, the overall risk of harm is estimated at less than 5% of that from smoking tobacco;4 the risk of cancer has been calculated to be less than 1%.16*"
Link:
https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review

PATH study by FDA in the US (prospective study of using e-cigarettes and subsequent change in smoking status)

"*After adjusting for covariates, cigarette smokers who initiated e-cigarette use between waves and reported they used e-cigarettes daily at wave 2 had 7.88 (95% CI 4.45 to 13.95) times the odds of 30-day cigarette cessation compared with non-users of e-cigarettes at wave 2. Cigarette smokers who began using e-cigarettes every day and did not achieve cessation had 5.70 (95% CI 3.47 to 9.35) times the odds of reducing their average daily cigarette use by at least 50% between waves 1 and 2 compared with e-cigarette non-users.*" Link: https://www.ncbi.nlm.nih.gov/pubmed/29986104