

Australian Senate Select Committee on
Tobacco Harm Reduction
Parliament House
Canberra
AUSTRALIA

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PUBLIC SUBMISSION

AUSTRALIAN SENATE SELECT COMMITTEE ON TOBACCO HARM REDUCTION

"If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement. This would only be the case if the recruitment of minors and non-smokers into the nicotine-dependent population is no higher than it is for smoking, and eventually decreases to zero. (Paragraph 5)

**WORLD HEALTH ORGANISATION, FCTC/COP/7/11
Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems 2016**

The Australian Senate Select Committee on Tobacco Harm Reduction will enquire into tobacco harm reduction strategies, with particular reference to Australia's current regulatory frameworks; international examples; the impact of vaping on smoking rates; and tobacco industry involvement in the selling and marketing of e-cigarettes. The Committee asks submitters to outline the issues and how they can be addressed. The Committee's powers allow it to report to Parliament with recommendations for changes to legislation, regulation and government policy. In line with this expectation, this submission by Juul Labs outlines and discusses these issues, as well as proposes recommendations for the Committee to consider as part of its deliberations.

About Juul Labs

Juul Labs was founded and is based in the United States, and it is operational in various countries. Our mission is transitioning the world's billion adult smokers away from combustible cigarettes, eliminating their use, and combating underage usage of our products. To accomplish that mission, we are committed to working with governments, regulators, and other stakeholders in all of our markets to create a responsibly regulated and adequately safeguarded vapour category.

Juul Labs believes robust and appropriate regulatory oversight is required for the nicotine vapour category, and that it should be designed to be proportionate to the risk of these products relative to combustible cigarettes. At the highest level, all countries should adopt risk-proportionate frameworks

that guard against access and appeal of all nicotine products to underage users, while facilitating the transition of adult smokers to less harmful products.

1. Tobacco Harm Reduction

The best way for smokers to reduce risk to their health would be to quit all tobacco and nicotine. Many, however, will not. The overwhelming majority of harm associated with smoking comes from combustion. When a cigarette is lit, the burning of tobacco, paper and additives produces smoke, which carries more than 7,000 chemicals, about 150 of which are known toxicants. The repeated inhalation of toxicants in cigarette smoke, not nicotine, is the primary cause of smoking related death and disease.

Nicotine is addictive and can cause harm; but in 2020 there are alternatives to cigarettes for nicotine delivery, and which can be delivered on a continuum of risk. Products that burn tobacco such as cigarettes have the greatest risk, and products that deliver nicotine without burning tobacco carry lesser risk of harm. Such products include those that heat tobacco known as heat-not-burn, those that produce nicotine vapour such as e-cigarettes, and pasteurised oral smokeless tobacco known as Swedish Snus.

A growing number of public health experts and scientists have concluded that delivering nicotine without smoke could prevent most of the harms associated with cigarette smoking. Removing the smoke is a fundamental principle of tobacco harm reduction. However, products that present less risk than smoking can only improve overall public health if significant numbers of adult smokers switch completely from using combustibles like cigarettes to these non-combustible products. For this to happen, non-combustible products must be able to compete with cigarettes. Adult smokers need access to alternative products and accurate information about these products.

Global experience shows that no single non-combustible product will be acceptable or work for all adult smokers. Therefore, policy makers should ensure that a diverse category of non-combustible alternatives be made available to those who would otherwise continue to smoke. This requires clear pathways to market for non-combustible products so that they are widely available as an alternative to smoking. Such regulatory pathways should include standards that ensure products meet quality and safety requirements, but they should not serve as de-facto bans or maintain the market dominance of existing tobacco products for smoking.

Government policy should not be so narrow as to favour any particular product or category of non-combustible product or favour any manufacturers or industry. Nor should government policy have the effect of stifling innovation or development of new novel products, or of preventing adult consumers from making an informed choice as to which non-combustible product works for them as an alternative to smoking.

At present in Australia, it is only combustible cigarettes and Nicotine Replacement Therapies (NRT) such as nicotine patches and gums produced by the tobacco and the pharmaceutical industries, that are legal. Effectively these industries are protected by Australia's policies, which are not realising the public health benefits available through developments in technology.

Unlike the UK, the US, Canada, the EU and New Zealand, adult smokers in Australia are denied access to or information about the potentially less harmful options to smoking cigarettes. The effect of the non-recognition of tobacco harm reduction by Australia has been not only the denial of the right of Australian adults to choose alternative products or the right to information on which to base choice, but Australian scientists and public health researchers are denied carrying out scientific research to develop information on which to understand and base risk decisions.

2. Risk Proportionate Regulation

Many smokers have used cigarettes for years, if not decades. For them, behavioural change is difficult. To encourage switching, non-combustible products must be able to compete with cigarettes. Regulation should recognise advances in technology and ensure that tobacco control policies incentivise access to the potential health benefits of these non-combustible products rather than favour combustible cigarettes.

Risk proportionate regulation should be applied to all tobacco and nicotine-containing products by applying the most restrictive regulation to the most harmful products, and less restrictive regulation to the products that present less risk. Risk proportionate regulation should both push smokers away from cigarettes, by making them less appealing, and pull those who find it difficult to quit towards non-combustible alternatives.

Risk proportionate regulation should:

a) Ensure Non-Combustible Products Deliver Nicotine at Comparable Levels to Cigarettes.

To successfully switch from cigarettes, adult smokers need a product that delivers acceptable levels of nicotine to reduce cravings and the urge to smoke. Regulation should ensure that non-combustible alternatives in the marketplace can do this to position them as a product that delivers acceptable nicotine while delivering less exposure to toxicants than cigarettes.

Some countries have implemented limits on the nicotine concentration of liquids in e-cigarettes. These limits, originally intended to allow early e-cigarettes to deliver nicotine at levels comparable to a cigarette, present a barrier to innovation. Today, smaller devices that operate at lower power levels and produce less aerosol have proved effective at switching smokers. However, these devices require higher concentrations of nicotine in e-liquids to deliver nicotine that can compete with cigarettes.

Rather than enabling competition from non-combustible alternatives, these restrictions protect cigarettes from competition – a missed opportunity to encourage adult smokers to switch. Instead of regulating based on the concentration of nicotine in e-liquids, countries that seek to regulate nicotine levels should do so on the basis of nicotine absorption through well-conducted pharmacokinetic studies. This basis for regulation more accurately reflects product and behavioural variables impacting nicotine delivery.

b) Allow Flavours in Non-Combustible Products

Flavours can help non-combustible products compete more effectively with cigarettes. Scientific evidence shows that flavours help adult smokers switch completely from cigarettes. However, there is a crucial balance to be struck with respect to risk of underage use. Where flavoured non-combustible products are available, they must be marketed in a way that can effectively inform adult smokers while limiting appeal and access to those who are underage. For example, youth orientated flavour descriptors, packaging and marketing should not be permitted.

c) Permit Accurate Information about Non-Combustible Products to Enable Smokers to Make Informed Decisions about their Health

Regulation of communications should ensure that adult smokers know that non-combustible alternatives are available, how they work, how they compare to cigarettes and who should not use them. Equally important is that smokers need to know why they should switch. Misperception of the risks of nicotine and non-combustible products prevents them from competing effectively with cigarettes. Communicating accurate, scientifically substantiated information about the potential benefits of non-combustible products improves smokers' chances of switching completely. Regulations should allow such communications, if they are properly substantiated. Ultimately, scientists and public health experts are the most credible messengers for health information, and can help the public, including smokers, understand the difference in risk between products that burn tobacco and those that do not.

d) Ensure that Fiscal Policies Encourage Smokers to Move Away from Cigarettes

Fiscal policies that create price differentials are powerful tools that can help push adult smokers away from cigarettes and pull them toward non-combustible products. A risk-proportionate taxation system would apply the highest taxation to the most harmful products while levying a much lower, or no excise tax on non-combustible products.

e) Recognise that Nicotine Products need Access Control

Regulators, policymakers, manufactures and the supply chain must work together to ensure that all tobacco and nicotine products are used only by adults and that appeal to underage persons is limited. Access control mechanisms that limit purchase to adults, such as those used currently with cigarettes, alcohol and other age-gated products can be instituted, as well as other more technological solutions that require ID to purchase, should be used.

Innovation has created a new portfolio of non-combustible products with the potential to dramatically change public health in the tobacco and nicotine sector. But to fully realise the opportunity presented, regulation and policy must encourage and incentivise adult smokers to move down the risk continuum, rather than to penalise them, or to prohibit less harmful alternatives as Australia currently does. A comprehensive risk-proportionate regulatory approach can put the end of the age of cigarettes within reach.

Many governments including NZ and the UK have stated their intention to achieve that by 2030. The World Health Organisation's Tobacco Free Initiative (TFI) also supports this principle.

"Tobacco product regulation must be evidence-based, suited to the needs of the country in question, and regularly monitored and reviewed for effectiveness, taking account of new evidence and knowledge to meet regulatory targets. (Page 19)

"For countries where novel TRPs are permitted, health authorities should at a minimum:

- *consider the possibility of message diversification in the case of potential harm reduction products, and/or legislation, in line with the fact that nicotine is delivered through products that represent a continuum of risk, and is most harmful when delivered through combusted products (21), while avoiding creating an overall impression that other tobacco products are without risk;"* (Pages 55-56)

WHO TFI, Tobacco Product Regulation: Basic Handbook, 2018

3. Australia's International FCTC Treaty Obligations to Protect People from Exposure to Tobacco Smoke

Australia became a Party to the Framework Convention on Control (FCTC) treaty on 27th October 2004, after participating in the treaty's multilateral negotiation between 2000 & 2003. The FCTC treaty, with 182 global Parties, nearly all of the WHO's 194 government membership, establishes in international law the regulatory framework for governments to set national tobacco control policy.

On becoming a Party to the FCTC, Australia has agreed to be bound in international law to implement national tobacco control policy measures in line with the treaty's framework. To date Australia has taken a leading role in FCTC implementation, including measures to implement Article 8 regarding public smoking bans; and has been a global leader in implementing the Article 11 packaging and labelling obligations with its introduction of plain packaging measures.

However, Australia has fallen behind in meeting the provisions and obligations relating to tobacco harm reduction. The FCTC definition of "tobacco control" in Article 1(d) is: *"a range of supply, demand and harm reduction strategies that aim to improve the health of the population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."*

The objective of the FCTC, as outlined in Article 3, is: *"to protect present and future generations from the devastating health, social, environmental 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."*

Further, in the context of a framework of tobacco control measures it is important to note the word "reduce" and "reducing" referenced in the above treaty Articles, as this infers a concept of reduction which is at odds with an interpretation of elimination only - the policy and regulatory path which Australia is following. The FCTC recognises that government policy should include harm reduction in

the measures nationally implemented. The definition of “tobacco control” in Article 1(d) states: *“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 the consumption of tobacco products and exposure to tobacco smoke.”* Australia is actively ignoring this fundamental provision by implementing only supply and demand measures.

The guiding principles of the FCTC are outlined in Article 4. These provide the principles by which the FCTC’s objective (above) should be met. Article 4.1 outlines the principle of information that people should have to be informed: *“... the mortal threat from tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke”.* Article 4.2 talks about the need for strong political commitment necessary to develop and support the objectives; and categorical in its intent is Article 4.2(a) which requires: *the need to take measures to protect all persons from exposure to tobacco smoke*.

It is interesting that the Australian government administration strictly adheres to FCTC Article 5.3 requiring governments to protect public health policies from commercial and vested interests of the tobacco industry, yet it chooses to ignore the FCTC provisions above requiring public health policy to protect people from exposure to tobacco smoke. By not permitting any smoke-free alternative consumer products to cigarettes, Australia does not appear to recognise the concept of harm reduction in its tobacco control policy and has not maximised the range of policy measures that are available to protect Australians from exposure to tobacco smoke. Instead it permits only the most lethal option – the combustible cigarette.

4. Australia’s International Human Rights Obligations with respect to Health

Australia also accepted the human rights obligations in the FCTC treaty when it became a Party. The FCTC’s human rights obligations are outlined primarily in the Preamble. Recitals 1, 19 and 20 are very clear regarding protection of public health. It is significant that the opening line of the FCTC reads: *“The Parties to this Convention, determined to give priority to their right to protect public health.”*

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 and which states: *“that it is right of everyone to enjoyment of the highest attainable standard of physical and mental health”.*

Also, the FCTC recalls the WHO Constitution to which Australia became a member and ratified on 2nd February 1948. The WHO constitution states: *“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...”* Australia was also instrumental during the FCTC negotiations to in ensure that these provisions noted deep concern regarding the high levels of smoking by indigenous peoples.

These human rights provisions require the Australian government to protect the right of everyone, including smokers. If smokers can’t quit, is it not their right to have access to smoke-free products to enable them to enjoy the highest attainable standard of health?

5. Comparisons with Global Governments on the Treatment of Nicotine Vaping Products

Australia's policy thinking on tobacco and nicotine is not in keeping with modern health economies such as the UK, NZ, EU, Canada and the US in so far as it prohibits rather than regulates vaping products. By comparison, Australia permits only the most harmful tobacco product – cigarettes. It permits NRT as the only nicotine alternative for smokers, although one which has not proven successful to the same extent as vaping products. While Australia has taken a restrictive path, by comparison both New Zealand and the United Kingdom have instituted national tobacco control plans which support tobacco harm reduction and both countries have aims to be Smoke-free by 2030.

New Zealand (NZ)

The New Zealand Parliament recently passed the Smoke-free Environments and Regulated Products (Vaping) Amendment Act 2020. The purposes of the Act include reference to a harm reduction approach *"to support smokers to switch to regulated products that are significantly less harmful than smoking..."* The legislation does not treat nicotine as a prohibited substance, rather the Act treats nicotine as a harmful constituent. The New Zealand approach focuses on the reduction of harm caused by the toxic constituents when a combustible cigarette is ignited by providing for less harmful alternatives.

The New Zealand Parliament has sought to strike a balance between its overarching objectives, including to prevent appeal of non-combustible products to underage people, while also ensuring flavours can be made available to support adult smokers in their transition from combustibles to less harmful alternative nicotine delivery systems. The New Zealand legislation focuses on discouraging people from smoking, encouraging them to quit and regulates the control of marketing, advertising, and promotion of tobacco products in order to improve public health.

The 2017/18 New Zealand Health Survey reported 2.6 percent of New Zealand adults vape daily and 18.5 percent have tried an electronic cigarette at least once. According to the 2018 Census, the proportion of regular cigarette smokers in New Zealand aged 15 years and over decreased to 13.2 percent, down from 15.1 percent in 2013. In 2018, 1 in 8 people stated they were daily cigarette smokers. Census General Manager Kathy Connelly said that: *"These changes are likely due to a number of factors, including rapidly rising costs of tobacco, a lower number of young adults taking up smoking, an increase in smoking alternatives such as vaping, and recent stop-smoking programmes"*.

United Kingdom (UK)

The UK government and Public Health England actively encourages smokers to switch to vaping for health reasons and the government runs TV campaigns to support nicotine vaping and support its policy objectives such as the annual **"Stoptober"** challenge during the month of October. The UK government also has a reduced level of VAT tax for vaping products as compared to cigarettes.

The England National Health Service (NHS) stated in its Live Well-Quit Smoking Report of 2019. *"Many thousands of people in the UK have already stopped smoking with the help of an e-cigarette. There's growing evidence that they can be effective."* The NHS Health Scotland in its 2017 e-cigarette consensus statement said: *"There is now agreement based on the current evidence that vaping e-*

cigarettes is definitely less harmful than smoking tobacco. Thus, it would be a good thing if smokers used them instead of tobacco."

UK data in terms of the impact of nicotine vaping on smoking rates is compelling. According to Professor David Levy et al, 2020: England SimSmoke: the impact of nicotine vaping on smoking prevalence and smoking-attributable deaths in England, *"An indirect method of simulation modelling indicates that substantial reductions in smoking prevalence occurred in England from 2012 to 2019 coinciding with the growth in nicotine vaping product use."*

The UK Smoking Toolkit Study, an ongoing series of monthly surveys of the population of England, has shown a clear association between changes in population rates of quitting smoking and prevalence of e-cigarettes use after adjusting statistically for a range of potential confounding factors. If the association is causal, e-cigarettes were responsible for an estimated 69,930 additional ex-smokers in England in 2017. According to the most recent 2020 Trends in electronic cigarette use in England: Smoking Toolkit Study the current use of e-cigarettes by never smokers remains very rare and similar to the use of licensed nicotine products. According to ASH e-cigarette briefing in 2019, only 0.8% of never smokers are current vapers.

Despite nicotine vaping being permitted in the UK for many years there has been no increase in youth smoking and vaping cannot be said to be a gateway to smoking. According to the UK NHS report on Smoking Drinking and Drug Use Among Young People Regular smoking of at least one cigarette a week among 11-15-year olds in England, it was 5% in 2010, 3.1% in 2014 and 2.7% in 2016 (the most recent year for data). According to the 2019 Smoking Toolkit Study, smoking prevalence among 16-18-year olds in England was 17% in 2010 and 12% in 2018.

According to the Vaping in England 2020 report commissioned by Public Health England, nicotine vaping in youth is mainly concentrated in young people who have experience of smoking. Less than 1% of young people who have never smoked are current vapers. According to the 2019 ASH Smoke-free GB Youth Survey, children under 16 are less likely to try e-cigarettes than 16-18-year olds, and 8.5% of 11-15-year olds have tried vaping, compared to 26.7% of 16-18-year olds. In addition, a large majority of never smokers age 11-18 (93.8% in total) have either never used an e-cigarette (87.8%) or are not aware of them (6%). Of young people aged 11-18 years old who have never smoked, 5.5% have ever tried e-cigarettes, 0.8% are current vapers, only 0.1% vape more than once a week, and not a single never smoker reported vaping daily. Although regular use of e-cigarettes has grown it continues to be rare in young people aged 11-18. In 2019, 1.6% of respondents said they use e-cigarettes at least weekly with another 3.3% using them less than weekly.

A comprehensive analysis funded in part by the US National Cancer Institute, examined the relationship between vaping and smoking among youth and young adults. The study published in the journal Tobacco Control, shows that cigarette smoking dramatically decreased between 2013 and 2017 just as e-cigarettes and vaping use became more popular. The study specifically looked at five different US population-level surveys that covered the four-year time frame in which vaping became increasingly popular. *"... the data shows consistent, accelerated reductions in youth and young adult smoking prevalence as vaping becomes more widespread..."*. *"We found a strong and consistent inverse relationship between vaping and smoking across the different datasets for both youth and young adults"* noted Professor David Levy, PHD, Professor of Oncology at Georgetown Lombardi Comprehensive Cancer Centre, a national Cancer Institute designated comprehensive cancer centre.

6. RECOMMENDATIONS

- Regulate alternative nicotine products rather than prohibit them.
- Implement risk proportionate regulation to encourage adult smokers to switch away from combustible cigarettes.
- In order to shift adult smokers to potential reduced harm alternative nicotine products as fast as possible, enable reasonable communication accurately informing adult consumers.
- Ensure taxation policy leads consumers to reduced risk alternatives and away from smoking.
- Ensure that all policy decisions in relation to alternative nicotine products are made on the basis of science, evidence, and consumer insights into what works to reduce consumption.
- Ensure that the definition of alternative nicotine products in any legislation and regulation is not so narrow as to favour any particular industry, product or category of reduced risk product, 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 a potentially less harmful product that works as an alternative to smoking. One-size does not fit all in shifting consumers from cigarettes to smoke-free alternatives.
- Regulate vaping products as consumer products rather than as medicinal products, however quality standards should be set, monitored and enforced.
- Allow Australian medical and scientific institutions to carry out nicotine research more freely than is currently possible. The current limited approach stifles innovation and limits the opportunity of potential scientific and medical breakthroughs.
- Australia should recognise the principle of harm reduction with respect to smoking, as it does with safe needle exchange for intravenous drug users, by accepting that not all smokers can or will quit; and that these people have a right to information about and access to potentially less harmful alternatives to smoking. This recognises the right that all people, including indigenous people, mentally ill people, low-income people, 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.
- Join other modern governments such as NZ and the UK to achieve a smoke-free Australia 2030.

Sincerely,



Jeannie Cameron
Vice President, International Regulatory Engagement