

FONTEM VENTURES BV

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Response to Western Australia's Select Committee Inquiry on Personal Choice and Community Safety:

Risk Reduction Products

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1. INTRODUCTION

- 1.1 Fontem Ventures welcomes the opportunity to provide evidence to Western Australia's Parliamentary Select Committee Inquiry on Personal Choice and Community Safety, with a particular reference to risk-reduction products such as e-cigarettes, e-liquids and heat-not-burn tobacco products, including any impact on the wellbeing, enjoyment and finances of users and non-users. As the Committee will appreciate, the current legal status of e-cigarettes and vaporisers in Australia, both federally and across the states and territories, is complex and confusing for all stakeholders.
- 1.2 Fontem Ventures is of the view that e-cigarettes, subject to an appropriately robust and enforced regulatory framework, offer the potential for significant public health benefits. Complete cessation of all tobacco and nicotine use is the best action smokers can take to improve their health. However for smokers who are neither interested nor willing to quit smoking, a growing number of bodies in the international scientific and public health community are now clear that encouraging and assisting them to switch to nicotine products that are substantially less harmful, is the next best option.
- 1.3 Fontem Ventures urges the Committee to review the substantial independent scientific evidence that clearly shows e-cigarettes are significantly less harmful than smoking and have the potential to generate substantial public health benefits if there is a switch from smoking to e-cigarette use at a population level.
- 1.4 Fontem Ventures believes the Australian Government should complement its current tobacco control measures with a commitment to embrace tobacco harm reduction strategies and allow less harmful, tobacco-free alternatives to cigarettes, such as e-cigarettes and vaporisers, to be made available to the nearly 3 million Australians who still smoke. Should a change in law permit the marketing and sale of tobacco-free e-cigarettes, Fontem Ventures intends to offer its range of high quality e-cigarettes and e-liquids to Australian adult smokers.

2. E-CIGARETTES ARE LESS HARMFUL THAN SMOKING: GROWING INTERNATIONAL PUBLIC HEALTH ENDORSEMENT

- 2.1 Following a review of the available scientific evidence in 2015 comparing conventional smoking to e-cigarettes, Public Health England characterised e-cigarettes as being "around 95% less harmful than smoking". This view was subsequently supported by numerous other UK public health organisations including the British Lung Foundation, Cancer Research UK and the Royal Society of Public Health. The following year, the UK Royal College of Physicians concluded the long-term health risks associated with e-cigarettes are "unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower".
- 2.2 A number of other public health organisations, agencies and governments have since reviewed the scientific and safety evidence on e-cigarettes and reached similar conclusions on the relative harms of e-cigarettes compared to cigarettes. For example:
 - In a statement, the US Food and Drug Administration (FDA) Commissioner stated "Make no mistake. We see the possibility for ENDS [electronic nicotine delivery system] products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco".⁴
 - Following a comprehensive review of the scientific literature, the US National
 Academies of Sciences, Engineering, and Medicine (NASEM) concluded "Evidence
 suggests that while e-cigarettes are not without health risks, they are likely to be far
 less harmful than conventional cigarettes".⁵
 - In an update position statement, the American Cancer Society stated that "Based on currently available evidence, using current generation e-cigarettes is less harmful than

¹ https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

² https://www.gov.uk/government/publications/e-cigarettes-a-developing-public-health-consensus

³ https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

⁴ https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm605432.htm

⁵ http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24952

smoking cigarettes, but the health effects of long-term use are not known" and "...individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products".

- Following the passing of new legislation that officially legalises and regulates vaping
 in Canada, the Government of Canada issued a position statement that stated "Vaping
 is less harmful than smoking" and "Switching from tobacco cigarettes to vaping
 products will reduce a person's exposure to many toxic and cancer-causing chemicals".7
- The British Medical Association updated its policy position on e-cigarettes based on
 the evidence that "There are clear potential benefits to e-cigarette use in reducing the
 substantial harms associated with smoking, and a growing consensus that they are
 significantly less harmful than tobacco use".8
- The New Zealand Ministry of Health have stated that "The evidence on vaping products indicates they carry much less risk than smoking cigarettes but are not risk free" and "The Ministry believes vaping products could disrupt inequities and contribute to Smokefree 2025".9
- The Royal Australian and New Zealand College of Psychiatrists stated that "E-cigarettes and vaporisers provide a safer way to deliver nicotine to those who are unable to stop smoking, thereby minimising the harms associated with smoking tobacco and reducing some of the health disparities experienced by people with mental illness". ¹⁰
- In its policy position paper, the Drug and Alcohol Nurses of Australasia concluded that "E-cigarettes are a much safer alternative to smoking for those who are unable to quit with conventional therapies" and "E-cigarettes are not risk free but evidence suggests they are around 95% safer than smoking".¹¹

 $^{^6\,\}underline{\text{https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html}}$

⁷ https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping.html

⁸ https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes

⁹ https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco

https://www.ranzcp.org/Files/Resources/Submissions/RANZCP_Standing-Committee_Vaporised-Nicotine-Bill.aspx

https://www.danaonline.org/wp-content/uploads/2017/09/DANA-Position-Statement-on-E-Cigarettes-2017.pdf

3. IMPACT ON HUMAN HEALTH: SMOKERS SWITCHING TO E-CIGARETTES

- 3.1 Cigarette smoke is created by the combustion of tobacco at 600-900°C which creates thousands of new and harmful or potentially harmful chemicals in the form of smoke particles and toxic gases which are reported to cause harm to smokers. By contrast, e-cigarettes use electrical heating to create an aerosol (popularly referred to as 'vapour') from an e-liquid (of known chemical composition). As a result, the toxicants in e-cigarette aerosols have been found to be at levels that are magnitudes lower than in conventional cigarette smoke with many of the toxicants in tobacco smoke simply not present at detectable levels or at levels equivalent to the tolerances allowed in medicinal products. 13,14,15,16,17,18
- 3.2 Importantly, recently published clinical research has shown that smokers who have switched to e-cigarettes have significantly lower exposure to carcinogens and toxicants found in cigarette smoke, with reductions largely indistinguishable from complete smoking cessation or use of licensed nicotine replacement products. ^{19,20,21,22}

¹² U.S.DHSS. How Tobacco Smoke Causes Disease The Biology and Behavioral Basis for Smoking-Attributable Disease A Report of the Surgeon General. Public Health. U.S. Dept. of Health and Human Services, Public Health Service, Office of the Surgeon General; 2010. 792

p 13 Goniewicz, M.L., et al., Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control, 2014. 23(2): p. 133-9

^{9. &}lt;sup>14</sup> Tayyarah, R. and G.A. Long, Comparison of select analytes in aerosol from e-cigarettes with smoke from conventional cigarettes and with ambient air. Regul Toxicol Pharmacol, 2014. 70(3): p. 704-10.

¹⁵ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Therapeutic Advances in Drug Safety 2014;5:67–86

¹⁶ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC Public Health 2014:14:18

¹⁷ Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction [Internet]. 2014 Aug 31

¹⁸ Margham J, McAdam K, Forster M, Liu C, Wright C, Mariner D, et al. Chemical Composition of Aerosol from an E-Cigarette: A Quantitative Comparison with Cigarette Smoke. Chem Res Toxicol. American Chemical Society; 2016 Oct17;29(10):1662–78

¹⁹ O'Connell, G et al: "Reductions in biomarkers of exposure to harmful or potentially harmful constituents following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers", Toxicol Mech Methods, 2016

²⁰ Goniewicz, M et al: "Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes", Nicotine & Tobacco Research, 2016

²¹ Shahab, L et al: "Nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users", Annals of Internal Medicine, 2017

²² Round EK, Chen P, Taylor AK, Schmidt E: Biomarkers of Tobacco Exposure Decrease After Smokers Switch to an E-Cigarette or Nicotine Gum. *Nicotine & Tobacco Research* 2018:nty140-nty140.

- 3.3 When assessing physiological endpoints, pulmonary function improvements have been noted when smokers switch to using e-cigarettes^{23,24} and a reduced incidence of airway infections observed.²⁵ It has also been reported that chronic conditions improve when a smoker switches to e-cigarettes, for example in the case of asthma^{26,27}, breathing problems²⁸ and lung function.²⁹ Clinical studies have also shown that smokers reducing or replacing smoking by switching to e-cigarettes does not lead to higher blood pressure or heart rate values^{30,31}, with blood pressure reductions particularly apparent in smokers with an elevated blood pressure over the long term.³²
- 3.4 Fontem Ventures recently published one of the first long-term clinical studies assessing use of a typical closed system e-cigarette by smokers over two years in the real world.³³ The findings of this study showed there were no safety concerns in smokers using the e-cigarette for 2 years; use of the ecigarette was associated with a reduction in conventional cigarette consumption and a reduced exposure to harmful cigarette smoke chemicals; and use of the e-cigarette did not lead to clinically significant adverse changes in biomarkers of haematology or lipid metabolism.
- 3.5 The scientific evidence to date indicates that the potential health risks associated with ecigarette use are much lower than continued cigarette smoking. However, e-cigarettes have not been around long enough to generate epidemiological data, which looks at health impacts after decades of use, and Fontem Ventures believe more research is needed into the long-term effects of their use.

²³ D'Ruiz, C.D et al: "Measurement of cardiovascular and pulmonary function endpoints and other physiological effects following partial or

complete substitution of cigarettes with electronic cigarettes in adult smokers", Regulatory Toxicology and Pharmacology, 2017.

²⁴ Cibella, F et al: "Lung function and respiratory symptoms in a randomized smoking cessation trial of electronic cigarettes", Clinical Science,

²⁵ Miler, J.A et al: "Changes in the Frequency of Airway Infections in Smokers Who Switched To Vaping: Results of an Online Survey", J Addict Res Ther, 2016.

²⁶ Polosa R et al: "Effect of smoking abstinence and reduction in asthmatic smokers switching to electronic cigarettes: Evidence for harm

reversal", Int J Environ Res Public Health, 2014.
²⁷ Farsalinos, K.E. et al: "Characteristics, perceived side effects and benefits of electronic cigarette use: a worldwide survey of more than 19,000 consumers", Int J Environ Res Public Health, 2014.

²⁸ Campagna D et al: "Changes in breathomics from a 1-year randomized smoking cessation trial of electronic cigarettes", Eur J Clin Invest, 2016.

²⁹ Polosa R: "Electronic cigarette use and harm reversal: emerging evidence in the lung", BMC Med, 2015.

³⁰ Farsalinos, K et al: "Effect of continuous smoking reduction and abstinence on blood pressure and heart rate in smokers switching to electronic cigarettes", Intern Emerg Med, 2016.

³¹ D'Ruiz, C.D et al: "Measurement of cardiovascular and pulmonary function endpoints and other physiological effects following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers", Regulatory Toxicology and Pharmacology, 2017.

³² Farsalinos, K et al: "Effect of continuous smoking reduction and abstinence on blood pressure and heart rate in smokers switching to

electronic cigarettes", Intern Emerg Med, 2016.

33 Walele, T., et al., Evaluation of the safety profile of an electronic vapour product used for two years by smokers in a real-life setting. Regulatory Toxicology and Pharmacology, 2018. 92: p. 226-238.

4. E-CIGARETTES AND SMOKING CESSATION

- 4.1 Significant numbers of smokers worldwide are switching to e-cigarettes, with an estimated over 100,000 Australians being daily users.³⁴ This demonstrates that, notwithstanding the current regulations for e-cigarettes in Australia, consumers are seeking e-cigarettes and vaporisers as an alternative to conventional cigarettes.
- 4.2 Although e-cigarettes cannot be marketed as smoking cessation devices in the UK, EU and US without a medicinal license, a growing body of evidence suggests e-cigarettes are an effective tool in helping people quit smoking. 35,36,37,38
- 4.3 E-cigarettes have become the most common quitting aid for smokers in England, a finding supported by recent data, suggesting that 38.2% of smokers in the last quarter of 2017 reported using an e-cigarette in their recent quit attempt compared with 18% using licensed nicotine replacement therapies (NRT) and 2.8% using Varenicline.³⁹ Success rates for quitting smoking are now at a record high in the UK, with almost 20% of attempts to quit successful in 2017 versus the past decade's average success rate of 15.7%. 40 The improvement in quitting success has been attributed to the increased prevalence of e-cigarettes in the UK, with Cancer Research UK commenting "Research has shown that e-cigarettes are the most popular way to quit". In 2015 alone, use of e-cigarettes resulted in an additional 18,000 long-term ex-smokers in England. 42
- 4.4 The UK Royal College of Physicians has concluded that "E-cigarettes are marketed as consumer products and are proving much more popular than NRT [nicotine replacement therapy] as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by

³⁴ https://www.aihw.gov.au/getmedia/15db8c15-7062-4cde-bfa4-3c2079f30af3/21028.pdf

³⁵ McNeill A, Brose LS, Calder R, Bauld L, Robson D: Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. In. Edited by England. PH. London; 2018.

³⁶ McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P: Electronic cigarettes for smoking cessation and reduction. *The Cochrane database* of systematic reviews 2014, 12:CD010216

37 Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P: Electronic cigarettes for smoking cessation. The Cochrane database

of systematic reviews 2016, 9:Cd010216.

38 Hajek P, Corbin L, Ladmore D, Spearing E: Adding e-cigarettes to specialist stop-smoking treatment: City of London pilot project. *J*

Addict Res Ther 2015, 6(2).

⁹ McNeill A, Brose LS, Calder R, Bauld L, Robson D: Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. In. Edited by England. PH. London; 2018.

⁴⁰ http://www.smokinginbritain.co.uk/read-paper/draft/8/Quit%20success%20rates%20in%20England%202007-2017

⁴¹ http://www.cancerresearchuk.org/about-us/cancer-news/news-report/2017-09-21-smoking-quit-rates-highest-in-10-years

⁴² Beard, E et al: "Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends", BMJ, 2016.

smokers as an aid to quitting smoking".⁴³ Consistent with this, a Cancer Research UK study found that smokers using e-cigarettes to replace smoking are 60% more likely to succeed than those using traditional, over-the-counter medicinal nicotine replacement therapies or willpower alone.⁴⁴ There is also emerging evidence that e-cigarettes can also encourage reduced cigarette consumption and cessation, even among those smokers not intending to quit or rejecting other support.⁴⁵

- 4.5 It has also been shown in the US that the increase in use of e-cigarettes, which became noticeable around 2010 and increased substantially by 2014, was associated with a statistically significant increase in the smoking cessation rate at the population level.⁴⁶ Furthermore, an analysis of the data from the 2014 and 2015 US National Health Interview Surveys (NHIS) found that over half of daily e-cigarette users had quit smoking in the last 5 years and daily e-cigarette users were 3 times more likely to quit than never-use e-cigarette smokers.⁴⁷
- 4.5 The major risk to the continued success of e-cigarettes, as a replacement for conventional cigarettes, is declining smoker confidence in the e-cigarette category, evidenced by the increasing misperceptions of the relative harmfulness of e-cigarettes in the UK⁴⁸, US⁴⁹ and elsewhere. This decline in consumer confidence is driven, at least in part, by sensationalist media headlines, misinformation, and misleading science that fails to compare the relative risks of vaping to smoking. In order to improve the accuracy of smoker's perception of vaping products compared to smoking, and to maximise the health benefits of switching, Health Canada is currently consulting on a "List of Statements for Use in the Promotion of Vaping Products" which, if approved, would be the first authorised promotional statements that would recognise and maximise the opportunities of vaping products in tobacco harm reduction. The proposed statements include, amongst others, "If you are a smoker, switching completely

⁴³ https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

⁴⁴ Brown, J et al: "Real-world effectiveness of e-cigarettes when used to aid smoking cessation", Addiction, 2014.

⁴⁵ Polosa, R et al: "Success rates with nicotine personal vaporisers", BMC public health, 2014.

⁴⁶ Zhu, S.-H., Y.-L. Zhuang, S. Wong, S. E. Cummins and G. J. Tedeschi (2017). "E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys." BMJ 358

⁴⁷ Giovenco, D.P. and C.D. Delnevo, Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers. Addictive Behaviors, 2018. 76: p. 129-134.

⁴⁸ http://ash.org.uk/media-and-news/press-releases-media-and-news/large-national-survey-finds-2-9-million-people-now-vape-in-britain-for-the-first-time-over-half-no-longer-smoke/

⁴⁹ Douglas Clifford, E., R. Henson, J. Drope and C. Wender Richard (2018). "The American Cancer Society public health statement on eliminating combustible tobacco use in the United States." CA: A Cancer Journal for Clinicians 0(0).

to vaping is a much less harmful option" and "Switching completely from smoking to e-cigarettes will reduce harm to your health".

4.6 Fontem Ventures urges the Committee to carefully consider how different regulatory environments may influence and impact the effectiveness of e-cigarettes as an alternative to conventional cigarettes. Indeed, a recent study found use of e-cigarettes in the real world "...appears only effective for sustaining smoking abstinence in a less restrictive [e-cigarette] environment suggesting that the benefits of [e-cigarettes] for smoking cessation are likely highly dependent on the regulatory environment". 50 This underscores the need for careful consideration on how best to regulate e-cigarettes so the public health benefits can be maximised.

⁵⁰ Yong, H.H et al: "Does the regulatory environment for e-cigarettes influence the effectiveness of e-cigarettes for smoking cessation?: Longitudinal findings from the ITC Four Country Survey", Nicotine Tob Res, 2017.

5. E-CIGARETTES ARE NOT A GATEWAY TO SMOKING

- Some regulators and public health officials have expressed concerns that e-cigarettes could act as a 'gateway' to smoking among non-smokers, particularly youth, or that vaping could 'renormalise' smoking. These fears are unfounded, primarily because the statistics to date do not support the view that significant numbers of non-smokers are regularly vaping and going on to smoke. In fact the opposite is true with data showing that vaping products are actually acting as a gateway *from* smoking, accelerating declines in both adult and youth smoking rates.
- 5.2 The largest ever analysis of available UK data recently showed that there is no evidence ecigarettes are leading young people into smoking. The study, which analysed five large-scale surveys conducted in 2015-2017 involving over 60,000 11-16 year-olds, found among young people who had never smoked, regular use of e-cigarettes was negligible between 0.1% and 0.5% across the five surveys.⁵¹ Whilst there is some experimentation amongst young (U18) UK 'never smokers', there was no evidence of this group regularly using e-cigarettes; indeed, regular use was almost entirely concentrated in young people who had already smoked.⁵² The UK Royal College of Physicians also concluded: "E-cigarettes are not a gateway to smoking in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco".⁵³
- The 2018 Public Health England comprehensive evidence review update also concluded "... the evidence suggests that EC [e-cigarettes] have contributed tens of thousands of additional quitters in England" estimating e-cigarettes contributed to an additional 57,000 quitters (lower bound estimate 22,000) in England in 2016 whereas "EC [e-cigarette] use among never smokers in GB remains very rare at less than 1%, similar to the level of use of NRT. Among never smokers who have ever used EC, a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use".⁵⁴

⁵¹ Bauld, L et al: "Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017", Int J Environ Res Public Health. 2017.

⁵² Bauld, L et al: "E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Nonsmokers", Nicotine & Tobacco Research, 2016.

⁵³ https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

⁵⁴ McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England

A recent systematic review of the literature by the University of Victoria, Canada also found "no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use". ⁵⁵ The New Zealand Ministry of Health has also said "There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it". ⁵⁶

An analysis of multiple years of nationally representative surveys in the US has also indicated that the majority of e-cigarette use among US youth was either infrequent or experimental, and negligible among never-smoking youth.⁵⁷ The majority of the very small proportion of US youth who use e-cigarettes on a regular basis, consume nicotine-free products.⁵⁸ The sharpest declines in US youth smoking rates have occurred as e-cigarettes have become increasingly available.⁵⁹ Indeed, the Monitoring the Future (MTF) survey showed that smoking peaked at 28.3% in 1996 and fell to 5.9% by 2016.⁶⁰ In fact, since 2011 when e-cigarette use began to rise in the US, there has been a particularly marked decline in teen cigarette smoking, from 11.7% to 5.9%.⁶¹

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⁵⁵ Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices, O'Leary, R. et al., University of Victoria, Centre for Addictions Research of BC, January 2017

 $^{^{56}\} https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco-control-vaping-smokeless-including-heated-tobacco-control-vaping-smokeless-including-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-tobacco-control-vaping-heated-h$

⁵⁷ Polosa, R et al: "A critique of the US Surgeon General's conclusions regarding e-cigarette use among youth and young adults in the United States of America", Harm Reduction Journal, 2017.

⁵⁸ Polosa, R et al: "A critique of the US Surgeon General's conclusions regarding e-cigarette use among youth and young adults in the United States of America", Harm Reduction Journal, 2017.

⁵⁹ Polosa, R et al: "A critique of the US Surgeon General's conclusions regarding e-cigarette use among youth and young adults in the United States of America", Harm Reduction Journal, 2017.

⁶⁰ Johnson, L et al (2016) Monitoring the Future: National Survey Results on Drug Use, 1975-2016: 2016 Overview, http://www.monitoringthefuture.org//pube/monographs/mff overview/2016 pdf

http://www.monitoringthefuture.org//pubs/monographs/mtf-overview2016.pdf

61 Johnson, L et al (2016) Monitoring the Future: National Survey Results on Drug Use, 1975-2016: 2016 Overview, http://www.monitoringthefuture.org//pubs/monographs/mtf-overview2016.pdf

6. E-CIGARETTES DO NOT NEGATIVELY IMPACT INDOOR AIR QUALITY

FOR BYSTANDERS

- 6.1 Fontem Ventures is of the view that vaping should be permitted in public places but e-cigarette users should be courteous to those around them. It is unjustified to apply smoke-free environment legislation to vaping products, since they are not tobacco products, do not contain tobacco, do not generate side-stream emissions, and pose no known risk to bystanders based on current science. Fontem Ventures believe it should be up to individual establishments and business owners to decide whether or not to permit the use of e-cigarettes and vaporisers inside their premises. Regulators considering legislation on indoor vaping should weigh up the existing scientific evidence on e-cigarettes, and should take into account the fact that forcing e-cigarette users the vast majority of whom are smokers trying to reduce or replace smoking to share a space with tobacco users could well undermine their attempts to quit smoking and expose them to tobacco emissions which the public health community has concluded is harmful.
- 6.2 The 2015 Public Health England evidence review report concluded that exposure to nicotine and other chemicals that may be present in exhaled e-cigarette aerosol was negligible, with chemical analyses to date indicating that exhaled aerosols are unlikely to warrant a concern to bystanders. ⁶² In 2018, Public Health England re-affirmed this conclusion by stating "to date there have been no identified health risks of passive vaping to bystanders". ⁶³
- 6.3 The UK Government advice published for employers in 2016 encouraged workplaces to adopt pro-vaping policies that make it as easy and convenient as possible for smokers to switch on the basis that there is "currently no evidence of harm from second-hand e-cigarette vapour." This view was subsequently shared by the UK National Health Service⁶⁵, Chartered Institute for Environmental

⁶² https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

⁶³ McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England

⁶⁴https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-

places-and-workplaces.PDF

65 http://www.nhs.uk/news/2015/08August/Pages/E-cigarettes-95-per-cent-less-harmful-than-smoking-says-report.aspx

Health⁶⁶, Cancer Research UK⁶⁷ and many others. Cancer Research UK went on to conclude that "passively breathing vapour from e-cigarettes is unlikely to be harmful".⁶⁸

- 6.4 In 2017, the British Medical Association stated in its updated key messages for policymakers "Although research in this area remains limited, there is a lack of evidence that exposure to the constituents of e-cigarette vapour poses specific health risks to bystanders" and "Current data on smoking and e-cigarette use does not support concerns that e-cigarettes are re-normalising cigarette smoking or undermining compliance with smoke-free legislation".⁶⁹
- 6.5 In France, following the Government's 2015 conclusion that "there is no evidence for passive vaping based on current scientific knowledge", in 2017 the Minister for Health and Social Services initiated a decree on indoor use of e-cigarettes signed by seven other Ministers to allow vaping in enclosed work places, including stadiums, bars, hotels, restaurants and other venues.
- 6.6 In the US, air quality checks of vape shops by California Department of Public Health and by the National Institute for Occupational Safety and Health in Cincinnati reported that even in a shop with relatively poor ventilation where 13 customers used e-cigarettes and vaporisers during the shift, creating a visible cloud, a range of flavouring compounds and formaldehyde were all below the lowest occupational exposure limit and nicotine was virtually undetectable.⁷¹
- In relation to exhaled e-cigarette particles, an extensive study measured indoor air quality in 193 households with children under 14 to assess the impact of a range of occupant activities and home characteristics. The study included week-long airborne particle measurements. Where cigarette and marijuana smoking, as well as other activities such as burning candles, affected mean weekly particle counts, vaping (present in 43 out of 193 homes) had no discernible effect on indoor air quality.

⁶⁶ http://www.cieh.org/CIEH-comment-PHE-report-e-cigarettes-190815.html

⁶⁷ http://www.cancerresearchuk.org/about-us/cancer-news/press-release/2017-02-06-e-cigarettes-safer-than-smoking-says-long-term-study

⁶⁸ http://scienceblog.cancerresearchuk.org/2017/02/06/new-study-comes-the-closest-yet-to-proving-that-e-cigarettes-arent-as-dangerous-as-smoking/

⁶⁹ https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes

⁷⁰ http://www.assemblee-nationale.fr/14/amendements/2302/CION-SOC/AS1413.asp

⁷¹ Zwack L, Stefaniak A, LeBouf R. Evaluation of chemical exposures at a vape shop: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 2017. Available from: https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf.

⁷² Klepeis NE, Bellettiere J, Hughes SC, Nguyen B, Berardi V, Liles S, et al. Fine particles in homes of predominantly low-income families with children and smokers: Key physical and behavioural determinants to inform indoor-air-quality interventions. PloS One. 2017;12(5):e0177718.

6.8 Fontem Ventures' own published scientific research has shown indoor vaping does not release chemicals or toxins into the air at levels that would pose any air quality issue to bystanders.⁷³ Ambient air in a room in which e-cigarettes were used continually for almost three hours still easily complied with indoor air quality regulations. Furthermore, Fontem Ventures' most recently published research on particles has shown that exhaled e-cigarette particles are in fact liquid droplets that evaporate rapidly following exhalation (within 10 seconds) whereas conventional cigarette smoke particles (emitted from the burning end of a cigarette + the smoke exhaled) are far more stable and linger in the room for a longer time (up to 45 minutes).74

⁷³ O'Connell, G et al: "An Assessment of Indoor Air Quality before, during and after Unrestricted Use of E-Cigarettes in a Small Room", Int

J Environ Res Public Health, 2015

74 Martuzevicius D, Prasauskas T, Setyan A, O'Connell G, Cahours X, Julien R, Colard S: Characterization of the Spatial and Temporal Dispersion Differences Between Exhaled E-Cigarette Mist and Cigarette Smoke. Nicotine & Tobacco Research 2018:nty121-nty121.

7. FLAVOURS ARE ESSENTIAL FOR ATTRACTING AND RETAINING SMOKERS TO THE E-CIGARETTE CATEGORY

- 7.1 A growing body of research shows flavours play a critical role in attracting and retaining smokers into the vaping category, directly contributing to tobacco harm reduction and declining smoking rates.
- 7.2 Flavours play an important role in adult e-cigarette product use, ensuring smokers find products palatable and therefore easier to switch to. Regular use of multiple e-liquid flavours is associated with significantly higher odds of having quit smoking. A study of 4,618 e-vapour product users found 63% vary their flavours on a daily basis, noting that flavours "appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking" and play a major role in reducing relapse into tobacco smoking. Furthermore, flavours have been shown to be associated with higher rates of smoking cessation. An analysis of data from the US Population Assessment of Tobacco and Health (PATH) study [2013/14] and the National Tobacco Behaviour Monitor (NTBM) study [2014/15] found that the adoption of flavoured e-cigarette products increased with decreasing smoking (including cessation), consistent with a transition away from smoking.
- 7.3 Preference for non-tobacco flavours is growing worldwide. Evidence from cross-sectional surveys of nationally representative samples of US adults and non-probabilistic surveys of dedicated ecigarette product users suggests that smokers tend to initiate e-cigarette use with tobacco flavoured products, but transition to exclusive or predominant use of non-tobacco flavoured products particularly fruit, sweet and dessert flavours with increased frequency and duration of e-cigarette product use.^{78,79}

⁷⁵ Farsalinos, K. E et al: "Impact of flavour variability on electronic cigarette use experience: an internet survey", *Int J Environ Res Public Health*, 2013

⁷⁶ Tackett, A. P., W. V. Lechner, E. Meier, D. M. Grant, L. M. Driskill, N. N. Tahirkheli and T. L. Wagener (2015). "Biochemically verified smoking cessation and vaping beliefs among vape store customers." Addiction 110(5): 868-874.

⁷⁷ Shiffman, S et al: "Flavoured e-cigarette use among US adults: results from two national surveys", CORESTA, 2017.

⁷⁸ Coleman, B.N., Rostron B., Johnson, S.E. et al. Electronic cigarette use among US adults in the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014. Tob Control, 2017, Jun 17, pii: tobaccocontrol-2016-053462. doi: 10.1136/tobaccocontrol-2016-053462 ⁷⁹ Harrell, M.B., Weaver, S.R., Loukas, A. et al. Flavoured e-cigarette use: Characterizing youth, young adult and adult users. Prev Med Reports 2017, 5: 33-40.

- Data from the US PATH study has also showed that the majority of daily e-cigarette product users were currently using non-tobacco flavours and were significantly more likely than moderate and infrequent users to have initiated vaping with a non-tobacco flavour.⁸⁰ At the same time, daily e-cigarette use was associated with higher odds of being a former smoker. Another study found most former smoker e-cigarette users initiated vaping with non-tobacco flavours, while initiation with tobacco flavours was more common for dual users.⁸¹ These data indicate that smokers who initiate e-cigarette use with a non-tobacco flavoured products are more likely to become daily users, and in turn, more likely to quit smoking.
- A separate analysis of the US PATH data found young adult (aged 18-34) cigarette smokers at Wave 1 (2013/14) who were using one non-tobacco/menthol flavour or multiple non-tobacco/menthol flavours in an e-cigarette product at Wave 2 (2014/15) were 2.5 and 3 times more likely to have quit or reduced smoking in the past year, respectively, compared to non-e-cigarette users.⁸² In a nationally representative survey, young US adult (18-29 years) and older US adult (≥ 30 years) former smokers who had become exclusive e-cigarette users were significantly more likely than dual users of conventional cigarettes and e-cigarette products to have initiated vaping with a non-tobacco flavour (65.7% vs. 47.3%).⁸³ Both former smoking exclusive e-cigarette users and dual users reported significantly higher rates of current use of a non-tobacco flavour − 72.5% and 72.9%, respectively − compared to initiation.
- An online survey study funded by Fontem Ventures that assessed first e-cigarette product flavour and current flavours used by a non-probabilistic sample of 20,836 adult frequent e-cigarette users in the US found the majority of frequent users, who had completely switched from smoking cigarettes to using vaping products (nearly 16,000), were increasingly likely to have initiated vaping

⁸⁰ Harrell, M.B., Weaver, S.R., Loukas, A. et al. Flavoured e-cigarette use: Characterizing youth, young adult and adult users. Prev Med Reports 2017, 5: 33-40.

 ⁸¹ Coleman, B.N., Rostron B., Johnson, S.E. et al. Electronic cigarette use among US adults in the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014. Tob Control, 2017, Jun 17, pii: tobaccocontrol-2016-053462. doi: 10.1136/tobaccocontrol-2016-053462
 ⁸² Chen, J.C. Flavoured e-cigarette use and cigarette smoking reduction and cessation – A large national study among young adult smokers.
 Subt Use Misuse. 2018, 1-15. doi: 10.1080/10826084.2018.1455704.

⁸³ Harrell, M.B., Weaver, S.R., Loukas, A. et al. Flavoured e-cigarette use: Characterizing youth, young adult and adult users. Prev Med Reports 2017, 5: 33-40.

with non-tobacco flavours, and to have transitioned from tobacco to non-tobacco flavours over time.⁸⁴ In the study the most popular currently used flavours were fruit/fruit beverage, where up to 82.9% of sampled users reporting regular purchase and use of vape liquids in this category, with dessert/pastry flavours next at 68.5%. Tobacco and menthol flavours ranked as the 5th and 6th most popular currently used flavours, respectively.

7.7 Overall, the available data shows an increasing number of e-cigarette users successfully replacing smoking altogether. There is a direct correlation between the two and it should be recognised the role of flavours in [1] encouraging adult smokers who have never vaped to try e-cigarettes for the first time and [2] offering smokers sufficient choice to stop them relapsing and to sustain their vaping behaviour over time so they can significantly reduce or eventually replace smoking. Restricting access to non-tobacco flavours may discourage smokers from switching. One of the concerns about flavourings is their potential appeal to minors and non-smokers. However, regular e-cigarette product use by young people who have never smoked is negligible and regular use is almost entirely limited to those who already smoke. Implementing regulatory restrictions on flavours could therefore cause harm to current smokers and vapers for no obvious public health gain amongst young people. Scientific research suggests that flavours are not a determinative factor in leading youth to start using e-cigarettes. 85 Flavour choice and variability should be maintained and any potential risk to young people should be minimised by strictly prohibiting sales to this age group and by ensuring industry advertising and labelling does not appeal to youngsters. Fontem Ventures would welcome the opportunity to discuss an appropriate naming convention for advertising, labelling and presentation of e-cigarette flavours with Australian regulators and policy makers.

7.7 Regulators should also be mindful of a number of unintended consequences of a flavour ban including: [1] deterring adult smokers from switching to vaping; [2] vapers could relapse to smoking if their preferred flavours are no longer available; [3] vapers could turn to DIY flavour-making; [4] an illicit trade in flavoured e-liquids or flavour agents could develop; and [5] vaping businesses may be

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⁸⁴ Russell, C., N. McKeganey, T. Dickson and M. Nides (2018). "Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA." Harm Reduction Journal 15(1): 33.

Pepper, J.K et al: "Adolescent Males' Awareness of and Willingness to Try Electronic Cigarettes." Journal of Adolescent Health, 2013

put out of business or otherwise economically harmed, thereby reducing the diversity and competition that drives innovation.

8. E-CIGARETTES ARE HIGHLY PRICE SENSITIVE

- 8.1 Fontem Ventures is of the view that as e-cigarettes do not contain tobacco, these products should not be subject to excise tax or incorporated into tobacco excise frameworks. In light of emerging consensus around the role of e-cigarettes in tobacco harm reduction, governments should endeavour to maintain their affordability - which would be undermined by an excise tax as it would likely force manufacturers to raise product prices.
- Price is an important factor in encouraging smokers to turn to e-cigarettes⁸⁶ and research shows 8.2 that consumer price sensitivity is much greater for e-cigarettes than it is for conventional cigarettes. Policies increasing the retail price of e-cigarettes would therefore likely cause a significant reduction in sales. 87 A recently published model predicted a 10% increase in price would reduce sales of disposable vaping products by approximately 12%, and by about 19% for reusable vaping products.⁸⁸
- 8.3 A study which aimed to comprehensively examine the own and cross-price elasticities of demand for tobacco, e-cigarettes and nicotine replacement therapies (NRT) in the US by analysing market-level quarterly data on sales and prices from 2007 to 2014 found that a 10% increase in ecigarette prices would reduce the quantity demanded by approximately 14% for reusable and 16% for disposable e-cigarettes, respectively, and a 10% increase in prices of NRT products would reduce demands for patches, gum, and dissolvable lozenges by roughly 14%, 11%, and 14%, respectively.⁸⁹ Given the demand of e-cigarettes is elastic, this underscores the need for policies to maintain the affordability of tobacco-free e-cigarettes to encourage smokers to switch.
- 8.4 Since initial costs for rechargeable and disposable e-cigarettes are already higher than those for tobacco cigarettes⁹⁰, further inflating prices via the imposition of excise would make them significantly more expensive than conventional cigarettes. This would be undesirable in public health terms. It also

⁸⁶ 33% of consumers surveyed in 2015 agreed that the fact that electronic cigarettes are cheaper than tobacco cigarettes was a driver in their use of the products: Ernst & Young, "E-cigarettes: An emerging category", 2016

⁸⁷ M. Stoklosa et al: "Prices and e-cigarette demand: evidence from the European Union", Nicotine Tob Res., 2016

⁸⁸ Huang, J. et al: "The impact of price and tobacco control policies on the demand for electronic nicotine delivery systems", Tob Control,

⁸⁹ Huang, J., C. Gwarnicki, X. Xu, R. S. Caraballo, R. Wada and F. J. Chaloupka (2018). "A comprehensive examination of own- and cross-

price elasticities of tobacco and nicotine replacement products in the U.S." Preventive Medicine.

90 WHO Framework Convention on Tobacco Control, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems, August 2016: P.5

illustrates the limited potential of governments to gain meaningful excise revenue from the category: demand is currently too sensitive to price to provide both excise revenue and category growth.

- In 2012, Italy's independent e-cigarette industry was expanding, with official statistics 8.5 forecasting three-figure growth rate at the end of 2012. However, the imposition of a nationwide 58.5% tax rate in 2014 hit manufacturers hard: it sparked a slump of almost 50% in the number of regular ecigarette users⁹¹ and the Italian vaping association, ANAFE, reported that small businesses had been hit particularly hard. 92 The tax also generated less than 3% of anticipated revenues meaning that the excise tax simultaneously harmed consumers and manufacturers while bringing negligible benefit to the state. 93 Given this, the current Italian government is reviewing the excise imposed upon tobacco-free ecigarette products.
- As most e-liquids contain nicotine derived from tobacco, regulators have deemed them subject 8.7 to full tobacco excise in the US state of Minnesota, resulting in the collapse of the vaping market in the state. The negative effect in the market caused a drop in sales of ~20,000 e-cigarette units (66% of the total market) in Minneapolis, the state's largest city. By comparison, in St. Louis, Missouri, a vapour market of comparable size to Minneapolis which did not apply an excise tax, sales remained relatively flat.94

⁹¹ F. Chaloupka et al: "New Research on Tobacco Taxation and Implications for Smokefree New Zealand", October 2015

⁹² Reuters: "Italian e-cigarette firms say new tax benefits tobacco", March 2015

 ⁹³ AgiVape News, Italy: "E-cig tax suspended and sent to the Constitutional Court", December 2015
 94 Public consultation – Excise duties applied to manufactured tobacco PwC Perspective - Supporting Document, February 2017 www.pwc.co.uk

9. INSIGHTS FROM THE UK PARLIAMENTARY SELECT COMMITTEE INQUIRY ON E-CIGARETTES

- 9.1 Fontem Ventures draws the Committee's attention to a recent report published by the UK Parliamentary Science & Technology Select Committee following its inquiry into e-cigarettes. The Committee concluded that e-cigarettes are too often being overlooked as a stop smoking tool, are not a significant 'gateway', including for young non-smokers, to conventional smoking and do not pose a significant risk through second-hand inhalation.
- 9.2 Following its evidence inquiry, the Committee has called upon the UK Government to consider relaxing current regulations, particularly around advertising restrictions, in order to maximize the public health benefit of e-cigarettes and vaporisers and move towards a risk-proportionate regulatory and excise framework for reduced risk products.

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 $^{^{95}\} https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/505.pdf$

10. REGULATION OF REDUCED RISK PRODUCTS

- 10.1 Fontem Ventures supports evidence-based regulation of tobacco-free e-cigarettes that is proportionate to their public health potential and that clearly sets them apart from *all* tobacco-containing products. Fontem Ventures believe e-cigarette regulation should not be modelled on tobacco product regulation, as this does not consider the important role e-cigarettes can play in harm reduction. Instead, a robust and enforced regulatory framework should be created that is based on mandatory compliance with robust product quality, manufacturing and safety standards to limit any thermal, mechanical, chemical or electrical risks, alongside a responsible marketing approach that ensures youth protection (aligned with the Australian Alcohol Beverage Advertising Code Scheme [ABAC code]). This should form the basis of a bespoke regulations for e-cigarettes that encourages product innovation and focuses on high quality standards which will ensure consumer safety, boost consumer trust in the category, and give Western Australian smokers access to high quality products and information they can trust. Only if e-cigarettes are of the highest quality with regard to manufacture, ingredients and electronic functioning, and provide smokers with the satisfaction they are looking for in a less harmful way, can the category offer a real alternative to smoking.
- 10.2 In order to remove the confusion around various potentially reduced risk products and their regulatory/excise implications, Western Australian regulators should establish a clear differentiation between tobacco-based (e.g. heated tobacco [so-called 'heat-not-burn]) and tobacco-free (e.g. e-cigarettes) products. Given the lack of independent scientific evidence and public health endorsement for new tobacco-based products, such as the emerging category of heated tobacco products, we would encourage the Western Australian authorities to regulate these products in the same way as tobacco. Strict enforcement of existing tobacco regulatory and excise frameworks would be necessary in this area and no labelling or marketing exemptions should be granted until such time these products have been deemed less harmful than conventional cigarettes. In addition, all new tobacco-based products should be excised as tobacco products at a rate comparable to their traditional equivalents if legalized.

11. CONCLUSION

- 11.1 Significant numbers of smokers worldwide are switching to e-cigarettes, with an estimated over 100,000 Australians being daily users. 96 This demonstrates that, notwithstanding the current regulations for e-cigarettes in Australia, consumers are seeking e-cigarettes and vaporisers as an alternative to conventional cigarettes. The growing weight of independent scientific evidence strongly points in favour of providing Western Australian adult smokers a choice to legally access, purchase and use less harmful tobacco-free e-cigarettes and vaporiser products.
- 11.2 Fontem Ventures urges the Committee to consider an appropriate regulatory framework, focusing on robust product quality and safety standards, which would maximize the role that ecigarettes can play as part of a comprehensive tobacco harm reduction approach that benefits individual smokers, and public health in Western Australia.
- 11.3 Should a change in law permit the marketing and sale of tobacco-free e-cigarettes, Fontem Ventures intends to offer its range of high quality e-cigarettes and e-liquids to Australian adult smokers.

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 $^{^{96}\} https://www.aihw.gov.au/getmedia/15db8c15-7062-4cde-bfa4-3c2079f30af3/21028.pdf$

11. ABOUT FONTEM VENTURES

Fontem Ventures is the business behind the blu® brand of electronic vaping products, which have been

marketed responsibly to adult smokers and vapers in the US and around the world since 2009.

Fontem Ventures is committed to leading the industry in both product standards and responsible

marketing. Our brands are subject to numerous rigorous quality checks, and their sale is governed by

strict marketing and advertising standards that ensure all communications are intended for, and

presented to, adult audiences only. Fontem takes proactive measures to ensure responsible sales

practices, both on our own online storefront and through third-party online and brick-and-mortar retail

locations.

Fontem Ventures has offices in Amsterdam, the Netherlands, and Charlotte, North Carolina. Fontem

Ventures BV is a subsidiary of Imperial Brands plc.

Fontem Ventures would be pleased to give further evidence to the inquiry if invited to do so.

Should you have any questions about our response, please contact Ross Parker, Director of

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Ross Parker

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