RESPONSE OF NICOVENTURES HOLDINGS LIMITED TO THE LEGISLATIVE COUNCIL'S PROPOSAL TO PROHIBIT THE IMPORT, MANUFACTURE, SALE, DISTRIBUTION AND ADVERTISING OF ELECTRONIC CIGARETTES

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I. INTRODUCTION

1. Nicoventures Holdings Limited ("Nicoventures") hereby responds to the paper submitted by the Food and Health Bureau and the Department of Health of the Hong Kong Government (the "Government") to the Panel on Health Services of the Hong Kong Legislative Council, entitled "Progress of Tobacco Control Measures" (LC Paper No. CB(2)1456/14-15(07) that proposes, amongst other things, to prohibit the import, manufacture, sale, distribution, and advertising of electronic cigarettes (the "Proposal").

2. The Proposal is contrary to the interests of Hong Kong residents and public health authorities. The weight of both current scientific evidence and robust regulatory policy analyses point in favour of allowing consumers access to electronic cigarettes ("e-cigarettes") as an important component of a public health and harm reduction strategy.

Nicoventures

3. Nicoventures[1] is engaged in the development and sale of innovative and high-quality e-cigarette products. Briefly, and as described in the accompanying Expert Report of Dr. Karl Fagerström (hereafter "Fagerström Report"), e-cigarettes do not contain tobacco. Rather, e-cigarettes contain a liquid which contains nicotine. When the user draws air through the e-cigarette, the electronic heating element vaporises the liquid. There is no combustion, so the e-cigarette user inhales vapour, not smoke.[2]

4. Nicoventures currently sells e-cigarette products under the "VYPE" brand (specifically, the VYPE "eStick" e-cigarette and the "ePen" vapour pen). VYPE products at present are sold only in the United Kingdom, but Nicoventures has registered "VYPE" as a trademark in Hong Kong, with such registration effective 19 April 2013 (registration number 302768897).

Overview of arguments

5. The existing evidence base indicates that health risks due to e-cigarette use are likely to be small. Banning e-cigarettes on the sole basis that they theoretically pose such small health risks to consumers does not form a rational policy basis. Indeed, many

1 Nicoventures is a wholly owned subsidiary of British American Tobacco, which is managed separately from BAT's tobacco business.

2 See Fagerström Report, ¶ 7.

common consumer products such as alcoholic beverages, sweets and fast foods are not free of health risks but are still made freely available to consumers nonetheless.

6. As set forth herein, the Proposal's recommendation to develop legislation that would ban e-cigarettes in Hong Kong should not be countenanced for the following reasons:

   6.1. The Proposal would ban e-cigarettes without first undertaking analysis of projected impacts, costs and benefits of the measure through a regulatory impact assessment.

   6.2. The Proposal is unconstitutional and illegal because the Government, in formulating and putting forward the Proposal, has taken into account irrelevant matters, and at the same time failed to take into account relevant matters, namely the numerous scientific studies, the necessary criteria to be evaluated in an impact assessment, the impact on Hong Kong's international law obligations and the possibility of introducing other less intrusive and alternative measures referred to below. The Proposal further deprives Nicoventures of fundamental property rights.

   6.3. The Proposal's ban on e-cigarettes in Hong Kong is irrational because it is based on entirely inadequate evidence, namely a single study that is erroneous and heavily criticised. The proposed ban is also disproportionate as it is not supported by, and in fact runs counter to, the growing scientific evidence which shows that a ban on e-cigarettes will not advance public health objectives. Indeed, such a ban could result in adverse consequences for public health given the weight of the scientific evidence that e-cigarettes are in fact a component of a public health strategy/harm reduction strategy. Moreover, there is no indication that the Government considered any less onerous or restrictive regulatory measures before proposing the e-cigarette ban.

   6.4. The Proposal violates Hong Kong's international treaty obligations under the World Trade Organisation's General Agreement on Tariffs and Trade 1994 ("GATT"), and the proposed e-cigarette ban would constitute an import ban contrary to Article XI:1 GATT which could not be justified on the basis of Article XX(b) of GATT. The Proposal must be notified to the WTO under Article 2.9 of the Agreement on Technical Barriers to Trade ("TBT Agreement").

7. A consensus of expert opinion, including the expert opinion of Dr. Fagerström,[3] a renowned expert in the study of tobacco, nicotine dependence, smoking cessation and harm reduction, as well as the peer-reviewed literature, support the following conclusions regarding e-cigarettes:

   7.1. E-cigarettes do not contain tobacco, and because there is no combustion during e-cigarette use, tobacco "tar" is not formed. E-cigarettes do not expose users to any significant level of toxicants, and nicotine itself is not related to chronic health effects such as cancer, heart disease or pulmonary disease. If e-cigarettes are appropriately regulated to ensure standards exist for devices and liquids then they should not contain any significant levels of toxicants.

   7.2. The scientific evidence does not support the conclusions contained in the Proposal regarding the health risks of e-cigarettes. Rather, while the long-term health effects of e-cigarettes are not yet known, there is increasing consensus in the scientific literature that e-cigarettes are unlikely to present significant health risks to users. There is also little evidence to suggest that e-cigarette vapour is harmful to non-users or bystanders.

   7.3. E-cigarette use is not a "gateway" to conventional cigarette use. While e-cigarette use is increasing among adults, there is little evidence of regular e-cigarette use by people with no history of cigarette smoking. Recent evidence indicates that regular e-cigarette use is limited to current and former cigarette smokers. E-cigarette use by never smokers is negligible, and regular e-cigarette use by children and young people is rare.

   7.4. The scientific evidence to date shows that consumers use e-cigarettes as a substitute for conventional cigarettes. Such evidence also indicates that e-cigarettes aid in facilitating successful smoking cessation, and can aid cessation at least as effectively as medical nicotine.

   7.5. Finally, the weight of the scientific evidence to date strongly points in favour of allowing consumers access to e-cigarettes that seem to be able to compete with cigarettes as an important component of a public health and harm reduction strategy, and also indicates that a ban on e-cigarettes would have significant adverse public health effects.

[3] See Fagerström Report, ¶¶ 6, 50-55.

8. Ultimately, the e-cigarette ban is neither necessary nor adequate to accomplish its stated objective to promote public health, and instead stands as an irrational and disproportionate measure that would work against public health. In addition, reasonable regulation of e-cigarettes as practiced by scores of jurisdictions around the world stands as a less restrictive, more beneficial public policy as compared to an outright ban.

II. BACKGROUND AND RELEVANT EVIDENCE

A. THE BASIS UNDERLYING THE PROPOSAL IS FLAWED AND UNSUPPORTED

1. The Government's Proposal To Ban E-Cigarettes

9. The Proposal recommends that the existing legislative framework be strengthened to prohibit the import, manufacture, sale, distribution and advertising of e-cigarettes.[4]

10. The road to that conclusion, however, is extraordinarily cursory and devoid of reliable evidence.

11. The Proposal urges three reasons for an e-cigarette ban.

    11.1. *First*, the Proposal contends that the "potential health effects" of e-cigarettes have the "potential to significantly undermine [Hong Kong's] tobacco control measures."[5] In support, the Proposal notes a single, flawed paper that has not been subject to peer review, reaches wrong conclusions and is refuted by the weight of scientific evidence that indicates minimal health risks associated with use of e-cigarettes. Thus, the evidence base cited in the Proposal is entirely insufficient to form the grounds of the proposed legal prohibition. The Proposal also claims that e-cigarettes "give rise to exposure to nicotine and other toxicants from passive smoking,"[6] again without reference to any scientific evidence that such theoretical bystander exposure constitutes a health hazard and again contrary to scientific evidence.

    11.2. *Second*, the Proposal notes WHO concerns about the alleged "gateway" and "renormalization" effects arising from the use of e-cigarettes. While pointing to no scientific study for supporting such assertions, the Proposal describes the "possibility" that e-cigarette use will lead children to switch from

4 Proposal, ¶ 30.
5 Id., ¶ 24.
6 Id.

e-cigarettes to conventional cigarettes (gateway) and that e-cigarettes may wind up making "e-cigarettes (smoking-like behavior) attractive and perpetuate the smoking problems" (renormalisation).[7] Such claims are entirely contrary to the weight of the evidence, as detailed below.

11.3. *Third*, the Proposal takes issue (again, without citing any support) with claims that e-cigarettes could help smokers of conventional cigarettes to quit smoking, a position that again is not supported by the evidence.[8]

12. As set forth below, the very limited evidence that the Proposal cites in support of the e-cigarette ban has significant limitations and has been roundly criticised in the scientific literature. Further, the weight of scientific evidence addressing the above issues shows that, rather than presenting public health detriments, ensuring consumer access to reasonably regulated e-cigarettes in fact should be a central component of public health strategy.

B. THE PROPOSAL TO BAN E-CIGARETTES IS INCONSISTENT WITH THE SCIENTIFIC EVIDENCE REGARDING THE RISK OF E-CIGARETTE USE

1. Health Effects Of E-Cigarettes—The Evidence

13. The Proposal claims that potential health effects from e-cigarettes are a significant concern.[9] However, as set forth in the Fagerström Report[10] and as noted herein, there is good evidence that the toxicant yield of e-cigarettes is low. This is because, as Dr. Fagerström states, "e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in cigarette smoke," and instead "deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke."[11]

14. Indeed, there is a consensus among all authorities that health risks from tobacco products arise not from the delivery of nicotine, but by other components of such products. Per Dr. Fagerström, "exposure to nicotine is not generally believed to be associated with any long term health effects such as cancer, heart disease or pulmonary disease."[12] As reported by the UK Royal College of Physicians, although nicotine is the addictive component of tobacco products, it is the toxins

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7 Id., ¶ 25.
8 Id., ¶ 30.
9 Id.
10 See Fagerström Report, ¶¶ 8-21.
11 See id., ¶ 18.
12 Id., ¶ 14.

and carcinogens in tobacco smoke that cause most of the harm from using tobacco.[13] The UK National Institute for Health and Care Excellence concludes similarly: "Most health problems are caused by other components in tobacco smoke, not by the nicotine."[14]

15. Thus, e-cigarettes provide consumers with a source of nicotine that is likely to be much less risky than that provided by tobacco products. This basic precept underscores the lack of any rational basis to ban e-cigarettes on the basis of the small risks to health theorised to be associated with this relatively new type of product.

16. As noted by Dr. Fagerström, a recent review of available research on content and safety of e-cigarettes, and their potential harm or benefit, concluded amongst other things that the e-liquids and aerosols tested contain toxicants in concentrations far lower than that of tobacco smoke, and also contain negligible concentrations of carcinogens. In terms of the potential for e-cigarettes to cause excess morbidity and mortality, the authors state:

> "[H]ealth effects of long-term EC [e-cigarette] use are currently not known and a degree of risk may yet emerge. However, based on the data available regarding the toxicant content of EC liquid and aerosol, long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders. *This is because unlike cigarettes, EC do not deliver combustion generated toxicants that are linked to cancer, chronic lung disease and cardiovascular disease (CVD)*."[15]

17. Another recent review of published e-cigarette vapour composition studies, also relied upon by Dr. Fagerström, found that, even when using "worst case" assumptions about potential health risks associated with e-cigarette use, the evidence showed that:

> "Current state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that

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13 Harm reduction in nicotine addiction. Helping people who can't quit. A report by the Tobacco Advisory group of the Royal College of Physicians. London RCP, 2007, at 100. (noting that "the absence of other toxins found in tobacco and particularly in its combustion products suggests strongly that these [alternative nicotine] products will be far safer").

14 Tobacco: Harm reduction approaches to smoking, National Institute for Health and Care Excellence (NICE) public health guidance (2013), at 10. See also Fagerström Report, ¶ 18.

15 Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 6 (emphasis added). See also Fagerström Report, ¶ 19.

vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. . . . *Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern*."[16]

18. A wide range of authorities have similarly concluded that e-cigarette use poses negligible risks to the health of bystanders. For example, over fifty international public health researchers recently petitioned the WHO to refrain from banning and/or unduly restricting e-cigarettes, noting that: "*It is inappropriate to apply legislation designed to protect bystanders or workers from tobacco smoke to vapour products.* There is no evidence at present of material risk to health from vapour emitted from e-cigarettes."[17]

19. Thus, even when compared to workplace standards for involuntary exposures, the exposures from using e-cigarettes fall well below the threshold for concern for compounds with known toxicity. As one study notes, "even ignoring the benefits of e-cigarette use and the fact that the exposure is actively chosen, and even comparing to the levels that are considered unacceptable to people who are not benefiting from the exposure and do not want it, the exposures would not generate concern or call for remedial action."[18]

20. In another study, a panel of experts in nicotine science, medicine, toxicology and public health policy applied a multi-criteria decision analysis approach to tobacco and nicotine products based on harms to users and harms to the wider society. The study attributed a relative harm score of 100% for conventional cigarettes, while giving a score of 4% for e-cigarettes (also known as electronic nicotine delivery systems or "ENDS"), as follows[19]:

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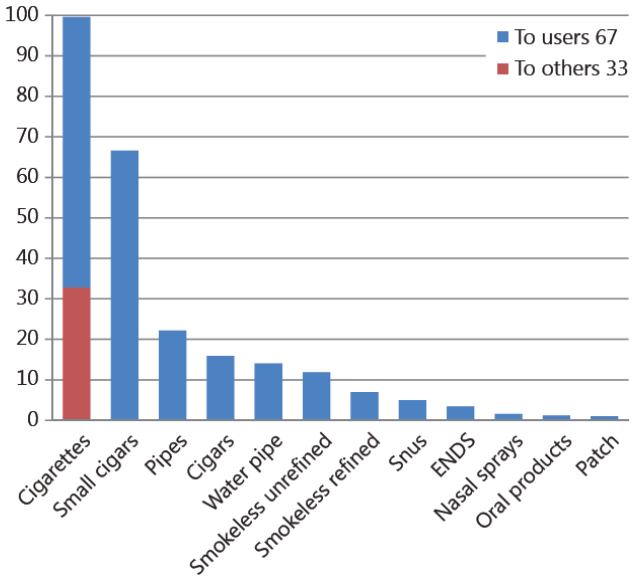
16 Burstyn, I. (2014). Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC public health, 14(1), at 1 (emphasis added). See also Fagerström Report, ¶ 20.

17 26 May 2014 Letter to Dr. Margaret Chan, Director General of WHO on "Reducing the toll of death and disease from tobacco" -Statement from specialists in nicotine science and public health policy "; available at http://ecigarette-research.com/WHO.pdf. See also Britton, J., Bogdanovica, I., Electronic cigarettes, A report commissioned by Public Health England (2014), at 14 ("The health risks of passive exposure to electronic cigarette vapour are therefore likely to be extremely low.).

18 Burstyn (2014) at 12.

19 Nutt et al, Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur Addict Res 2014;20:218–225, at 224, Fig 3 at 223. See also Fagerström Report, ¶ 20 and fn. 18.



21. Conversely, the only "evidence" cited in the Proposal to address the Government's concerns regarding health effects is a single (non-peer reviewed) letter to the editor of the New England Journal of Medicine (the "Jensen letter") suggesting that high levels of certain formaldehyde-releasing agents could be formed during vaporisation of e-liquid.[20] Significantly, the results reported in this letter have never been verified, duplicated or validated, much less relied on by any other regulators for the drafting of health-related laws.

22. On the contrary, and as stated by Dr. Fagerström, this letter and its conclusions have subsequently been called into serious question.[21] One commentator, for example, noted that the experimental conditions employed for the e-cigarette analysis described in the letter bear no resemblance to how people actually use e-cigarettes.[22] Another recent study directly refuted the findings of the Jensen letter, leading to the conclusion that far lower and minimal amounts of aldehydes are released in the e-cigarette aerosol at normal vaping conditions.[23] In addition, a study that analysed levels of selected toxicants and carcinogens in vapour from commercial e-cigarettes, and an inhalator as reference product, found formaldehyde in inhalators at "levels that overlapped with those found in e-cigarette vapour." The authors concluded that e-cigarette toxicant and carcinogen

20 See Jensen, R. P., et al., Hidden Formaldehyde in E-Cigarette Aerosols, N Engl J Med 2015; 372:392-392 (January 22, 2015), cited in Proposal, ¶ 24.

21 See Fagerström Report, ¶ 10.

22 Nitzkin JL, Farsalinos K, Siegel M. More on hidden formaldehyde in e-cigarette aerosols. N Engl J Med. 2015 Apr 16;372(16):1575. doi: 10.1056/NEJMc1502242#SA1.

23 Farsalinos KE, Voudris V, Poulas K. E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions. Addiction. 2015 May 20. doi:10.1111/add.12942.

yields are "in many cases comparable with the trace amounts present in pharmaceutical preparations."[24]

23. Thus, there is no substantial support for the Jensen letter referenced by the Proposal regarding either claims of high formaldehyde releasing agents formed during vaporisation of e-cigarette liquid or estimated increase in health risk with e-cigarette use, and as Dr. Fagerström notes, the results reported in the Jensen letter have not been verified, duplicated or validated.[25] Thus, the weight of evidence indicates that the assertions made in the Jensen letter are inaccurate.

24. The Proposal also claims that "most e-cigarettes contain propylene glycol which is a known irritant when inhaled."[26] However, it has been reported that "[t]he results of extensive studies on animals, reviewed elsewhere, suggest that PG [propylene glycol] should be safe for inhalation in humans, although in children, chronic exposure to PG in indoor air may exacerbate or induce rhinitis, asthma, eczema and allergic symptoms. Acute and chronic respiratory effects, including reduced lung function, were reported in people chronically exposed to theatre fogs containing PG."[27] The authors' concluded that "PG and glycerol inhalation is likely to pose a low risk, although their long-term effects as well as the effects of long-term inhalation of EC flavourings and additives need to be studied."[28]

25. Finally, Dr. Fagerström opines, with respect to the purported risks of e-cigarettes to non-users (bystanders), that "the clear conclusion that there is no known risk to health from being exposed to second hand vapour from e-cigarettes," which conclusion "is evidenced scientifically by expert analysis of air quality in a vaping environment."[29] For example, one study concluded that "[f]or all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed."[30]

26. Ultimately, while the Proposal has at best made a general *claim* that e-cigarettes present certain undefined health risks, the prevailing *evidence* indicates that e-

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24 Goniewicz, et al.." Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," Tob Control 2014;23:133–139 at 138.
25 See Fagerström Report, ¶ 10.
26 Proposal, ¶ 24.
27 Hajek (2014), at 3.
28 Id.
29 Fagerström Report, ¶ 17.
30 Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. McAuley et al, Inhal Toxicol. 2012 Oct:24(12):850-7. doi: 10.3109/08958378.2012.724728.

cigarettes present a low health risk profile as they do not contain tobacco and do not involve combustion. As UK public health authorities stated recently, "[w]hile nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in tobacco."[31]

2. "Gateway" Effect And "Renormalization" Of Smoking—The Evidence

27. The Proposal claims, again without any support, that the availability of e-cigarettes may act as a gateway to the use of conventional cigarettes, especially amongst children, and may also undermine tobacco control measures and in effect "renormalize" smoking.[32]

28. As Dr. Fagerström states, however, there is "no meaningful data" to support these gateway concerns.[33] Instead, the evidence shows that "[r]egular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible," and that "[r]egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked."[34] Nationally representative survey data from Action on Smoking and Health UK ("ASH UK") show that even having tried e-cigarettes is rare among children, particularly those under the age of 15.[35]

29. Similarly, a recent review of the available research concluded that "although there have been claims that EC [e-cigarette] is acting as a 'gateway' to smoking in young people, the evidence does not support this assertion. Regular use of EC by non-smokers is rare and no migration from EC to smoking has been documented (let alone whether this occurred in individuals not predisposed to smoking in the first place). The advent of EC has been accompanied by a decrease rather than increase in smoking uptake by children."[36]

30. A report commissioned by Public Health England also found no data to support a claim of gateway effect or increased smoking uptake, especially amongst youth:

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31 Cancer Research UK Briefing: Electronic Cigarettes (May 2014), available at http://www.cancerresearchuk.org/sites/default/files/policy_may2014_e-cigarette_briefing.pdf.

32 Proposal, ¶ 25.

33 See Fagerström Report, ¶ 23; see also id., ¶¶ 22-29.

34 ASH UK Fact Sheet May 2015, Use of electronic cigarettes (vapourisers) among adults in Great Britain; see also ASH UK Fact Sheet May 2015, Use of electronic cigarettes among children in Great Britain).

35 ASH UK survey conducted by YouGov. ASH Briefing, November 2014, available at www.ash.org.uk.

36 See Hajek 2014, citing US Center for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). Smoking and Tobacco Use. 2012.

> "There have been some suggestions that among non-smokers, electronic cigarettes might be used as a gateway to smoking and promote smoking uptake and nicotine addiction, particularly among children and young people. However, to date there is no data supporting this claim. Experimentation with electronic cigarettes among non-smoking children in the UK is currently rare, and only about 1% of 16 to 18-year-old never smokers have experimented to electronic cigarettes and few if any progress to sustained use. Furthermore, experimentation with electronic cigarettes should be considered in the context of current levels of experimentation with tobacco cigarettes, which in Great Britain currently generates a prevalence of smoking of 15% among 16 to 19-year olds, and 29% in 20 to 24-year olds…. It is therefore relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present."[37]

31. Thus, despite the Proposal's contrary assertion, the available evidence indicates that use or experimentation with e-cigarettes is most likely to occur predominantly in the same group that currently experiments with tobacco. Therefore, the availability and use of e-cigarettes do not increase cigarette smoking prevalence among young people.[38]

3. Cessation And E-Cigarettes—The Evidence

32. E-cigarettes' potential to assist motivated smokers in achieving successful cessation is recognised to hold promise in contributing to tobacco harm reduction. As the Fagerström Report recounts, there is emerging evidence from around the world regarding growing use of e-cigarettes by smokers as a substitute for conventional cigarettes. This evidence is based on population level surveys of representative samples and randomised controlled clinical trials using e-cigarettes for smoking cessation, and large scale surveys from e-cigarette forums further

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37 Britton J, Bogdanovica I. (2014). Electronic cigarettes: A report commissioned by Public Health England, citing ASH, Use of e-cigarettes in Great Britain among adults and young people, May 2013 (citations omitted). See also Fagerström Report, ¶ 29.

38 See id. See also Hajek (2014), at 6, which also noted the renormalisation assertions and based on the evidence found that "there are no signs that the advance of EC is increasing the popularity of smoking or sales of cigarettes."

show that e-cigarettes are proving effective as a substitute for conventional tobacco cigarettes.[39]

33. For example, the ASH UK surveys show that the increase in the numbers of UK residents using e-cigarettes between 2014 and 2015 came almost entirely from former smokers (that is, smokers who have substituted e-cigarettes for cigarettes). The proportion of ex-smokers using e-cigarettes rose from 4.5% in 2014 to 6.7% in 2015. And, among current e-cigarette users, the principal reasons given by ex-smokers for e-cigarette use are "to help me stop smoking entirely" (61%) and "to help me keep off tobacco" (53%). The main reasons given by current e-cigarette users who still smoke are "to help me reduce the amount of tobacco I smoke, but not stop completely" (43%) and "help me stop smoking entirely" (41%).[40]

34. The Cancer Research UK sponsored Smoking Toolkit Study, for its part, found that people trying to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies (e.g., patches or gum).[41]

35. The Fagerström Report also reviews two published randomised controlled clinical trials that suggest that e-cigarettes may prove efficacious as a smoking cessation aid.[42] As noted in the Report, a recent pooled analysis appeared in a Cochrane Review of e-cigarettes' efficacy in aiding smoking cessation and reduction. The review concludes: "There is evidence from two trials that ECs help smokers to stop smoking long term compared with placebo ECs."[43] In addition, nicotine-containing ECs were significantly more effective than placebo ECs and also significantly more effective than nicotine patches in helping people achieve a 50% or greater reduction in smoking.

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39 See Fagerström Report, ¶¶ 30-49.

40 ASH Fact Sheet, May 2015 Use of electronic cigarettes (vapourisers) among adults in Great Britain. See also Fagerström Report, ¶¶ 33-35.

41 See Cancer Research UK, Smoking Toolkit Study, available at http://www.smokinginengland.info/; Brown J, et al. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. Addiction (2014) 109: doi: 10.1111/add.12623. See also Fagerström Report, ¶¶ 36-38.

42 See Fagerström Report, ¶¶ 39-44.

43 McRobbie, et al., "Electronic cigarettes for smoking cessation and reduction (Review)," Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2, at 2. See also Fagerström Report, ¶ 44.

36. A worldwide survey of e-cigarette users similarly found that over 15,000 vapers (80%) of the respondents had quit smoking altogether using e-cigarettes.[44] Furthermore, a recent study concluded that among smokers attempting to quit without professional support, those who use e-cigarettes have higher reported cigarette abstinence rates as compared to those who use over-the-counter nicotine replacement therapy or no cessation aid.[45]

37. Thus, evidence continues to accumulate that e-cigarettes assist smokers in successfully quitting smoking.

38. Furthermore, a broad array of tobacco and nicotine specialists have recognised that e-cigarettes hold real potential to act as a substitute and substantially less harmful product for cigarette smokers who do not want to give up nicotine and certain of the rituals involved in smoking, and in this way may contribute to smoking cessation. In May 2014, for example, over fifty interested researchers and specialists in the areas of tobacco control, nicotine science and public health policy publicly urged both the WHO and signatories to the World Health Organisation's Framework Convention on Tobacco Control ("FCTC") to refrain from imposing bans on the sale and promotion of ENDS, including e-cigarettes, to the public.[46] These researchers (from around the world, including China) constitute a wide spectrum of authorities who have historically differed on other matters of appropriate tobacco product regulation but who joined together to help ensure that this crucial tool for improving public health and combatting the health effects of smoking is not eliminated by misguided, if well-meaning, legislation. In particular, these authorities observed that "experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them."[47]

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44 Farsalinos KE, 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, 11(4), 4356-4373. See also Fagerström Report, ¶¶ 45-49.

45 Brown, et al., "Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study," Addiction, 109, 1531–1540 (2014).

46 See 26 May 2014 Letter to Dr. Margaret Chan, Director General of WHO on "Reducing the toll of death and disease from tobacco" - Statement from specialists in nicotine science and public health policy "; available at http://ecigarette-research.com/WHO.pdf.

47 Id.

4. As Other National Regulators Have Shown, A Ban On E-Cigarettes Is Not Necessary To Effect Responsible Public Health Regulation

39. While the Proposal refers in summary to steps taken by national regulators around the world with respect to e-cigarettes (specifically referring to bans purportedly instituted by Brazil, Singapore, the United Arab Emirates and others),[48] it fails to note that its proposed product category ban has been adopted by only this small minority of nations that have enacted e-cigarette regulations. For example, the US Food and Drug Administration ("FDA"), as part of its mandated responsibility of regulating a range of tobacco and nicotine-containing products, after extensive study has specifically refrained from adopting anything remotely resembling the outright, draconian ban summarily endorsed in the Proposal.

40. Rather, in April 2014, the FDA issued proposed "deeming regulations" regarding e-cigarettes and other products not currently regulated by the FDA.[49] At present, these deeming regulations remain a proposal, though FDA has indicated its intent to issue final deeming regulations shortly. Crucially, the deeming regulations as proposed would allow e-cigarettes to remain widely available to consumers in a robust market subject to certain regulation, indicating a respect for consumers' rights to choose among a spectrum of tobacco and nicotine products.

41. With regard to e-cigarettes, it is respectfully submitted that since the FDA's stance on e-cigarettes is referenced by the Proposal, that agency's current view on regulation of e-cigarettes should be examined as a model for a more effective, and less restrictive, regulatory measure. In particular, the FDA has not characterised any potential health risks of e-cigarettes as a sufficient basis to make them illegal.

42. Instead, FDA has recognised that there are distinctions in the hazards presented by various nicotine-delivering products, noting that:

> "Some have advanced views that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products given the carcinogens in smoke and the dangers of secondhand smoke. To the extent that certain products are

[48] Proposal, Annex C.

[49] Pursuant to the US Family Smoking Prevention and Tobacco Control Act, enacted in June 2009, the FDA's initial regulatory authority was limited to regulation of cigarettes, smokeless tobacco, cigarette tobacco and roll-your-own tobacco. The deeming regulations, once final and in effect, would extend FDA's authority to additional products, including e-cigarettes.

shown to be less harmful, they could help reduce the overall death and disease toll from tobacco product use at a population level in the United States. This is a function of the existence of a continuum of nicotine-delivering products that pose differing levels of risk to the individual."[50]

43. Given this evidence-based view, while the specific details of e-cigarette regulation have yet to be fully defined by FDA, the agency has refrained, after extensive consultation, from advocating any ban on e-cigarettes.

44. Similarly, UK regulatory authorities have refrained after significant consideration from adopting or suggesting any categorical ban on e-cigarettes like that contained in the Proposal, and instead anticipate following regulation of e-cigarettes contained in the revised European Union Tobacco Products Directive ("TPD2"). These regulations (specifically, Article 20 of TPD2) contain provisions with respect to content, manufacture, labelling and warnings of e-cigarettes (discussed at Paragraph 83, below) that warrant evaluation by Hong Kong regulators and legislators, as a potential alternative to an outright ban.

45. These regulations specifically allow for continued marketing of e-cigarettes within the European Union, a policy choice completely at odds with the categorical ban advocated in the Proposal.

III. ARGUMENTS

A. A REGULATORY IMPACT ANALYSIS IS REQUIRED TO ASSESS THE LEGITIMACY AND PROPORTIONALITY OF THE PROPOSAL

46. Pursuant to Chapter V, Legal Matters of the HKSAR General Regulations, when a government department or agency proposes new or amending legislation, it must secure support from the appropriate Director of Bureau. For this purpose, a clear statement of the proposal in general terms is required, which demonstrates that:

    46.1. The legislation is necessary in the public interest;

    46.2. All major implications of the proposal, i.e. in policy, implementation, human rights, binding effect on the "State" or particular organs of it, treaty obligations, Basic Law, resources and public relations terms, have been

[50] US FDA, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; 79 Fed. Reg. 23142 (April 25, 2014), at 23147.

considered and that the Financial Services and the Treasury Bureau have been consulted if additional resources will be required;

46.3. The proposal is consistent with the Basic Law; and

46.4. The views of other parties affected have been considered.

47. The Proposal is silent on all of the required aspects listed above.

48. Specifically, for the reasons discussed below, the Proposal is inconsistent with, inter alia, Article 115 of the Basic Law. It is submitted that any statement of proposal considered or relied upon by the Food and Health Bureau and/or Department of Health in putting forward the Proposal has failed to take into account, or sufficient account, the implication of the Proposal on the Basic Law. The Proposal is therefore unconstitutional and illegal, or is at least not a sufficient or rational basis on which to impose a ban on e-cigarettes.

49. A regulatory impact assessment ("RIA") is effectively required for the purpose of complying with the requirements under the HKSAR General Regulations mentioned above. RIA is the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the Organisation for Economic Co-operation and Development ("OECD") with which Hong Kong is a Partner through its membership in the APEC-OCED Co-operative Initiative on Regulatory Reform. The failure to undertake a proper evidence-based RIA prior to making a legislative proposal violates these principles or the obligations under World Trade Organisation ("WTO") Agreements including the General Agreement on Tariffs and Trade 1994 ("GATT") to "ensure" that requirements do not constitute an "unnecessary obstacle to trade."

50. There is no evidence that the Government has conducted any RIA. Further, Nicoventures understands that no consultation has been made with other parties affected by the Proposal, including industry members, and therefore any statement considered or relied upon by the Government in issuing the Proposal does not meet legal requirements. The Proposal is therefore entirely premature at this stage.

51. Further, the weight of the evidence in fact supports keeping e-cigarettes on the market and regulating them to achieve a public health benefit. As Dr. Fagerström states:

"The scientific evidence further demonstrates that e-cigarettes are as effective as nicotine replacement products in helping cigarette smokers to quit smoking. *It is my view, therefore, that the weight of the scientific evidence to date demonstrates that e-cigarettes are an important component of a public health and harm reduction strategy*. The e-cigarette category should be regulated appropriately so as to ensure that products meet high quality and safety standards expected from such consumer goods. The toxicity of the major compounds of e-cigarette vapour are well known and not of concern. Effective regulation should ensure product components are safe and that flavours used are not toxic or degradable to toxic compounds in use. *A complete prohibition on e-cigarettes would benefit the traditional cigarettes and rather than leading to a public health benefit, would instead likely result in significant adverse public health effects.*"[51]

52. It is clear that the mere assertion that some minimal health risk may be associated with e-cigarette use cannot suffice under a rational basis test to ban the product. If this were the case, other consumer products known to be associated with some health risk, such as alcoholic beverages, would also be subject to a ban. Ultimately, this lack of a valid RIA process and the concomitant lack of a cost/benefit analysis underscore the illegitimacy of the e-cigarette ban.

53. Accordingly, a proper impact assessment should be carried out before proceeding further with the Proposal to ban the import, manufacture, sale, distribution, and advertising of e-cigarettes in Hong Kong.

B. THE PROPOSAL IS UNCONSTITUTIONAL AND ILLEGAL

54. Article 115 of the Basic Law provides, inter alia, that Hong Kong shall pursue the policy of free trade and safeguard the free movement of goods. This means Hong Kong maintains no barriers on trade. There is no customs tariff on goods imported into or exported from Hong Kong. Import and export licensing are kept to a minimum. Most products do not need licences to enter or leave Hong Kong and where licences or notifications are required, they are only intended to fulfil obligations under various international undertakings, or to apply for public health, safety or security reasons.

[51] Fagerström Report, ¶ 6 (emphasis added).

55. The objective of the Proposal to ban outright any import, manufacture, sale or distribution of e-cigarettes in Hong Kong would betray the longstanding free trade policy of Hong Kong, and would accordingly constitute a contravention of Article 115. The Proposal is therefore unconstitutional. The failure to take into account the impact of the Proposal on the Basic Law also renders the Proposal illegal.

56. The Government refers to and relies principally upon one study (the aforementioned Jensen letter) to justify the Proposal. However, as pointed out above, the Jensen letter's claims of high formaldehyde uptake by e-cigarette users or estimated increase in lung cancer risk are baseless. The Government's reliance on the Jensen letter was misconceived and it should not have been taken into account.

57. The Government has at the same time failed to take into account relevant matters in making the Proposal, namely the numerous scientific studies, the necessary criteria to be evaluated in an impact assessment, the impact on Hong Kong's international law obligations and the possibility of introducing other less intrusive alternative measures referred to in this submission.

58. By taking into account, and indeed relying on the Jensen letter, and by failing to take into account the above relevant matters when considering the regulatory measures to be adopted in respect of e-cigarettes, the proposed outright ban of e-cigarettes is illegal.

59. Finally, as noted above, Nicoventures has registered "VYPE" as a trademark for its VYPE e-cigarette brand, with such registration effective 19 April 2013 (registration number 302768897). While VYPE e-cigarettes are not sold at present in Hong Kong, the Proposal would make it illegal for such products to be sold or marketed in Hong Kong. In so doing, the Proposal would infringe, and in fact entirely eliminate, Nicoventures' right to commercialise and use its registered trademarks and thus preclude Nicoventures from communicating with adult consumers regarding their e-cigarette products. Thus, the Proposal's elimination of Nicoventures' trademarks would result in the unlawful taking of Nicoventures' property rights, including the deprivation of intellectual property rights and the goodwill associated with them.

C. THE PROPOSAL TO BAN E-CIGARETTES IS IRRATIONAL AND DISPROPORTIONATE

1. The Proposal Is Irrational Because It Failed To Account For Relevant Evidence

60. As elaborated above, the Government has taken into account irrelevant matters and has failed to take into account relevant matters when putting forward the Proposal. The substance and the supporting materials of the Proposal are fundamentally flawed and deficient. Accordingly, the Government has proposed an outright ban on e-cigarettes in circumstances when there is no factual basis at all for that proposal, and in so doing reached a decision which was irrational in the sense that it is beyond the range of responses open to a reasonable decision-maker.

61. Ultimately, the Government, whether by failure of investigation or by failure to take account of relevant (and disregard irrelevant) information, issued the Proposal when there was no factual basis for a rational conclusion that an e-cigarette ban would fulfil a public health objective.

62. The Government fundamentally failed to take reasonable steps to acquaint itself with the relevant information necessary to assess whether e-cigarettes present significant health risks to users and non-users. If the Government had taken account of relevant evidence, it could not reasonably have decided to issue the Proposal.

2. The Proposal Is Disproportionate

63. The Proposal is also unwarranted and should be abandoned because it is manifestly disproportionate, as it seeks to impose an outright ban on e-cigarettes without recognising their potential as a low-risk alternative to smoking.

64. The Administrative acts, under well-established proportionality principles, must demonstrate that the restrictions or limitations which they would impose meet the following factors:

    64.1. The restrictions or limitations must pursue a legitimate aim;

    64.2. The restrictions or limitations must also be rationally connected to that legitimate aim; and

64.3. The restrictions or limitations must also be no more than is necessary to accomplish that legitimate aim.[52]

65. The Government has the burden of showing that the Proposal meets the above requirements. As noted, the Government has not undertaken an RIA in relation to the Proposal. Without this, it cannot be demonstrated that the above requirements have been met. Notwithstanding this threshold failing, Nicoventures undertakes to assess the Proposal's e-cigarette ban in light of the foregoing proportionality principles.

a. The E-Cigarette Ban Set Forth In The Proposal Has Not Been Shown To Advance The Legitimate Purpose Of Improving Public Health

66. Any RIA must first identify the problem that the resulting regulation is intended to remedy. Thus, the Government must be able to point to a specific problem, which can be addressed via the proposed e-cigarette ban, before it can show why the proposed ban on e-cigarettes in Hong Kong is required.

67. The Government has not done this. The Proposal does not explain how a ban on e-cigarettes would achieve its public health objectives, especially with respect to improving public health and reducing the uptake of youth smoking. Rather than engage in a careful analysis of the impact of e-cigarettes on public health and youth smoking, the Proposal instead seeks to prohibit e-cigarettes without showing the prospective effect such a ban will have on the marketplace or consumers, much less that such a ban is appropriate to achieve the Government's goals.

68. The Proposal asserts that (i) e-cigarette use is significantly associated with health risks; (ii) e-cigarette use is subject to a "gateway" effect that leads e-cigarette users to take up smoking and otherwise "renormalize" conventional cigarette use; and (iii) there is little evidence that e-cigarettes contribute to smoking cessation. However, while the Government has made these claims regarding alleged problems resulting from e-cigarette use, it has not identified reliable evidence to support these claims.

69. Rather, as set forth by Dr. Fagerström, the weight of the scientific evidence addressing the health effects, "gateway" effects and cessation issues relating to e-cigarettes instead establishes that:

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[52] *Mok Charles v. Tam Wai Ho,* (2010) 13 HKCFAR 762.

69.1. There is an increasing consensus in the scientific literature that e-cigarettes do not deliver combustion-generated toxins that are linked to disease.[53]

69.2. The evidence does not indicate that a "gateway" effect is taking place. In fact, while e-cigarette use is increasing among adults, there is little evidence of regular e-cigarette use by people with no history of cigarette smoking.[54]

69.3. The scientific evidence to date shows that consumers use e-cigarettes as a substitute for conventional cigarettes. Furthermore, scientific evidence indicates that e-cigarettes in fact aid in facilitating successful cigarette smoking cessation.[55]

70. The only evidence that the Proposal has produced is a single study, whose myriad flaws have been discussed previously. Thus, the Government has not adduced any evidence to show either that (i) e-cigarettes pose health risks to users or non-users, or that (ii) a ban on e-cigarettes will result in a benefit to public health.

71. Moreover, as Dr. Fagerström has opined:

> "[T]he Proposal fails to recognise that the weight of the scientific evidence to date strongly points in favour of allowing consumers access to e-cigarettes that seem to be able to compete with cigarettes as an important component of a public health and harm reduction strategy, and that a ban on e-cigarettes would have significant adverse public health effects."[56]

72. Given this absence of evidence showing a problem that requires an e-cigarette ban, the proposed ban is disproportionate as it is not necessary nor can it serve a legitimate objective.

b. The Proposed E-Cigarette Ban Is Not Adequate For The Purpose Of Reducing Risks To Public Health

73. A proper evidence-based analysis demonstrates that there is an insufficient scientific basis to conclude that never smokers who try e-cigarettes tend to migrate

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53 See Fagerström Report, ¶ 51-52.
54 Id., ¶ 53.
55 Id., ¶ 54.
56 Id., ¶ 55.

from e-cigarettes to conventional cigarettes, which is one of the chief putative justifications for the ban set forth in the Proposal.

74. As detailed above, and in the opinion of Dr. Fagerström, the evidence actually shows that regular e-cigarette use is negligible amongst never smokers and rare amongst children and young people. The evidence base indicates that use or experimentation with e-cigarettes is most likely to occur predominantly in the same group that currently experiments with tobacco. Thus, there is no evidence that the availability and use of e-cigarettes increases cigarette smoking prevalence, especially among young people.

75. The Government has not undertaken any assessment to establish whether an e-cigarette ban would in fact prospectively reduce smoking prevalence in Hong Kong as compared to making e-cigarettes available to consumers with proportionate and reasonable regulations. If the Government had conducted any such analysis of the current evidence, it would have found that, to the contrary, banning e-cigarettes would likely result in no prospective reduction effect on future prevalence of conventional cigarette smoking in Hong Kong.

c. The Proposal Would Deprive Consumers Of Their Freedom To Choose E-Cigarettes For The Benefits They Confer In The Absence Of Any Proof Of Unacceptable Risks To Health

76. The Proposal to ban e-cigarettes is disproportionate because it would deprive Hong Kong consumers of an alternative nicotine-containing product that (i) does not produce combustion-generated toxicants and (ii) for which the evidence indicates a substantial likelihood of minimal health risks associated with its use. By banning e-cigarettes, in other words, the Proposal would ban a product with the potential to make a positive contribution to public health since evidence shows that e-cigarettes may aid in facilitating successful smoking cessation.

77. As demonstrated above, since the Government has not adduced any authoritative evidence that its proposed e-cigarette ban will reduce future smoking prevalence or that significant adverse health effects are caused by e-cigarette use, there is no basis to conclude that prohibiting the sale of e-cigarettes in Hong Kong will provide any public health benefits.

78. The Government's Proposal to prohibit e-cigarettes is being undertaken (i) without an RIA; (ii) in the absence of evidence supporting the ban, including evidence showing that a ban on e-cigarettes is necessary to promote the public health and would in fact do so; and (iii) despite clear evidence that e-cigarette use by individuals seeking to quit smoking cigarettes is associated with increased success in quitting.

79. The Government, however, still proposes to deprive consumers of their freedom to choose a product offering significant benefits at minimal risk but also without any evidence-based foundation. Depriving consumers of such freedom of choice without any justification in public health is the epitome of a disproportionate regulatory measure, especially where such deprivation, rather than leading to a public health benefit, would instead likely result in significant adverse public health effects.[57]

80. Because the asserted public health benefit is speculative under the explicit terms of the Proposal, and since the evidence shows that the ban's unintended adverse consequences would in fact undermine public health, there is no basis—and certainly no proportionate basis—to justify an e-cigarette ban.

d. There Are More Effective And Less Onerous Alternatives

81. Basic principles of Hong Kong law hold that restrictions or limitations embodied in legislative proposals must be no more extensive than is necessary to accomplish the legitimate aim of the legislation. As articulated, the Proposal seeks to develop "tobacco control policy and proposes additional measures to enhance its effectiveness in protecting public health."[58] It is submitted that the Proposal's outright ban of e-cigarettes is far more extensive and restrictive than is necessary to achieve this objective.

82. There are various alternative regulatory options, short of an outright ban, that Hong Kong could pursue to the extent it seeks to ensure that e-cigarettes meet certain prescribed quality standards and also cannot be purchased by youth. Moreover, because e-cigarettes likely have an important role in public health in

[57] See Fagerström Report, ¶¶ 6, 55.
[58] Proposal (Introduction).

terms of harm reduction, it is critical that e-cigarettes be regulated in a reasonable and responsible way.

83. Thus, rather than an outright ban, a more appropriate regulatory framework for e-cigarettes is necessary to make sure that e-cigarettes meet appropriate criteria with regards to quality and safety whilst remaining available to adult consumers. As an example, the requirements under the TPD2 regime include (but are not limited to):

    83.1. A pre-market notification regime which requires notification to regulators by e-cigarette manufacturers and importers, in advance of introducing products to the market, that address ingredients, toxicology, nicotine pharmacology, and production processes, amongst others;

    83.2. Requirements addressing technical design parameters (including volume limitations on pre-filled cartridges and dedicated refill containers and reasonable limitations on nicotine content);

    83.3. Restrictions on e-liquid manufacture to high purity ingredients;

    83.4. Limiting ingredients (aside from nicotine) to those that do not pose a risk to human health in heated or unheated form;

    83.5. Informational leaflet requirements addressing instructions for use and storage, contra-indications, warnings for specific risk groups, possible adverse effects, and addictiveness/toxicity;

    83.6. Warning requirements for external packaging;

    83.7. Requirements that e-cigarettes and refill containers be child and tamper proof, protected against breakage and leakage, and have a mechanism to ensure leak-free refilling;

    83.8. Post-market surveillance for adverse effects; and

    83.9. Submission of sales and marketing data to regulators.[59]

[59] See TPD2, Article 20.

84. Whilst the entire TPD2 regulatory regime would likely not benefit consumers (such as the prohibitions against e-cigarette communications and promotion), the TPD2 regulatory framework enables e-cigarettes to remain available for commercial distribution while ensuring that post-market e-cigarette developments are reviewed by both regulators and manufacturers.

85. There is no indication that the Government, in the Proposal or otherwise, ever considered these or any other alternatives, or any less onerous measures to achieve its stated objectives.

D. HONG KONG'S PROPOSAL TO BAN E-CIGARETTES WOULD VIOLATE ITS WTO OBLIGATIONS

1. Inconsistency With Hong Kong's WTO Obligations

86. The Government proposes to "prohibit import, manufacture, sale, distribution, and advertising of e-cigarettes."[60] The proposed import ban would be contrary to Hong Kong's World Trade Organisation ("WTO") legal obligations. It would be a straightforward violation of Article XI:1 of the General Agreement on Tariffs and Trade 1994 ("GATT") which cannot be justified under the General Exceptions clause of Article XX(b) of the GATT.

87. Given that the proposed measure "lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory," the proposal must be notified to the WTO under Article 2.9 of the Agreement on Technical Barriers to Trade ("TBT Agreement"). Because the proposed measure is not based on "a relevant international standard" and will have "a significant effect on trade of other Members," it must be notified to WTO Members "at an early appropriate stage" and allow comments to be received and taken into account in the regulatory and consultation process. Failure to do so would violate Article 2.9 of the TBT Agreement.

[60] Proposal, ¶ 30.

2. GATT Article XI:1—An Import Ban On E-Cigarettes Violates Hong Kong's WTO Obligations

88. Article XI:1 of the GATT, entitled "Elimination of Quantitative Restrictions," prohibits measures that prohibit or restrict the importation of products, other than through duties, taxes or other charges. It provide as follows:

> "*No prohibitions or restrictions other than duties, taxes or other charges*, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the *importation* of any product of the territory of any other contracting party or on the *exportation* or *sale for export* of any product destined for the territory of any other contracting party." (emphasis added)

89. A restriction is a broad term referring to "a limitation on action, a limiting condition or regulation" as described by the panel in *India – Quantitative Restrictions*[61] and as supported by numerous WTO panels.[62] An import prohibition is the ultimate restriction on importation. As the Appellate Body has stated, a prohibition is a "legal ban on the trade or importation of a specified commodity,"[63] and is thus undoubtedly a measure that violates Article XI:1.

90. Because Hong Kong proposes to prohibit the import, manufacture, sale, distribution and advertising of e-cigarettes, the proposed measure would impose a prohibition on importation which thereby violates Article XI:1 of the GATT.

3. GATT Article XX—An Import Ban On E-Cigarettes Cannot Be Justified Under The General Exception For Measures "Necessary" To Protect Health

91. Measures that otherwise violate the GATT can be justified if they comply with the General Exceptions of GATT Article XX. GATT Article XX (b) concerns measures "necessary" to protect health. It provides as follows:

> Article XX: General Exceptions
>
> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between

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61 Panel Report, *India – Quantitative Restrictions*, ¶ 5.128.

62 See Panel Reports, *India – Autos*, ¶ 7.270; *Colombia – Ports of Entry*, ¶¶ 7.233-7.234; *Brazil – Retreaded Tyres*, ¶ 7.371; *Dominican Republic – Import and Sale of Cigarettes*, ¶¶ 7.252 and 7.258.

63 Appellate Body Report, *China – Raw Materials*, ¶ 319.

countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: …

(b) necessary to protect human, animal or plant life or health….

92. While a complaining Member has the burden to prove a violation of WTO law in the first instance, a Member seeking to justify that violation bears the burden of proof.[64] This means that the burden of proof that such justification exists rests with Hong Kong, the Member imposing the GATT-inconsistent measure. In particular, it will be for Hong Kong to establish, first, that its proposed import ban is justified as a measure "*necessary*" to protect health and, second, that this measure is not applied in a manner that would constitute an *arbitrary or unjustifiable discrimination* between countries where the same conditions prevail or a disguised restriction on trade. Hong Kong will fail in respect of both aspects of this defence.[65]

93. Under sub-paragraph (b), an assessment of necessity to protect health requires a relational analysis of the contribution of the measure to its objective and the measure's trade-restrictiveness.[66] In *Korea – Various Measures on Beef*, the Appellate Body explained that determining whether a measure is "necessary" within the meaning of Article XX(d):

> "... involves in every case a process of weighing and balancing a series of factors which prominently include the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports."[67]

94. The Appellate Body has also observed that "[a] measure with a relatively slight impact upon imported products might more easily be considered as 'necessary' than a measure with intense or broader restrictive effects"[68] like a total ban on the importation and sale of the product. As the Appellate Body found, "when a measure produces restrictive effects on international trade as severe as those

64 Appellate Body Report, *US – Gasoline*, at 21.
65 Appellate Body Report, *US – Gasoline*, at 22.
66 See, e.g., Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 178.
67 Appellate Body Report*, Korea – Various Measures on Beef,* ¶ 164.
68 Appellate Body Report, *Korea – Various Measures on Beef*, ¶ 163.

resulting from an import ban, it appears to us that it would be difficult for a panel to find that measure necessary unless it is satisfied that the measure is apt to make a *material contribution* to the achievement of its objective."[69] A conclusion that the measure is "necessary" cannot be based on speculation but must be based on evidence of its material contribution such as "quantitative projections in the future, or qualitative reasoning based on a set of hypotheses that are tested and supported by sufficient evidence."[70] Additionally, a comparative analysis of the measure and available alternative regulatory measures will need to be undertaken to confirm the necessity of a measure. That is, a measure is not necessary where less trade-restrictive alternative means are reasonably available and make an equivalent contribution to achieving the objective.[71]

95. Beginning with the relational analysis, it is clear that the proposed import ban is the most trade restrictive measure possible. An import ban is in the words of the Appellate Body, the "heaviest 'weapon' in a Member's armoury of trade measures."[72] However, there is no evidence that the proposed measure will make any contribution to the protection of public health, much less the required "material" contribution.

96. To determine the contribution of the import ban to public health, Hong Kong must identify the relevant health risks and then provide sufficient evidence to prove the "necessity" of the measure to prevent that risk. The Proposal, however, cites only the "*apparent* health effect and hazards arising from the use of e-cigarettes" and "the wider long-term impact to students and youngsters (e.g. inducing them to smoke)" without providing any evidence to support these alleged risks. In fact, there is significant evidence showing that e-cigarettes are unlikely to present significant health risks to users. E-cigarettes are proven to assist motivated smokers in quitting and thus positively contribute to the protection of health. E-cigarettes are a less harmful substitute product for smokers who have difficulty quitting because of nicotine addiction. To ban e-cigarettes will therefore not contribute to the protection of health, but will actually go against this health

69 Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 150 (emphasis added).
70 Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 151.
71 See, e.g., Appellate Body Report, *EU – Seal Products*, ¶ 5.215.
72 Appellate Body Report, *US – Shrimp*, ¶ 171.

protection objective. A measure that "goes against this objective, to however small a degree"[73] cannot be justified under Article XX b as "necessary" to protect health.

97. While the measure is not supported by evidence to make a contribution to the protection of public health, its trade-restrictive impact is great. This is because a product import/sales ban is the most trade-restrictive type of measure that can be adopted, as recognised by the Appellate Body. Thus, based on the relational analysis—which shows no contribution to public health but high trade-restrictiveness—it is clear that the measure cannot be seen as necessary to protect public health.

98. In such a situation, there is no need to conduct the comparative analysis of the measure and less trade-restrictive alternatives because there is no "contribution" to compare against.[74] However, for the sake of completeness, it must be noted that a number of less trade-restrictive measures exist which would address the objectives pursued by Hong Kong. These include restrictions on purchases by youth and the imposition of quality standards and labelling requirements.

99. Thus, the proposed e-cigarette ban is not a measure "necessary" to protect human health or life within the meaning of Article XX(b). In this case, there is no further need to consider the second stage of the Article XX analysis by reviewing the requirements of the chapeau of GATT Article XX related to "arbitrary or unjustifiable" discrimination in the application of the measure. Yet again, for the sake of completeness, it must be noted that the measure fails to satisfy the chapeau's requirements.

100. The chapeau's focus on "arbitrary or unjustifiable discrimination" and "disguised restriction[s] on international trade" emphasises the fact that, even if a measure ostensibly might contribute to a legitimate aim—which this import ban does not—it would still fail under the Article XX chapeau where discriminatory or protectionist application of the measure may be found to exist. The Appellate Body has stated that "there is arbitrary or unjustifiable discrimination when a measure provisionally justified under a paragraph of Article XX is applied in a discriminatory manner …

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73 Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 228.

74 See, in the context of the Agreement on Technical Barriers to Trade, Appellate Body Reports, *US – Tuna II (Mexico)*, n.647 and *US – COOL*, ¶ 461, n. 929. Also see Panel Report, *Colombia – Ports of Entry*, ¶¶ 7.610 – 7.619. If a Member fails to establish a prima facie case of necessity, there is no need to examine less trade restrictive alternatives.

and when the reasons given for this discrimination bear no rational connection to the objective falling within the purview of a paragraph of Article XX, or would go against that objective."[75] In other words, the assessment of whether discrimination is arbitrary or unjustifiable should be made in the light of the health objective of the measure.

101. In this case, it is clear that the measure arbitrarily and unjustifiably discriminates between nicotine products that are banned—e-cigarettes—and those that are not banned—traditional cigarettes. However, there is no rational basis that is related to the objective of health protection to justify this discrimination given that the harmful nature of traditional cigarettes that are not banned is beyond doubt. Hong Kong's proposal to ban a less harmful alternative for nicotine delivery based on no credible scientific evidence, while continuing to allow the combustible form of cigarettes defies logic and thus is arbitrary and unjustifiable. The regulatory distinction that is drawn between traditional cigarettes and e-cigarettes is not related to the objective of health protection and is thus unjustifiable. As noted by the Appellate Body, "discrimination can result from a rational decision or behaviour, and still be 'arbitrary or unjustifiable,' because it is explained by a rationale that bears no relationship to the objective of a measure provisionally justified under one of the paragraphs of Article XX, or goes against that objective."[76] That is exactly the case for Hong Kong's proposed measure.

102. In this light, the ban on e-cigarettes cannot satisfy the requirements of the chapeau, in addition to the fact that it cannot be provisionally justified under sub-paragraph (b). The measure thus fails on both prongs of the Article XX analysis.

4. Article 2.9 TBT Agreement—An Import Ban Proposal Must Be Notified To The WTO Before Adoption So As To Allow For Comments To Be Made And To Be Taken Into Account

103. Under Article 2.9 of the Agreement on Technical Barriers to Trade ("TBT Agreement"), Members are obliged to be transparent about the regulatory process leading up to the adoption and implementation of measures in the case that "a *relevant international standard does not exist* or the technical content of a proposed technical regulation is not in accordance with the technical content of

[75] Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 227.
[76] Appellate Body Report, *Brazil – Retreaded Tyres*, ¶ 232.

relevant international standards, and if the technical regulation may have a *significant effect on trade* of other Members."

104. In the case of e-cigarettes, no international standards for regulation of e-cigarettes exist, as the "recommendation" of the WHO referred to by the Proposal[77] does not meet the TBT Agreements requirements for such a standard.[78] Further, a strict regulation such as an import ban clearly would have a significant trade impact, as discussed above.

105. In this case, then, Hong Kong is required by Article 2.9 to take the following actions prior to implementing the regulation:

    105.1. To provide public notice of its proposed regulation at "an early appropriate stage" so as to allow Members to review and comment on it (Article 2.9.1);

    105.2. To notify the WTO of the proposed regulation at "an early appropriate stage" when comments can be considered and amendments made (Article 2.9.2);

    105.3. To provide Members with particulars or copies of the proposed regulation (Article 2.9.3); and

    105.4. To allow Members time to make comments in writing, discuss the comments if requested and to take them into account (Article 2.9.4).

106. Failure to comply with these important transparency obligations will constitute another violation of Hong Kong's WTO obligations.

107. In sum, Hong Kong's proposal to ban the import, sale and distribution of e-cigarettes is a clear violation of Hong Kong's WTO obligations under GATT Article XI which prohibits such import bans. The lack of any sound evidence that this most trade restrictive measure possible will materially contribute to the protection of health implies that Hong Kong's defence under GATT Article XX b) for measures "necessary" to protect health must fail. In addition, the arbitrary and unjustifiable discrimination inherent in the decision to ban e-cigarettes while

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77 Proposal, ¶ 30.

78 See, e.g., Appellate Body Report, *US – Tuna II*, ¶¶ 343-399.

allowing the importation and sale of traditional cigarettes further confirms that Hong Kong will not be able to justify its WTO violations by recourse to the public health exception of Article XX(b) of the GATT.

108. Finally, the Framework Convention on Tobacco Control ("FCTC"), an international tobacco control treaty negotiated under the auspices of the WHO, does not specifically address e-cigarettes nor does it purport to regulate them under its provisions. While the FCTC has discussed potential regulatory options that could be undertaken with respect to e-cigarettes (including requiring manufacturers to provide scientific support for any claims regarding the product, appropriate age restrictions, and product warning and informational statements), it does not require FCTC members to take any actions regarding e-cigarettes.

IV. CONCLUSION

109. The Proposal to ban e-cigarettes should be abandoned. The Proposal ignores the fundamental nature of e-cigarettes—namely, that because e-cigarettes do not contain tobacco and do not involve combustion of tobacco, they likely present minimal health risks to users and non-users alike. The Government's failure to consider evidence demonstrating what e-cigarettes are and what role they can play in public health underscores that its proposed e-cigarette ban is not evidence based, and instead rests on the mere premise that an e-cigarette ban will result in a public health benefit to users (and non-users) of e-cigarettes.

110. Current evidence, however, suggests that a ban on e-cigarettes would likely result in significant adverse public health effects, especially given the increasing use of e-cigarettes by smokers as an aid to smoking cessation. Ultimately, the Government's unfounded Proposal to ban e-cigarettes is an irrational and disproportionate measure that has no justification or evidentiary underpinning, and also violates international treaty obligations. This, coupled with the fact that the Government has not undertaken any analysis illustrating that any supposed benefits of the Proposal will outweigh its considerable public health costs, demonstrates that the Proposal is not a legitimate exercise of regulatory authority.

Expert Report of Karl Olov Fagerström, Ph.D.

BACKGROUND AND QUALIFICATIONS

1. My name is Karl Olov Fagerström. I studied at the University of Uppsala and graduated as a licensed clinical psychologist in 1975. Since 1975, my work has focused on behavioural medicine, nicotine dependence and smoking cessation. I received a Ph.D. in Medical Psychology (with a dissertation in nicotine dependence and smoking cessation) from the University of Uppsala in 1981.

2. I have over 150 publications in the scientific literature in the field of tobacco, nicotine dependence and smoking cessation. I developed the Fagerström Test for Nicotine Dependence, which continues to be the most widely used test. I was editor of the Scandinavian Journal for Behaviour Therapy from 1975 to 1977, and from 1978 to 1982 I served as editor-in-chief of this Journal. I was Manager, Research and Development, Nicotine Replacement Products, for Pharmacia AB, from 1983 to 1997, and I worked in smoking cessation clinical trials for Pharmacia/Pfizer from 1985 to 1997. I have worked with and contributed to the development of nicotine replacement therapy products such as nicotine gum, patches, sprays and inhalers. Since 1997, I have been working with my private consultancy, Fagerström Consulting AB. I am a consultant to companies with an interest in nicotine dependence treatment products. From 1998 to 2010, I was Director and owner of The Smokers Information Center in Sweden. I am also a founding member of the Society for Research on Nicotine and Tobacco and Chairman of the European Society for Research on Nicotine and Tobacco.

3. In 1999, I was awarded the World Health Organisation's medal for outstanding work in tobacco control. I am also the recipient of the 2013 Award on Clinical Science from the Society for Research on Tobacco and Nicotine. Further details of my publications and affiliations may be found in my attached curriculum vitae.

SCOPE AND SUMMARY OF OPINIONS

4. At the request of Nicoventures Holdings Limited, and having seen its prior regulatory submissions, I have reviewed the paper of the Hong Kong Legislative Counsel, Panel on Health Services, entitled "Progress of Tobacco Control Measures" (LC Paper No. CB(2)1456/14-15/(07)) and in particular its proposal to prohibit the import, manufacture, sale, distribution and advertising of electronic cigarettes ("e-cigarettes") in Hong Kong, which I refer to here as the "Proposal".

5. The Proposal seeks to justify a ban on e-cigarettes through assertions that (1) e-cigarettes present health risks both to users, including, for example, from the formation of formaldehyde during vaporisation, and to non-users, purportedly from "exposure to nicotine and other toxicants from passive smoking" (Proposal, ¶ 24); (2) e-cigarettes may act as a "gateway" to eventual cigarette smoking, after e-cigarette users, and in particular youth, have become "addicted to nicotine through e-cigarettes" (Proposal, ¶ 25); and that (3) there is only "limited and inconclusive" evidence that e-cigarettes help smokers to stop cigarette smoking (Proposal, ¶ 30).

6. As I explain below, and based on my medical and scientific background and expertise, there is insufficient scientific evidence to support the Proposal's assertions regarding e-cigarettes. Rather, while long term epidemiological data with respect to e-cigarettes is not yet available, and contrary to the suggestions in the Proposal, evidence to date indicates that e-cigarettes are unlikely to present significant health risks to both users and non-users. The available evidence indicates that e-cigarette use is not a gateway to the uptake of cigarette smoking. The scientific evidence further demonstrates that e-cigarettes are as effective as

nicotine replacement products in helping cigarette smokers to quit smoking. It is my view, therefore, that the weight of the scientific evidence to date demonstrates that e-cigarettes are an important component of a public health and harm reduction strategy. The e-cigarette category should be regulated appropriately so as to ensure that products meet high quality and safety standards expected from such consumer goods. The toxicity of the major compounds of e-cigarette vapour are well known and not of concern. Effective regulation should ensure product components are safe and that flavours used are not toxic or degradable to toxic compounds in use. A complete prohibition on e-cigarettes would benefit the traditional cigarettes and rather than leading to a public health benefit, would instead likely result in significant adverse public health effects.

THE SCIENTIFIC EVIDENCE DOES NOT SUPPORT THE PROPOSAL'S CONTENTIONS

7. E-cigarettes typically consist of a battery, a heating coil and a liquid. These liquids generally contain nicotine, water, a "diluent" such as propylene glycol and/or glycerol, and sometimes flavourings. They do not contain tobacco. The liquid is pulled into the coil by a wicking mechanism. Drawing on the e-cigarette or pressing a switch activates the battery to heat the coil, which vaporises the liquid. This vapour is then inhaled by the e-cigarette user. There is no combustion, so the user inhales vapour, not smoke, and no tobacco "tar" is produced. E-cigarettes and the liquids can be sold as integrated units or with liquids sold separately.

A. Claimed Health Risks Regarding E-Cigarettes

8. As set forth above, the Proposal contends that e-cigarettes present health risks to users, including, for example, from the formation of formaldehyde during vaporization) as well as to non-users, due to (in the Proposal's view) the exposure to nicotine and other toxicants from passive exposure to e-cigarette vapour (Proposal, ¶ 24).

9. The scientific evidence does not support this contention.

10. The only study cited in the Proposal regarding health effects is a single (non-peer reviewed) letter to the editor of the New England Journal of Medicine suggesting that high levels of certain formaldehyde-releasing agents could be formed during vaporisation of e-liquid[1]. The results reported in this letter have not been verified, duplicated or validated. In fact, this letter and its conclusions have subsequently been called into serious question. One commentator, for example, noted that the experimental conditions employed for the e-cigarette analysis described in the letter bear no resemblance to how people actually use e-cigarettes[2]. Another recent study directly refuted the findings of the letter, leading to the conclusion that far lower and minimal amounts of aldehydes are released in the e-cigarette aerosol at normal vaping conditions[3].

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[1] Jensen, R P, et al. Hidden Formaldehyde in E-Cigarette Aerosols, N. Engl J Med 2015; 372:392-392 (January 22, 2015) (see Proposal, ¶ 7).
[2] Nitzkin JL, Farsalinos K, Siegel M. More on hidden formaldehyde in e-cigarette aerosols. N Engl J Med. 2015 Apr 16;372(16):1575. doi: 10.1056/NEJMc1502242#SA1.
[3] Farsalinos KE, Voudris V, Poulas K. E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions. Addiction. 2015 May 20. doi:10.1111/add.12942.

11. As to formaldehyde, it has been reported that formaldehyde is present in the vapour from e-cigarettes, but where found this is at levels 6-50 times lower than found in conventional cigarette smoke[4].

12. It should be noted that low levels of carcinogens are found almost everywhere in the environment and the air that we breathe and the food that we eat. It is not merely the presence of trace amounts of carcinogens, but whether these carcinogens cause exposures at levels and via pathways that pose material risk. The largest study to date on toxicants in e-cigarette vapour concluded: "The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference [pharmaceutical nicotine] product"[5].

13. While formaldehyde can be generated in small quantities in e-cigarettes, a systematic review of e-cigarette vapour composition published in 2014 concluded that: "Current state of knowledge about chemistry of liquids and aerosols associated with e-cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces"[6].

14. With respect to nicotine, while it has the potential to cause dependence, exposure to nicotine is not generally believed to be associated with any long term health effects such as cancer, heart disease or pulmonary disease[7]. The Medicines and Healthcare products Regulatory Agency ("MHRA") assessed the health effects of nicotine and stated "there is a large body of evidence that medicinal nicotine (in current licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease"[8].

15. The Proposal also asserts that "most e-cigarettes contain propylene glycol which is a known irritant when inhaled" (Proposal, ¶ 24). However, it has been reported that "[t]he results of extensive studies on animals, reviewed elsewhere, suggest that PG [propylene glycol] should be safe for inhalation in humans, although in children, chronic exposure to PG in indoor air may exacerbate or induce rhinitis, asthma, eczema and allergic symptoms. Acute and chronic respiratory effects, including reduced lung function, were reported in people chronically exposed to theatre fogs containing PG"[9]. The authors' concluded that "PG and glycerol inhalation is likely to

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[4] Farsalinos K. E-Cigarette Research Blog, 27 November 2014, available at http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/188-frm-jp.

[5] Goniewicz M, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 2014 Mar;23(2):133-9.

[6] Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. Igor Burstyn. BMC Public Health (2014).

[7] Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007.

[8] UK MHRA Public assessment report: The use of nicotine replacement therapy to reduce harm in smokers, February 2010, available at http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con068571.pdf.

[9] Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 3.

pose a low risk, although their long-term effects as well as the effects of long-term inhalation of EC flavourings and additives need to be studied"[10].

16. As to "passive vaping," it is noteworthy that the proposed ban on public place vaping recently suggested in Wales (UK) was opposed by a number of highly reputable health organisations and public health bodies as detailed in the quotations reported below:

    a. "There isn't enough evidence to justify a ban on using e-cigarettes indoors. The measure could create more barriers for smokers trying to quit tobacco." Cancer Research UK[11].

    b. "[I]n the absence of evidence of significant harm to bystanders, ASH does not support the inclusion of electronic cigarettes in smokefree laws which would completely prohibit their use in enclosed public places." Action on Smoking and Health UK[12].

    c. "To date, we can see no suggestion in the existing evidence base that would support an outright ban on the use of e-cigarettes." Action on Smoking and Health Wales[13].

17. The foregoing quotations sum up the clear conclusion that there is no known risk to health from being exposed to second hand vapour from e-cigarettes, and it is evidenced scientifically by expert analysis of air quality in a vaping environment. For example, one study concluded that "[f]or all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed"[14].

18. Ultimately, the Proposal asserts that the claimed health effects from e-cigarettes are a significant concern (Proposal, ¶ 30). However, there is good evidence that the toxicant yield of e-cigarettes is low, because e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in cigarette smoke. Instead, e-cigarettes deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke. As reported by the UK Royal College of Physicians: "Cigarette smoke is harmful primarily because it delivers nicotine in conjunction with an extensive range of toxins and carcinogens"[15]. The UK National Institute for Health and Care Excellence concludes similarly: "Most health problems are caused by other components in tobacco smoke, not by the nicotine"[16].

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[10] Id.

[11] George Butterworth, Tobacco Policy Manager at Cancer Research UK, available at http://www.cancerresearchuk.org/about-us/cancer-news/news-report/2015-06-09-welsh-government-proposes-banning-e-cigarettes-in-public-places.

[12] ASH Briefing, Electronic Cigarettes, Nov. 2014, available at http://www.ash.org.uk/files/documents/ASH_715.pdf.

[13] Electronic cigarettes ASH Wales Cymru, available at http://ashwales.org.uk/en/information-resources/topics/electronic-cigarettes.

[14] Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. McAuley et al, Inhal Toxicol. 2012 Oct:24(12):850-7. doi: 10.3109/08958378.2012.724728.

[15] Harm reduction in nicotine addiction. Helping people who can't quit. A report by the Tobacco Advisory group of the Royal College of Physicians. London RCP, 2007, at 220.

[16] Tobacco: Harm reduction approaches to smoking, a report by the UK National Institute for Health and Care Excellence (NICE), 2013.

19. A recent review of available research on content and safety of e-cigarettes, and their potential harm or benefit, concluded that the e-liquids and aerosols tested contain toxicants in concentrations far lower than that of tobacco smoke, and also contain negligible concentrations of carcinogens. In terms of the potential for e-cigarettes to cause excess morbidity and mortality, the authors stated: "[H]ealth effects of long-term EC [e-cigarette] use are currently not known and a degree of risk may yet emerge. However, based on the data available regarding the toxicant content of EC liquid and aerosol, long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders. This is because unlike cigarettes, EC do not deliver combustion generated toxicants that are linked to cancer, chronic lung disease and cardiovascular disease (CVD)"[17].

20. Another review of published e-cigarette vapour composition studies conducted in 2014 found that the "[c]urrent state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. . . . Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern"[18].

21. In 2014, an open letter to WHO Director-General, Margaret Chan, undersigned by 53 leading scientists and public health officials, summarised the risk to public health in banning e-cigarettes on the basis of the precautionary principle: "regulators should avoid support for measures that could have the perverse effect of prolonging cigarette consumption. Policies that are excessively restrictive or burdensome on lower risk products can have the unintended consequence of protecting cigarettes from competition from less hazardous alternatives, and cause harm as a result. Every policy related to low risk, non-combustible nicotine products should be assessed for this risk"[19]. Accordingly, because evidence to date indicates that e-cigarettes present minimal health risks to both users and non-users of e-cigarettes (recognising that long term epidemiological data with respect to e-cigarettes is not yet available), it is my opinion that e-cigarettes are an important part of the public health strategy for harm reduction, and a ban on e-cigarettes will work against that strategy.

B. The Purported "Gateway" Effect

22. The Proposal further contends that e-cigarettes are a "gateway" to eventual cigarette smoking, after e-cigarette users, and in particular youth, have become "addicted to nicotine through e-cigarettes" (Proposal, ¶ 25).

23. There is no meaningful data to support such concerns.

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[17] Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 6.

[18] Burstyn, I. (2014). Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC public health, 14(1), at 1. See also Nutt et al, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach.* Eur Addict Res 2014;20:218–225 (attributing a relative harm score of 100 % for conventional cigarettes, while giving a score of 4% for electronic cigarettes (also known as "Electronic Nicotine Delivery Systems")).

[19] Letter to WHO Director from 53 Specialists in nicotine science and public health policy, 26th May 2014, available at http://nicotinepolicy.net/documents/letters/MargaretChan.pdf.

24. Current evidence from the UK suggests this phenomenon is not occurring. Rather, the evidence shows that "[r]egular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible," and that "[r]egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked"[20]. Nationally representative survey data from the UK anti-smoking organisation ASH show that even having tried e-cigarettes is rare among children, particularly those under the age of 15[21].

25. The UK's ASH 2013 Fact Sheet on e-cigarettes states:

> "Among children regular use of e-cigarettes is extremely rare. Children who had heard of e-cigarettes were asked about their use and knowledge of them. What little use that is reported is confined almost entirely to children who currently smoke or used to smoke.
>
> - 1 in 10 16-18 year olds who had heard of e-cigarettes (1 in 20 among 11-15 year olds) has "tried e-cigarettes once or twice".
>
> - 1 in 100 16-18 year olds (0% 11-15 year olds) uses e-cigarettes more than once a week."

26. The ASH survey data also indicate that:

    - Among young people who have never smoked 1% have "tried e-cigarettes once or twice", 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon.

    - Among adults e-cigarette current use has grown among smokers and ex-smokers and remains at 0% among those who have never smoked. Ex-smokers report having used e-cigarettes to help a quit attempt (48%) to prevent relapse to tobacco use (32%).

27. Further studies tracking the use of e-cigarettes in the population and especially among children and youth are being published. At present, there is no indication that e-cigarettes are acting as a gateway into smoking; however this needs to be continuously monitored in the future.

28. In their paper published in the British Journal of General Practice, Professor Robert West and Jamie Brown from the University College London state that "[t]o date, studies that have been claimed as addressing the gateway issue in relation to e-cigarettes have not in fact done so. Moreover, warnings about a rapid rise in e-cigarette use among the young have been based on the proportion of young people who report ever having tried an e-cigarette, not the proportion of current users. In

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[20] ASH UK Fact Sheet May 2015, Use of electronic cigarettes (vapourisers) among adults in Great Britain; see also ASH UK Fact Sheet May 2015, Use of electronic cigarettes among children in Great Britain).

[21] ASH UK survey conducted by YouGov. ASH Briefing, November 2014, available at www.ash.org.uk.

England, the proportion of current users in people who have not smoked regularly remains extremely small at 0.2%"[22].

29. The concerns around a potential gateway effect and the current evidence base are well summarised by the report on e-cigarettes by Public Health England: "Experimentation with electronic cigarettes among nonsmoking children in the UK is currently rare, and only about 1% of 16 to 18-year-old never smokers have experimented to electronic cigarettes and few if any progress to sustained use. Furthermore, experimentation with electronic cigarettes should be considered in the context of current levels of experimentation with tobacco cigarettes, which in Great Britain currently generates a prevalence of smoking of 15% among 16 to 19-year olds, and 29% in 20 to 24-year olds. Experimentation with electronic cigarettes is most likely to occur predominantly in the same group that currently experiment with tobacco, as indeed is suggested by recent US data. It is therefore relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present"[23]. At this point, I see no evidence to suggest that this would be different in different cultures.

C. E-Cigarettes And Cessation

30. The Proposal also asserts that there is only "limited and inconclusive" evidence that e-cigarettes help smokers to quit cigarette smoking (Proposal, ¶ 30).

31. There is emerging evidence from around the world regarding growing use of e-cigarettes by smokers as a substitute for conventional cigarettes. This evidence is based on population level surveys of representative samples (e.g. ASH UK surveys, Professor Robert West's Smoking Toolkit Study data) and randomised controlled clinical trials using e-cigarettes for smoking cessation (e.g. Dr Bullen's clinical trial in New Zealand, Prof Polosa's ECLAT study in Italy).

32. Large sample-sized surveys from e-cigarette forums (e.g., a worldwide survey of over 19,000 e-cigarette users published by Dr Farsalinos) also confirm that e-cigarettes are indeed proving effective as a substitute for conventional tobacco cigarettes.

1. Representative population surveys

a. The ASH UK surveys[24]

33. Action on Smoking and Health, UK has conducted annual surveys for the past four years using representative samples of thousands of adults and children.

34. According to ASH, the increase in the numbers of people using e-cigarettes in the UK between 2014 and 2015 came almost entirely from "ex-smokers" (i.e. smokers who have substituted e-cigarettes for cigarettes). The proportion of ex-smokers using e-cigarettes rose from 4.5% in 2014 to 6.7% in 2015.

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[22] West, R, Brown, J. Electronic cigarettes: fact and faction, 1 September 2014. DOI: 10.3399/bjgp14X681253.

[23] Electronic Cigarettes: A report commissioned by Public Health England, John Britton and Ilze Bogdanovica, May 2014, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf.

[24] Action on Smoking and Health, UK, Surveys, generally available at www.ash.org.uk.

35. Among current "vapers" (e-cigarette users), the principal reasons given by ex-smokers are "to help me stop smoking entirely" (61%) and "to help me keep off tobacco" (53%). The principal reasons given by current vapers who still smoking are to "to help me reduce the amount of tobacco I smoke, but not stop completely" (43%) and "help me stop smoking entirely" (41%)[25].

b. The Smoking Toolkit Study[26]

36. The Cancer Research UK sponsored Smoking Toolkit Study is headed by Professor Robert West at the University College London. Worldwide, the Smoking Toolkit Study is considered important for tobacco control policymaking purposes and for establishing efficacy of smoking cessation therapies in a real world setting.

37. The recently published findings from this study used data collected from 2009 onwards of 5,863 adults who had smoked within the previous 12 months (from the date of survey). They found that people attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum[27].

38. These findings are a strong endorsement of e-cigarettes' potential in reducing smoking prevalence in the population.

2. Randomised controlled clinical trials

39. There are already two published randomised controlled clinical trials that suggest that e-cigarettes may prove efficacious as a smoking cessation aid.

a. Dr Chris Bullen's e-cigarette clinical trial in New Zealand[28]

40. A team at the University of Auckland, New Zealand, led by smoking cessation expert Dr Chris Bullen, conducted a clinical trial comparing e-cigarettes with nicotine patches in 657 people. The results published in the Lancet, a very prestigious medical journal, showed 7.3% using e-cigarettes had quit after six months compared with 5.8% using patches.

41. Also, after six months, 57% of e-cigarette users had halved the number of cigarettes smoked each day compared with 41% in those using patches.

b. Professor Riccardo Polosa's ECLAT trial in Italy[29]

42. In a prospective 12-month randomised, controlled trial that evaluated smoking reduction/abstinence in 300 smokers not intending to quit smoking, Prof Polosa

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[25] ASH Fact Sheet, May 2015 Use of electronic cigarettes (vapourisers) among adults in Great Britain.
[26] Cancer Research UK, Smoking Toolkit Study, available at http://www.smokinginengland.info/.
[27] Brown J, Beard E, Kotz D, Michie S, and West R. (2014). Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. Addiction 109: doi: 10.1111/add.12623; see also Press Release, available at http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates.
[28] Electronic cigarettes for smoking cessation: a randomised controlled trial. Bullen et al, Volume 382, No. 9905, p1629–1637, 16 November 2013.
[29] Caponnetto, P, Campagna, D, Cibella, F, Morjaria, JB, Caruso, M, Russo, C, & Polosa, R. (2013). EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomised control design study. PloS one, 8(6), e66317.

found that the use of e-cigarettes, with or without nicotine, decreased cigarette consumption and elicited enduring tobacco abstinence without causing significant side effects.

43. In this study, smoking reduction was documented in 22.3% and 10.3% at week-12 and week-52 respectively. Complete abstinence from tobacco smoking was documented in 10.7% and 8.7% at week-12 and week-52 respectively. Also, a substantial decrease in adverse events from baseline was observed and withdrawal symptoms were infrequently reported during the study. Participants' perception and acceptance of the product under investigation was satisfactory.

44. The findings from published clinical trials of e-cigarettes are summarised in the Cochrane Review led by Prof Peter Hajek: "Combined results from two studies... showed that using an [e-cigarette] containing nicotine increased the chances of stopping smoking long-term compared to using an [e-cigarette] without nicotine. Using an [e-cigarette] with nicotine also helped more smokers reduce the amount they smoked by at least half compared to using an [e-cigarette] without nicotine... This study showed that people who used [e-cigarettes] were more likely to cut down the amount they smoked by at least half than people using a patch. The other studies were of lower quality, but they supported these findings. There was no evidence that using [e-cigarettes] at the same time as using regular cigarettes made people less likely to quit smoking"[30].

3. Worldwide survey of e-cigarette users[31]

45. Dr Farsalinos' team conducted an online questionnaire in 10 languages and had a total of 19,441 participants from around the world. This was the first such globally comprehensive survey of e-cigarette users, and confirmed findings from national surveys and randomised controlled clinical trials. The key finding from this survey was that over 15,000 vapers (80%) of the respondents had quit smoking altogether using e-cigarettes.

46. One key finding was the improvement in the quality of life of the smokers who had quit using e-cigarettes, and e-cigarettes helped these former smokers remain smoke free.

47. Although the survey was not designed to be representative due to the nature of sampling from e-cigarette users' fora, given the sample size, the findings give a compelling insight into the real-world safety and effectiveness of e-cigarettes as a smoking substitute.

48. Although these studies indicate an emerging trend in use among smokers and impact on smoking prevalence, they will need to be supported by more in depth, better designed studies, to confirm the longer term individual and population level impact of e-cigarettes on public health.

49. Some of the abovementioned studies and survey findings are based on older products, and as the quality and performance of e-cigarettes keep on improving in

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[30] McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2.

[31] Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers. Farsalinos et al. Int. J. Environ. Res. Public Health 2014, *11*(4), 4356-4373.

newer generations of products, it is expected that their effectiveness as a cigarette substitute will improve even further.

CONCLUSION

50. Based on the foregoing, I hold the following opinions with respect to e-cigarettes and their role as part of a public health and tobacco harm reduction strategy:

51. E-cigarettes do not contain tobacco, and because there is no combustion during e-cigarette use, tobacco "tar" is not formed. E-cigarettes do not expose users to any significant level of toxicants, and nicotine itself is not related to chronic health effects such as cancer, heart disease or pulmonary disease. If e-cigarettes are appropriately regulated to ensure standards exist for devices and liquids then they should not contain any significant levels of toxicants.

52. The scientific evidence does not support the conclusions contained in the Proposal regarding the health risks of e-cigarettes. Rather, while the long-term health effects of e-cigarettes are not yet known, there is increasing consensus in the scientific literature and although less so among anti-smoking advocates that e-cigarettes are unlikely to present significant health risks to users. There is also little evidence to suggest that e-cigarette vapour is harmful to non-users or bystanders.

53. The evidence does not indicate a "gateway" effect with respect to e-cigarettes. While e-cigarette use is increasing among adults, there is little evidence of regular e-cigarette use by people with no history of cigarette smoking. Recent evidence indicates that regular e-cigarette use is limited to current and former cigarette smokers. E-cigarette use by never smokers is negligible, and regular e-cigarette use by children and young people is rare.

54. The scientific evidence to date shows that consumers use e-cigarettes as a substitute for conventional cigarettes. Such evidence also indicates that e-cigarettes aid in facilitating successful smoking cessation, and can aid cessation at least as effectively as medical nicotine as e-cigarettes address not only pharmacological dependence, but also the behavioural component.

55. In conclusion, it is my opinion that there is insufficient evidence to support the Proposal's assertions regarding the health, "gateway" or smoking cessation effects of e-cigarettes. Moreover, the Proposal fails to recognise that the weight of the scientific evidence to date strongly points in favour of allowing consumers access to e-cigarettes that seem to be able to compete with cigarettes as an important component of a public health and harm reduction strategy, and that a ban on e-cigarettes would have significant adverse public health effects.

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Date