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Chair, Committee of Trade and Industry
House of Representatives
Quezon City, PHILIPPINES
By email

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Dear Mr Gatchalian and Dr Tan

Comments for the Joint Committee hearing on electronic cigarettes

With your permission, I wish respectfully to submit comments to the Joint Trade & Industry and Health Committee hearings on electronic cigarettes to be held on 2nd and 10th December 2019. I am former Director of the UK's main anti-smoking organisation, Action on Smoking and Health (UK), and a long-standing advocate of rational tobacco control policies. I have also been a senior civil servant and now run a sustainability and strategy consultancy. *I have no conflicts of interest with respect to tobacco, e-cigarette or pharmaceutical industries*.

I hope to address a number of issues that are likely to emerge in the debate about e-cigarettes and 'tobacco harm reduction'. This is the public health strategy of reducing harm to tobacco users by switching from the most dangerous combustible products like cigarettes to much safer non-combustible products like e-cigarettes and heated tobacco products.

I have set out comments under the following headings. The first section (a Q&A) is intended as a short overview of the main issues arising in public and political debate in the Philippines today. I would be grateful if this submission could be shared with the Joint Committee, as appropriate.

3 The recent outbreak of serious lung injuries in the United States is not due to conventional e-cigarettes and should not form a basis for e-cigarette policy

News of serious injuries and deaths from vaping has attracted concern worldwide, including in the Philippines and including concern expressed by President Duterte. In forming a policy response, it is important to understand the actual causes of these injuries and deaths. The causes are not what many have assumed.

As of 20 November 2019, there had been 2,290 cases of serious vaping-related lung injury and 47 deaths in the United States. These cases have been widely but incorrectly attributed to regular e-cigarettes. Beyond any reasonable doubt, the cause is unrelated to the conventional nicotine e-cigarettes that are used as substitutes for cigarette smoking. The problem has emerged in the illegal supply chain for cannabis-containing vaping products sold in the US black market. According to the United States Centers for Diseases Control & Prevention, CDC:

> *CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). Recent CDC laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in all of the samples. Vitamin E acetate is used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.* [link]

Vitamin E Acetate is a 'lipid' (a fatty substance) that causes a range of lung conditions when inhaled. It is used as a thickener in THC (a cannabinoid) vapes. This allows the THC oil to be diluted ('cut') for economic reasons. This substance cannot be used in conventional nicotine e-cigarettes and it would serve no purpose – there is no reason to thicken nicotine e-liquids, which are cheap and easy to make compared to THC liquids.

It is possible that other thickeners or problematic agents will be found in the illegal supply chain for cannabis THC vapes. However, the chance that a second, independent cause would arise in the completely separate legal and regulated supply chain for nicotine e-cigarettes at exactly the same time, with exactly the same limited geography and identical symptoms is vanishingly small. Around 50 million people currently use nicotine vaping products world-wide and they have been in use since 2007 with very few problems so far. We cannot rule out some risks in the longer term, but the recent outbreak of lung injuries has a different and completely separate cause.

3.1 Conclusion

Policy for nicotine e-cigarettes should be disconnected from the lung injury outbreaks because they are unconnected to conventional e-cigarettes. It would be like closing pizza restaurants everywhere because of a food-poisoning problem in one hamburger outlet. The underlying problem with the lung injury is bad practice in a rogue black-market supply chain. Prohibitions or excessive regulation is a cause of black markets and malpractice – what looks like a tough measure backfires and increases risk.

4 Youth use of e-cigarettes is complex: poor policies can cause harm to youth

The sharp rise in youth vaping in the United States since 2017 has generated considerable concern and led to a range of proposed policy responses by US lawmakers and regulators. Many of these policy proposals are based on a limited understanding of the underlying data and threaten to do more harm than good because of their likely negative effect on adults and on adolescent smokers.

How should youth e-cigarette data be interpreted? The headline US youth vaping figures have caused alarm: there has been a sharp increase in high school age e-cigarette use: 11.7% in 2017: 20.8% in 2018; and 27.5% in 2019. However, the headlines are misleading and before these data are considered for policy purposes it is important to drill down into the data, asking three questions:

1. The headline figures refer to any use of e-cigarettes, even a single puff, in the past 30 days. What is the breakdown between infrequent and frequent use?
2. Many e-cigarettes users have also used other tobacco products and may be at risk of becoming smokers. How many of these users, especially the frequent users have already used other tobacco products? For them, e-cigarette use may be *beneficial* – a diversion from smoking.
3. The rise in youth e-cigarette use has been described as an 'epidemic of nicotine addiction'. However, use of a product, especially occasional use, does not inevitably mean dependence. Among the adolescent users of e-cigarettes, how many show signs of dependence?

What is the frequency of vaping and prior tobacco use patterns of US adolescents? The data to address the first two questions is only available for 2018 and this provides a useful illustration.[2]

NYTS 2018 data	Percentage of high school students using e-cigarettes Total = 20.8%	
High school students	No past tobacco use	Any past tobacco use
Frequent e-cig use: ≥ 20 days per month	0.6%	5.2%
Infrequent e-cig use: ≤ 19 days per month	4.7%	10.3%

It is evident from the table that: (1) most adolescent vapers (72%) are not frequent users and provide less reason to be concerned; (2) most frequent adolescent vapers (90%) had prior tobacco use. Only 0.6% of high school age vapers are both frequent users and have no prior history of tobacco use – and it is also important to recall that vaping in much less harmful than smoking.

Are youth vapers showing signs of dependence? Turning to the third question. The analysis of US youth e-cigarette data by epidemiologists Martin Jarvis, Robert West and Jamie Brown shows little sign of teenage vaping causing nicotine addiction. The authors conclude:[3]

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[2] Jarvis M, Bates C. Analysis of National Youth Tobacco Survey 2018 data. July 2019. See table with full frequency distribution here.

[3] Jarvis MJ, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios. 2019 Oct 2; [link

Data from the National Youth Tobacco Survey do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence.

Is youth e-cigarette use a major public health problem in the United States? Youth vaping should also be placed in context with other youth risk behaviours. The US Youth Risk Behavior Surveillance system provides insights into adolescent risk-behaviours, such as alcohol use (29.8% in the past 30 days), binge drinking (13.5%), cannabis use (19.8%), carrying a weapon (15.7%), and texting or emailing while driving (24.6%). During the 12 months before the survey, 19.0% had been bullied on school property and 7.4% had attempted suicide. Young people have tried heroin (1.7%), methamphetamine (2.5%), hallucinogenic drugs (6.6%) and prescription painkillers without a prescription (14.0%).[4]

It is legitimate to be concerned about the rise of youth vaping in the United States. While vaping is not benign, it does not loom large in the range of harmful risks facing young Americans today. It does not, for example, cause the violence, road traffic and other accidents, or the sexual vulnerability caused by alcohol use. The most lasting consequence of vaping would be if an adolescent who vapes takes up smoking and continues for decades, never returning to vaping.

Have we seen similar increases in youth e-cigarette use elsewhere? The sharp rise in youth vaping experienced in the United States has not been universal. It is not mirrored in the United Kingdom, for example. In the UK in 2019, only 1.8% of 16-18-year-olds were using e-cigarettes more than once per week, and as with the United States, the more frequent users were likely to be users of other tobacco products and therefore may be benefitting from displacing smoking with vaping.[5]

4.1 Conclusions

Policymakers should respond to reasonable concerns about youth vaping through measures that are proportionate to risk and are targeted at youth. This would mean measures to control:

- *Access* – stricter age restrictions and verification, retailer compliance, control over retail settings (for example, sale only permitted in age-restricted environments such as vape stores or with strong online age verification)
- *Marketing* – control of advertising themes, placement and time; restrictions on branding and flavour descriptors designed to appeal to adolescents; restriction of flavour descriptors to literal and informative descriptions.
- *Communications* – information campaigns can be targeted at youth to highlight risks of uptake of any tobacco product.

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4 Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance — United States, 2017. *MMWR Surveill Summ* 2018;67(No. SS-8):1–114.

5 Action on Smoking and Health (UK). Use of e-cigarettes among young people in Great Britain. June 2019 [link]

5 Limiting the nicotine level in e-cigarettes will cause more harm than good

American experts Neal Benowitz, Eric Donny, Dorothy Hatsukami argue that it would be a mistake to make e-cigarettes less viable as alternatives to cigarettes. [6]

> *To facilitate the transition from combusted to non-combusted forms of nicotine, we recommend that regulations regarding e-cigarettes and other ANDS focus on toxicity, safety and limiting youth uptake, but do not disrupt features that make them viable alternative to cigarette smoking.*

The European Union nicotine cap (20mg/ml – approximately 2% solution) is the outcome of a back room unscientific political deal made late in 2013. The intention of the European negotiators was to set a limit that allows the nicotine delivery of an e-cigarette to match that of a cigarette. In fact, this limit has been set too low – effectively making cigarettes relatively more competitive in the European Union. There are four specific problems that arise from setting a nicotine cap too low:

1. E-cigarettes will be unsatisfactory for many heavier smokers, yet this group is at greatest risk of serious smoking-related disease.
2. Some smokers will struggle to switch from smoking to vaping because the initial experience will be unsatisfying while they are still learning to use an e-cigarette. Higher strength liquids may help people make a transition from smoking to vaping.
3. Generally, smokers and vapers will moderate consumption of nicotine to achieve the level that satisfies them. Weaker liquids mean consuming more liquid for a given nicotine dose and therefore more exposure to any harmful agents in the aerosol.
4. High strength liquids are important for innovation and new designs. For example, to build a compact device that can only accommodate a small battery it is necessary to use stronger liquids if it is to compete with cigarettes.

The Juul product has attracted much attention because it uses a strong nicotine liquid (59mg/ml). Juul has been extremely successful in appealing to adult smokers by virtue of its nicotine delivery, compact size and ease-of-use. It has played a key role the recent rapid decline in cigarette consumption in the United States. However, the e-cigarette and Juul nicotine delivery does not exceed what is possible from larger e-cigarette devices or from cigarettes[7] [8].

5.1 Conclusion

The is no reason to make cigarettes more competitive by making e-cigarettes less competitive by inhibiting their nicotine delivery. A limit on nicotine is not justified and would be another form of protection of the cigarette trade, which is, in practice, unconstrained by limits on nicotine delivery.

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6 Benowitz NL, Donny EC, Hatsukami DK. Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game. Addiction. Wiley/Blackwell (10.1111); 2017 Jan;112(1):6–7. [link]

7 Yingst JM, Hrabovsky S, Hobkirk A, Trushin N, Jr JPR, Foulds J. Nicotine Absorption Profile Among Regular Users of a Pod-Based Electronic Nicotine Delivery System. 2019;2(11):15–8. [link]

8 Voos N, Goniewicz ML, Eissenberg T. What is the nicotine delivery profile of electronic cigarettes? Vol. 16, Expert Opinion on Drug Delivery. Taylor and Francis Ltd; 2019. p. 1193–203. [link]

6 Prohibitions of e-cigarettes or most e-cigarette flavours would create black markets, lead to more dangerous products, and protect the cigarette trade

6.1 Negative impact of prohibitions

Regulators should not assume that products that have been banned just disappear and that everything else will carry on as before. A prohibition is an intervention in a market, and it may have a number of harmful unintended consequences as consumers and suppliers (legal and illegal) respond.

- Existing vapers or dual users may revert to smoking or the use of other tobacco products and current smokers who would otherwise switch to vaping in the future may remain as smokers;
- The development of a new and flourishing black market in flavoured nicotine e-liquids manufactured by amateurs, opportunists, and criminal enterprise – this will *increase* health risks;
- A transfer of the supply of flavoured products from legitimate businesses in the Philippines to highly professional consumer-facing international internet-based suppliers (see the Hong Kong based Fast Tech, for example);
- Migration of users to the existing unregulated sub-culture of home mixing of nicotine and food flavours – this brings new risks;
- Some may switch to whatever vaping products are permitted – providing these are pleasurable, affordable and accessible;
- Some may quit vaping and smoking altogether (though may increase other risk behaviors).

The experience with other prohibitions has generally been very poor, promoting criminality, violence, corruption and the sale of dangerous adulterated products made in unsanitary conditions.

6.2 Negative impact of banning e-cigarettes or e-cigarette flavours on adults

For adults, there is plenty of data showing strong preferences for non-tobacco flavours. Based on experimental data, Bucknall et al. 2019 estimated the effect of a flavour ban in cigarettes and e-cigarettes. The authors concluded [9]

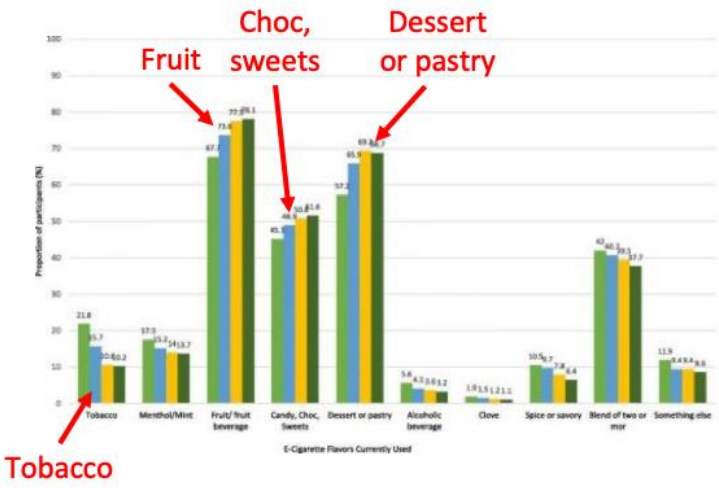
> *A ban on flavoured e-cigarettes alone would likely increase the choice of cigarettes in smokers, arguably the more harmful way of obtaining nicotine*

This was elaborated as follows:

> *[…] banning flavours in e-cigarettes, while allowing menthol in cigarettes would result in the greatest increase in the selection of cigarettes (8.3%), and a decline in the use of e-cigarettes (−11.1%). A ban on all flavours, but tobacco in both products would increase 'opting-out' the most (5.2%) but would also increase choice of cigarettes (2.7%) and decrease choice of e-cigarettes (−7.9%).*

[9] Buckell J, Marti J, Sindelar JL. Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment. Tob Control. 2019 Mar 1;28(2):168–75. [link]

Surveys of adult users also show a strong preference for flavoured e-cigarette products. See, for example, Russell et al. 2018, which shows fruit, candy and dessert dominating the flavour preferences of adults.[10]



Many use flavours to leave behind the experience of smoking altogether and have higher switching rates if they use flavoured products.[11] We need to take care that a flavour ban aimed at protecting teens from a relatively minor risk does not end up exposing adults to far greater risks. A broad flavour ban is likely to have exactly that effect.

It is hard to know in advance how vapers (adult or adolescent) will respond to a broad flavour ban. It would depend on its extent and what remains available, what happens in the black market, alternative commercial options etc.

6.3 Prohibitions of e-cigarettes will protect the cigarette trade

In the United States in last two years, cigarette sales volumes have been falling at up to four times the long-term trend rate – likely attributable to the rise of e-cigarettes and especially Juul in the adult market. Numerous stock analyst reports have linked a possible flavour ban to an improved outlook for cigarette sales but with no real benefit to teenagers. For example, Bonnie Herzog, Wells Fargo Securities, September 18, 2019:

> *Our recent survey revealed: Almost 50% of retailers believe the removal of flavours in e-cigs won't help reduce youth usage of e-cigs as kids are more likely to turn to the black market/D.I.Y. for product […] The majority of retailers believe that removing non-tobacco e-cig flavours (esp mint/menthol) would be positive for combustible cigs (>70%) & oral nicotine (~60%) and negative for e-cigs (85%).*

[10] Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavour used and current flavours used by 20,836 adult frequent e-cigarette users in the USA. Harm Reduct J. *BioMed Central*; 2018 Jun 28;15(1):33. [link]

[11] Russell C, Haseen F, McKeganey N. Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months. *Harm Reduct J*. 2019 Nov 7;16(1). [link]

6.4 Clarity about flavours

it is important to be clear what a flavour is. It can be three things:

1. A chemical formulation. A recipe with precisely specified ingredients
2. A subjective sensation. For example, a user perception that it tastes like apple
3. A descriptor. The name given the product, which may or may not faithfully reflect the sensation.

In considering interventions on flavours, the following approach should be adopted:

- Interventions on the chemical formulation should be focussed only on controlling particular hazards (e.g. allergens, respiratory sensitisers, carcinogens etc)
- Interventions to ban a particular sensation are difficult and will reduce appeal to adults. This should be avoided.
- Interventions to control branding and names that appeal to children is possible. For example, it could be made illegal to use trademarks from children's products, to use cartoon imagery, or frivolous brand or flavour names.

6.5 Conclusion

If there are concerns about youth vaping in the Philippines, I would recommend addressing this through the restrictions on marketing (flavour descriptors and imagery, promotion) and access (enforcement of age restrictions and sales in age-restricted environments) and not an attempt to regulate sensory characteristics of e-liquids.

7 Safety – is it fair to say to say "e-cigarettes have 95% lower risk than smoking"?

In 2016, the UK's oldest and most distinguished medical society, the Royal College of Physicians (RCP), made the following statement in its major report on tobacco harm reduction.[12]

> *Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure".*
> (Section 5.5 page 87)

The government public health agency, Public Health England (PHE), made a similar statement in 2015[13] which it reaffirmed in 2018.[14] PHE concluded in 2018:

> *Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.*

In both cases, these judgements were reached by independent experts with no industry connections following the extensive evidence reviews presented in the reports. There work has often been misrepresented or misunderstood.

The US National Academies of Science, Engineering and Mathematics also conducted an extensive review of e-cigarette evidence. It drew similar conclusions to the RCP and PHE – that e-cigarettes are "likely to be far less harmful" than cigarettes – though without providing a quantified guideline.[15]

- *While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.*
- *E-cigarettes contain fewer numbers and lower levels of toxic substances than conventional cigarettes*
- *The long-term health effects of e-cigarettes are not yet clear.*

The reason that both RCP and Public Health England have made statements like this is that UK public perception of the relative risk of smoking and vaping is far out of line with expert perception. These agencies worry, therefore, that public misunderstanding is a barrier to smoking cessation via switching to vaping.

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12 Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

13 McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [link]

14 McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

15 National Academies of Science, Engineering and Medicine NASEM (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [link] Launch presentation summary (slide 44) [link][link]

Public Health England summarised the state of relative risk evidence evidence in its 2018 report:

- One assessment of the published data on emissions from cigarettes and e-cigarettes calculated the lifetime cancer risks. It concluded that the cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking.
- Comparative risks of cardiovascular disease and lung disease have not been quantified but are likely to be also substantially below the risks of smoking. Among e-cigarette users, 2 studies of biomarker data for acrolein, a potent respiratory irritant, found levels consistent with non-smoking levels.
- There have been some studies with adolescents suggesting respiratory symptoms among e-cigarette experimenters. However, small scale or uncontrolled switching studies from smoking to vaping have demonstrated some respiratory improvements.
- E-cigarettes can release aldehydes if e-liquids are overheated, but the overheating generates an aversive taste.
- To date, there is no clear evidence that specific flavourings pose health risks but there are suggestions that inhalation of some could be a source of preventable risks.
- To date, the levels of metals identified in e-cigarette aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary.
- Biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed in this chapter, similar levels to smokers abstaining from smoking or non-smokers were observed.
- One study showed no reductions across a range of biomarkers for dual users (either for nicotine replacement therapy or e-cigarette dual users).
- To date, there have been no identified health risks of passive vaping to bystanders.
- Reporting of some academic studies has been misleading

7.1 "Long term effects are unknown"

We will not be certain of the long-term effects until several decades have passed. Even then it may be impossible, as products will evolve, and most users will also have been smokers and may use a variety of products. It is true that we do not have 50 years of data on e-cigarette use – the products have only been in widespread use for less than 10 years. However, if we focus on *what we do know*, then there is a great deal of data suggesting much lower risk.

The important data show much lower levels of toxins in vapour aerosols and much lower concentrations of toxins when measured in the blood, urine and saliva. Because there is no combustion, toxins that are generated by combustion are generally absent or much lower.

8 Policy proposals – regulating e-cigarettes with risk-proportionate regulation

In a recent submission to the Government of New Zealand we argued for risk proportionate regulation.[16] The following summarizes the main policy

Effective regulation involves striking a balance between measures that are so weak they do not have the intended effect and measures that are so excessive that they cause unintended harm, for example, by obstructing smokers switching from smoking to becoming smoke-free by making smoke-free alternatives more expensive, less appealing, or more difficult to access. The way to strike this balance is to adopt 'risk-proportionate regulation'. This imposes regulatory burdens and controls in proportion to the risk posed by the product, but also taking account of the opportunities it offers.

Key features of such framework would include the following:

- **Differentiation between smoked and smokefree products**. A comprehensive framework would cover all forms of consumer nicotine product. The key differentiator for policy purposes is whether the product is for smoking. Combustion is far more important than the distinction between tobacco and non-tobacco products. Smokefree tobacco and nicotine products can displace smoking and greatly reduce health burdens. It follows that they should be treated differently to smoked products – reflecting opportunity as well as risk.
- **A nuanced approach to youth use of smokefree products**. Measures introduced to protect youth should focus primarily on responsible marketing and not on modifying or limiting the appeal of the product itself to adults. Youth use may be beneficial for some young people who are smokers or would-be smokers – it is important, therefore, to recognise that some young people could be potentially harmed by measures aimed to protect youth.
- **Recognising that flavours play an important role**. Flavours are integral to the appeal of smokefree alternatives and an essential part of the proposition to smokers to try switching and remain smokefree. They also raise concerns about attracting non-smoking youth. We recommend focussing controls on marketing, branding, and flavour descriptors rather than on banning particular flavour chemicals or categories (except where there are safety concerns).
- **Controls on advertising, not an outright ban**. Advertising allows new smokefree products and innovation to reach smokers and encourage switching. It is, in essence, anti-smoking advertising. Controls on themes, placement, timing and media are appropriate, but not a ban. It is important to recognise that a ban on advertising of smokefree alternatives has the effect of protecting the dominant cigarette trade and discouraging smoking cessation.
- **The policy for use of smokefree products in public spaces should be a matter for owners or managers**. In the absence of evidence of a plausible material risk to bystanders arising from vaping or heated tobacco products, the government should not mandate wide-ranging bans; nor should it treat smokefree vapour products as though they are smoked products. The same reasoning applies to limitations by local authorities on vaping in outdoor places, e.g., central

[16] Bates CD, Beaglehole R, Sweanor DT, Youdan B. A Surge Strategy for Smokefree Aotearoa 2025 The role and regulation of vaping and other low-risk smokefree nicotine products, October 2019 [link][summary][press notice]

business districts, beaches, and parks. The government's role should be to provide information to assist decision-making by owners and managers of properties.

- **Warning and packaging labels should convey accurate information including messages that explain relative risk**. Warnings should not be misused to scare users out of trying products that could be life-saving for them. They should be focussed on helping smokers make better-informed decisions by communicating relevant risk information, including risks relative to smoking, ideally using a range of statements authorised by health officials.
- **Smokefree products should have access to the market via a notification regime**. There should be no requirement for pre-market authorisation, but post-market surveillance and a system for product stewardship that allows improvements and innovations to assist in mitigating safety risks or emerging problems.
- **Products should meet specific safety standards for devices, liquids and ingredients**. Such standards for chemical, thermal, mechanical and electrical safety are emerging internationally. For heated tobacco, standards should provide assurance that there is no combustion. There are established and recommended standards for smokeless tobacco to draw on.
- **Plain-packaging should be mandatory for smoked products only**. The rationale for standardised plain packaging does not apply to smokefree alternatives, which both impose low risks and offer substantial benefits to smokers who switch. Different packaging would also help convey to consumers the different risk profile of these products in a clear and intuitive manner.
- **The fiscal regime should create a strong incentive to switch from smoking to smokefree products**. Most smokefree products should attract only standard sales taxes and zero excise duties. If excise duty is applied, it should leave the highest-taxed smokefree product with vii a much lower tax burden than the lowest-taxed smoked product to support switching.
- **Public health agencies should provide well-crafted communications to help smokers make informed choices**. Public health communicators should engage all relevant stakeholders in communicating risk and the case to switch from smoking to smokefree products.

The key policy challenge for e-cigarettes is avoiding harmful unintended consequences. The problem is that because e-cigarettes are alternatives to the much more harmful cigarettes it is very easy for policies designed to control e-cigarettes to have the effect or protecting cigarettes. The next section provides a checklist of plausible unintended consequences that should be carefully assessed before proceeding with any policy initiative.

9 Checklist of plausible unintended consequences of excessive regulation

In its 2016 report on tobacco harm reduction, the Royal College of Physicians summarised the possible risks of unintended consequence arising from excessive regulation[17]:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.*
>
> *However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult*. (Section 12.10 page 187)

The table below provides a checklist of the possible unintended consequences arising from excessive regulation of reduced-risk nicotine products - vaping, heated and smokeless tobacco.

Policy	Plausible unintended consequence
High compliance costs or barriers to market entry	A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy - users may find the experience less satisfactory, so continue to smoke or relapse. Alternatively, a black or grey market of possibly unregulated products develops – responsible domestic producers are destroyed and cross-border trade meets demand. Cumbersome or expensive authorisation regimes make innovation more difficult and expensive, so there will be less innovation and experimentation with consumer preferences.
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping. Heavier or more dependent smokers may find e-cigarettes unsatisfying – so those most at risk are denied the products more likely to work. May drive users to black market and/or home mixing with high strength liquids. Barrier to successful innovation like the Juul products, which use high strength e-liquids (~5%).
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased – creating points for possible relapse. Poisoning risk is not normally managed by limiting container size (e.g. for medicines, alcohol).
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking. May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.

[17] Tobacco Advisory Group of the Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

Policy	Plausible unintended consequence
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control products may become dull and sterile, diminishing appeal. Almost all e-cigarette advertising is a form f anti-smoking advertising provided without any call on public funds – it would be perverse to stop this and spend public money instead.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users without needing thousands of shops holding very large stocks of slow-moving inventory. If users are forced to purchase from 'bricks and mortar' outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive.
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market and reduce the pace of innovation.
Bans on flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black-market flavours – which may be more dangerous. Even with young people, there is the possibility that any attraction to flavours is an attraction away from cigarette smoking and may be beneficial, meaning a ban would be harmful.
Bans on refillable systems	This idea was proposed by some tobacco companies for commercial and anti-competitive reasons. It means removing the 'open system' 2nd and 3rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black-market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.

Policy	Plausible unintended consequence
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco (e.g. "This is not a safe alternative to smoking") Warnings do not adequately communicate relative risk and, therefore, understate smoking risks or downplay the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications. Warnings about nicotine may exacerbate misperceptions about the (minimal) role of nicotine in causing disease. Warnings about addiction play on fears of loss of control or harm to the user that exaggerate the consequences of nicotine use through vaping.
Ban sales to under-18s	There is near universal support for this policy. But US studies found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
Controls on "addictiveness"	Limiting the psychoactive impact of nicotine by, for example, controlling pharmacokinetics (PK), acidity, additives etc. risks limiting the capability of e-cigarettes to replace cigarettes for some smokers – and therefore implies a trade off in favour of reducing dependence rather than reducing serious disease. The problem of 'abuse liability' is why NRTs have not been that successful.
Prohibit health or relative risks claims	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers. Those determining whether a health claim should be allowed are often "loss averse" – concerned about what might go wrong if they allow a claim to be made. However, they rarely pay equivalent attention to the "false negative" error: the lost benefit arising from rejecting a claim that is in fact valid.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT. Establishing a tax regime is costly for both authorities and manufacturers – those costs are passed on to consumers depressing demand and reducing the price sensitivity of users to increases in cigarette prices. If the tax is made risk-proportionate, it would likely to be too low to be worth the expense of collecting – so any tax on vaping is likely to be disproportionate be default.

Appendix 1: Commentary about tobacco harm reduction in *The Lancet*

Article: Nicotine without smoke: fighting the tobacco epidemic with harm reduction. Lancet. 2019 Aug 31;394(10200):718–20. [link]

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Nicotine without smoke: fighting the tobacco epidemic with harm reduction

Richard Baker/Getty Images

The rapid rise of smoke-free nicotine products, especially vaping, is the most disruptive influence on smoking in decades. These products are challenging not only smoked tobacco's stranglehold on the nicotine market but also the public health response to tobacco harm reduction, including by WHO.[1] In October, 2018, 72 experts with no connections to the tobacco industry wrote to the WHO Director-General to argue that WHO should embrace innovation and more actively include tobacco harm reduction in its strategy to tackle the burden of smoking-related disease.[2] However, the *WHO Report on the Global Tobacco Epidemic, 2019*[3] continues to underappreciate the potential of low-risk alternatives to smoking.

The tobacco harm minimisation strategy complements other tobacco control strategies but has been underappreciated because for many in tobacco control the emphasis has been on achieving abstinence of all tobacco and nicotine use. However, abrupt cessation of nicotine has had low population success rates—for example, 4–5% in the USA.[4] Regrettably, many smokers find it hard to quit and go on to die prematurely—around 8 million a year.

The latest WHO report on the global tobacco epidemic stresses the importance of best-practice tobacco cessation services based on a medical treatment model. Unfortunately, this approach has had limited population level impacts because of low uptake, and is in contrast to the much more promising consumer-led approach to cessation based on safer alternatives to smoked tobacco. The potential of vaping is that it combines high efficacy with widespread uptake. The latest WHO report is a missed opportunity to embrace innovation and to exploit the potential of low-risk alternatives to smoking.

People smoke cigarettes for the nicotine but die from the tar.[5] The modern tobacco epidemic is based on factory-made cigarettes, a commercially successful product that has barely changed in 75 years. There are 1·4 billion tobacco users aged 15 years and older worldwide—1·07 billion smokers and 367 million smokeless tobacco users—a small number of whom use both smoked and smokeless tobacco.[3] Tobacco smoking's dominance of the nicotine market comes at huge cost with over a billion lives expected to be lost to tobacco smoking this century.[6]

Nicotine replacement therapy (NRT) has been available since 1978. These products are designed to partly mitigate nicotine withdrawal and assist an attempt to quit smoking and nicotine use. While this approach suits some people, absolute success rates are low.[7] It is hard to defend the pharmaceutical model as best practice when there is an increasing body of evidence that people who use electronic vaping products to quit are achieving better quit rates than those on phamacotherapies.[8]

Electronic vaping products (e-cigarettes) deliver nicotine through a heated aerosol consisting of a diluent, nicotine, and flavourings; it is inhaled much like smoking but without the damaging by-products of burnt tobacco. Heated tobacco products use a similar approach, with a vapour aerosol drawing the added flavour and nicotine from tobacco that has been heated rather than burnt, but with more toxins in the vapour than in that of e-cigarettes.

The key to the public health impact of vaping will be the willingness of more smokers to switch the way they use nicotine rather than to quit completely. Vaping meets the needs of some ex-smokers by substituting physical, psychological, social, cultural, and identity-related aspects of tobacco addiction. Some vapers report that they find vaping pleasurable and enjoyable—being more than a substitute but actually preferred, over time, to tobacco smoking. This suggests that vaping is a viable long-term substitute for smoking, with substantial implications for tobacco harm reduction.[9]

The long-term health implications of vaping cannot be known for certain for decades. However, evidence on the toxicology of aerosols and human exposure to toxins informs judgments about the likely effects of vaping. Estimates suggest that the risks of vaping are unlikely to exceed 5% of those associated with smoked tobacco products.[10,11] The precise figure has been controversial, but other assessments have concurred that e-cigarettes are considerably less harmful than smoking.[12] In April, 2019, the US Food and Drug Administration (FDA) made its first approval of a heated tobacco product, noting "While the authorization of new tobacco products doesn't mean they are safe, the review process makes certain that the marketing of the products is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole."[13]

Estimates from 50 countries suggest that at least 40 million adults were vapers in mid-2018.[14] If use of e-cigarettes leads to people stopping smoking completely, this would substantially reduce the population health impacts of tobacco. Evidence on this point comes from trials and real-world experience. For example, a 2019 randomised controlled trial[8] set in stop smoking services, showed e-cigarettes to be approximately twice as effective as NRT, aligning with real-world survey data on quitting.[4,15] Further trials and observational studies, especially on dual use of cigarettes and vaping, will be informative.

A major concern raised about vaping is youth uptake, especially in the USA, where former FDA Commissioner Scott Gottlieb claimed there is an "epidemic" of youth vaping.[16] It has been widely reported that one in five US high school students had used e-cigarettes in the past 30 days when surveyed in 2018.[17] However, a more detailed examination of these data suggests that almost three-quarters (72%) of the students were not regular vapers, but experimental and occasional users.[17] Since most regular US youth vapers have also used other tobacco products, it raises the prospect that vaping might be a gateway out of, not into, tobacco use. In the UK and New Zealand, where youth e-cigarette use is also measured, prevalence of vaping in the age groups surveyed shows e-cigarette use by never smokers is less than 0·4% in both countries.[18,19]

Although increases in youth vaping are likely,[20] the public health impacts of these trends will be small;[21] this issue, however, requires further research from large, long-term longitudinal studies, with assessment of potential confounders. The suggestion that the nicotine from vaping harms the brains of young people is based mainly on rodent studies.[22] We are not aware of any evidence to suggest brain impairment in the generations of smokers who have used nicotine as adolescents.

Smoke-free products are disrupting traditional cigarette markets. In Japan, which has led the world in the use of heated tobacco products, cigarette unit sales declined by a third between 2016 and 2019.[23] In Sweden, oral tobacco (snus) has impacted the smoked tobacco market such that, by 2017, daily smoking among adults had fallen to just 5% compared with the European Union average of 24%.[24]

Some of the responses from the public health and policy community to these disruptive technologies have been negative and focused on minor risks, such as malfunctioning devices, uncertainty about the long-term effects of e-cigarettes, and tobacco industry involvement in the vaping market, rather than appreciating the opportunities. In 2018, WHO reported that e-cigarettes had been banned in 30 of its 194 member countries.[25] Prohibition or regulations, such as banning flavours, and restrictions on marketing, advertising, and sponsorship comparable to smoked tobacco products, will disadvantage smokers wanting to quit and further embed smoking as the most accessible option for nicotine use (perversely privileging the cigarette). Invoking the precautionary principle to prevent the use of smoke-free products is unjustified in the face of the massive burden of smoked tobacco products, which are ubiquitously available.

The policy response to smoke-free products has to be different from existing tobacco control strategies, which

include tax increases, advertising bans for cigarettes, and upstream restrictions on supply. Instead, policy priorities for smoke-free products should be to exempt them from excise taxes to maintain a fiscal incentive to switch; control rather than ban marketing to allow smoke-free products to challenge the dominance of the cigarette; provide public education campaigns on harm minimisation; not force vapers to share smoking areas; and support use of smoke-free products as a quit aid. Risk-proportionate regulation will help adults quit smoked tobacco as well as protecting against being appealing to young people.

Vaping and other smoke-free products have the potential to reduce the enormous harm of smoked tobacco products. The stakes of getting policy responses to smoke-free products wrong are high, especially if such restrictions stop millions of the world's smokers accessing safer alternatives. It is disappointing that in its latest tobacco report,[3] WHO clings to outdated orthodoxy when it could embrace innovation. Equating smoke-free products with cigarettes only serves to protect the stranglehold of the cigarette trade on the world's nicotine users and will nullify the potential of modern tobacco harm reduction strategies.

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Appendix 2: Letter to the Director General of WHO

Letter: Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction

From: Seventy-two independent specialists in nicotine science, policy and practice

To: Dr Tedros Adhanom Ghebreyesus, Director General, World Health Organisation

Date: 1 October 2018

Pages: 3 (or 7 including signatures)

Link: https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf

Letter from seventy-two specialists in nicotine science, policy and practice

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1 October 2018

Dear Dr. Adhanom Ghebreyesus

Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction

We write to express our hope that WHO will assume a leadership role in promoting effective and fast-acting policies for regulating tobacco and nicotine. In this letter, we propose that WHO and related stakeholders adopt a more positive approach to new technologies and innovations that have the potential to bring the epidemic of smoking-caused disease to a more rapid conclusion.

In the field of tobacco control and public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user *without combustion of tobacco leaf and inhalation of tobacco smoke*. These technologies offer the prospect of significant and rapid public health gains through 'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4).

The concept of tobacco harm reduction is coded into the definition of 'tobacco control' set out in the FCTC (Article 1.d), and we believe it now needs to be fully expressed in the FCTC and by the Parties in their approach to implementation. To that end, we offer some guiding principles for your consideration for the development of the next phase of global tobacco control, starting from the next Conference of the Parties (COP-8, 1-6 October, Geneva).

- *Tobacco harm reduction is integral to tobacco control*. Harm reduction is a widely practiced strategy in public health (e.g. HIV, drug use, sexual health) and should become an integral component of tobacco control – helping smokers to quit smoking or diverting them from ever starting, and, in either case greatly reducing their risk.
- *From a health perspective, the major distinction between nicotine products is whether they are combustible or non-combustible.* It is not whether they are tobacco or non-tobacco products or whether they are established or novel. Given the principal focus of the FCTC is management of health risks, this distinction should be integral to the design and implementation of the FCTC[1].

[1] We recognise that poor production standards and the inclusion of slaked lime (calcium hydroxide), areca nut and other hazardous ingredients in some traditional tobacco-containing products such as gutka and paan can make these products much more hazardous than other smokeless tobacco products.

- *Tobacco harm reduction is supportive and synergistic with the 'MPOWER' policies that underpin the FCTC.* By providing more diverse options for users to respond to taxes or other measures, harm reduction can improve the effectiveness of conventional measures and mitigate the unintentional harmful consequences of such policies to continuing users, for example the impact of cigarette taxes on people who would otherwise continue to smoke.
- *Stakeholders should give appropriate weight to the benefits and opportunities of tobacco harm reduction*. They should not focus exclusively on unknown risks to health, especially when these are minor or improbable risks. A lost opportunity for a public health gain represents a real harm to public health, and should be recognised as such.
- *Youth uptake of any tobacco or nicotine product demands a coherent and adaptable strategy focussed on reducing present and future harms to young people.* Policies to address youth nicotine use should be based on an understanding of youth risk behaviours, the interactions between use of different products (for example, for some young smokers the potential displacement of smoking by low risk products may be beneficial), and due regard for the overall balance of harms and benefits to both adults and to youth arising from interventions.
- *Uncertainty about long-term effects should not be a reason for paralysis*. It is true we will not have complete information about the impacts of new products until they have been used exclusively for several decades – and given the complex patterns of use, we may never. But we already have *sufficient* knowledge based on the physical and chemical processes involved, the toxicology of emissions, and biomarkers of exposure to be confident these non-combustion products will be much less harmful than smoking. We also know with certainty that the incumbent product (cigarette) is extremely harmful.
- *FCTC and its implementation should embrace "risk-proportionate regulation".* This means that the stringency of regulation or taxation applied to product categories should reflect risk to health. For example, there should be high taxes on cigarettes, but low or no taxes on vaping products. It is reasonable to ban all advertising of combustible products, but to place controls on advertising for non-combustible products (to protect never-smoking youth in particular) and so allow enough promotion so that smokers can still learn of alternatives and can be encouraged to switch. This risk-proportionate approach should be adopted throughout the FCTC.
- *WHO and Parties to the FCTC should be aware of and careful to avoid the harmful unintended consequences of prohibitions or excessive regulation*. If WHO-endorsed policies make non-combustible alternatives to smoking less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibit innovation and development of new and improved products, then these policies can cause harm by perpetuating smoking.
- *The FCTC negotiations should become open to more stakeholders*. There are many stakeholders, including consumers, the media and public health experts with pro-harm-reduction views, who should be part of the process. We are concerned that the FCTC has been excluding appropriately diverse perspectives and that its deliberations and decisions could be more robust and credible if its proceedings were more open.

We are concerned that WHO and the Convention Secretariat are not embracing these principles and in many cases are doing the opposite. We have seen the more detailed letter to you of 3 September

by Abrams et al regarding prohibition and excessive regulation[2]. We recommend that this letter be read carefully by everyone with an interest in the future of tobacco control.

We believe that it is time for tobacco control to embrace tobacco harm reduction. We hope that WHO and Parties to the FCTC will advance this agenda at the Eighth Conference of the Parties of the FCTC, starting today. We will share this letter with relevant stakeholders.

The authors of this letter confirm no conflicts of interest with respect to the tobacco industry and that no issues arise with respect to Article 5.3 of the FCTC.

Yours sincerely,

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Letter from seventy-two specialists in nicotine science, policy and practice

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