

Potential amendments to the regulation of nicotine vaping products

Coalition of Asia Pacific Tobacco Harm Reduction Advocates (CAPHRA)

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by: Nancy Loucas, Executive Coordinator on behalf of the member organisations of CAPHRA

Executive Summary:

We are the Coalition of Asia Pacific Tobacco Harm Reduction Advocates - a coalition of 11 consumer advocacy groups in Asia Pacific who work alongside government and public health officials towards risk proportionate regulation in our respective countries. All of us are former adult smokers, some of us for over a decade, and some of us for only a couple of years. All member organisations are run by volunteers who are not paid for their advocacy in the field of tobacco harm reduction. Nor do the principals of the organisations have any vested financial interest in the industry.

We kindly ask that you accept and review our commentary below with regards to the Amendment to the Tobacco and Related Products Order. As consumers of safer nicotine products, we are keenly and intimately aware of the benefits that these products have offered us, and we view ourselves as the evidence of their effectiveness to assist adults switch off combustible smoking. We also thank you for the opportunity to comment on the amendments put forth to the committee.



Main Submission:

The member organisations of CAPHRA recognize the need for regulations, as regulations are necessary to guarantee the safety of e-cigarettes and to limit the accessibility to youth.

However, as we noted in our submissions to the Therapeutic Good Administration, following the medical model as the only access to nicotine, has caused harm in the community - not only with access issues for adults who smoke, but the prevalence of unregulated black-market products that have no regulatory controls for either contents or access to those under the age of 18.

We remind you that keeping the product that can and will kill half its users readily available whilst limiting access to the product that is 95% less harmful defies logic. Public health is about the public, the people, not corporates. One need only look across the Tasman to New Zealand to see that a risk proportionate consumer market for safer nicotine products has worked to drastically reduce the adult smoking rates in the two years since regulation was introduced.

Our submission will outline and address several inaccuracies made within the discussion document and the suggested options presented in this consultation, by providing further options to build upon what is presented. The proposed options suggested by this latest amendment are only going to further complicate people who smoke to have access to significantly safer alternatives and limit Australia's ability to be fully smoke free.

Several countries in the world, including UK, Canada and New Zealand, have implemented sensible regulations that strike the right balance between making sure that vaping is easily available for smokers while ensuring vaping products are not marketed or sold to young people. Our shared vision, is for a Smoke Free Australia. Therefore, we will address the following:

Of Australia's nearly 130,000 registered medical practitioners who are able to write nicotine prescriptions there are, according to latest statistics from November 2022, only 1513 authorised prescribers in the entire country. Of those, only 474 authorised prescribers had consented to TGA publication of their name and surgery. This means that a little over 1% of those who are able to write nicotine scripts do so. And less than 1/3 of those who are authorised prescribers are publicly available for adult smokers who wish to switch to nicotine vaping.

It is more than apparent that the regulations are not achieving their intended purpose. It is clear that a black market of NVPs exists, and that NVPs are being readily accessed unlawfully by children and adolescents, and by adults for 'recreational' purposes (i.e. not for smoking cessation), without a prescription. This was something that you were informed could and would happen if you were to proceed with the medicalisation model. By



advocates, domestic and international health professionals who had far more experience and knowledge than you had regarding the process.

The proposed amendment states that there is evidence that vaping leads to smoking in adolescents ("Gateway Theory"). A theory fully disproven by various studies as outlined in the enclosed reference document at the end of this submission. The only youth who have been converted to smoking from vaping are those whose parents have made the suggestion it was *safer* to smoke. Based on information provided by the Australian government and health "experts".

More concerning: recently a registered Australian GP has publicly admitted how he handled the situation when his own child was found to be vaping - it was preferrable for the youth to smoke. How is it, especially for a GP, to believe that smoking is less harmful than vaping, this clearly shows the great disconnect between science, evidence and the diktats of the AMA, the TGA and the Ministry of Health in Australia.

While we agree that vaping products should be regulated, a sensible set of quality and safety standards can be implemented following a risk proportionate approach that ensures equal access to these products as consumer products while limiting the uptake of these products by never-smokers as any other consumer product with age-restricted access - such as implementing restrictions on advertising, as currently required for alcohol and cigarettes, as is the case in NZ, Canada, UK and Europe.

- Vaping has a similar risk when compared to conventional NRT, but increasing evidence suggests that is at least 70% more effective than NRT.
- E-cigarettes are 95% safer than smoking, enabling access will only help Australians to be smoke free sooner, and access to e-cigarettes will only contribute a drastic reduction in the 21,000 deaths each year in Australia directly attributed to the consumption of combustible tobacco.
- Australian smoking rates have remained stubbornly flat in the last decade, especially
 among the most vulnerable and disadvantaged communities. Cigarettes not only cause
 harm, but also current taxation models perpetuate poverty rates. NRT has been
 proven to be very limited in effectiveness, while vaping is one of the most effective
 methods used by smokers to quit cigarettes around the world.
- Vaping and harm reduced products are currently used by several countries around the world including the European Union, UK, NZ and Canada to influence a rapid acceleration on the reduction of the current smoking prevalence in these countries.
- While there are no long term studies (>20 years cohort), vaping has been widely available in the world since 2003 and several studies have evaluated the same long term biomarkers used to assess the prospective harm caused by tobacco smoking.
 Vaping has been found to possess only a small fraction of the risk when compared to smoking cigarettes.



From the consumer perspective, the basis used to justify the tightening of controls to continue on the path of medicalized are limited and biased, with several statements obviously aligned with the flawed and based agendas from some medical and community associations, particularly those from the United States. Lastly, it shows a decided lack of consultation with the community within Australia, particularly smokers and vapers, and harm reduction advocates in the medical and scientific community in country.

We categorically believe that the narrative used in the consultation document and the options presented therein completely miss the point with regards to utilizing nicotine to drastically reduce the harm from combustible tobacco in Australia. The vision of this consultation document only contributes to perpetuate misperceptions around vaping, providing information that is not factually correct, while ignoring the harms of smoking and cigarettes and leaving those readily available at every Newsagent / Corner store / Supermarket / Alcohol Store in the country.

Current misperceptions around vaping and exaggerations on the harm of nicotine ignore the actual relative efficacy of NRT (products of all forms) compared to vaping, while a double standard approach on nicotine from vaping and NRT keeps ignoring the harm of combustible tobacco that kills 21,000 Australians each year.

Current treatments available for smokers are significantly less effective than vaping (These include Sprays - Gums - Patches - Medications). Recent restrictions on access to vaping only help to perpetuate the harms of combustible cigarettes on millions of Australians.

In countries where vaping is available, smoking rates are falling faster. For example: the UK had in 2016 had a smoking prevalence higher than Australia, but after enacting amendments to the Tobacco Product Directive in 2016 wide access of vaping helped to reduce smoking rates 6 times faster than in Australia.

Other countries can share the same experience. This is the case in NZ, where smoking rates have decreased thanks to a set of regulations that are set to mitigate the risks while ensuring that vaping is equally accessible to smokers as cigarettes are.

Countries that have used ineffective frameworks for regulations, like the United States, or have implemented bans, such as India, have enabled the creation of black markets, fostering the misuse of vaping products by non-smokers. Such environments failed to use a risk proportionate approach. They have also greatly benefitted the tobacco industry as their products remain freely available.



When evaluating impact what should really matter is the risk relative to smoking, which is in fact very much lower, and the absolute risk compared to other benchmarks of comparable risk in society, such as occupational health exposures, which is also significantly much lower. Talking about 'dangers' without discussing magnitude and context is meaningless and does not provide reasonable sense in policy rationale.

Tobacco smoking is by far the leading cause of cancers in Australia: 22% of the total cancer burden is attributed to smoking as stated by the latest report on cancer in Australia. Vaping helps to battle both the harms that tar and cancer substances produced by combustion by assisting smokers to transition to a product that resembles more closely the sensorial effects of cigarettes while reducing the potential cancer risk to just a small fraction when compared to combustible cigarettes.

These are the statistics that need to be first and foremost when developing policy around nicotine vaping. This was also noted in a report that the Australian government commissioned from Llewellyn Associates in October 2022 entitled "Tobacco and Vaping products in Australia: An economic assessment."

On page 5 of this report, the consultants stated that Australia is losing between 1-3 billion dollars per year in excise from illicit tobacco.

They also outline the impacts of the medicalised nicotine model:

- 22.1. From a financial perspective, every vaping product sold illegally represents a lost tax-revenue opportunity.
- 22.2. From a public health perspective, there are no controls over who buys vaping products and where they buy them. Packaging and health warnings cannot be monitored and enforced. And there are no mechanisms to restrict the ingredients used, including limits on nicotine content.

They made suggestion that Australia had three options to proceed, with the third option being a regulated consumer market having the least amount of negative impacts for both the government and the population: "Legalise the use of nicotine vaping products, regulating them as an adult consumer good through properly licenced retailers."

"This approach would enable the Australian Government to properly monitor and regulate the use of vaping products as adult consumer goods as well as generating additional revenue streams."



"If it were possible to convert each of the 1.1 million adult consumers currently using illicit vaping products to legally prescribed products via Medicare - which is moot — this would require an additional budget amount from the Australian Treasury of approximately AUD 45 million per year."

"In contrast, were vaping products legalised as described above, and each of the 1.1 million adults currently using illicit vaping products were being serviced by the legal, properly regulated — and inclusive of Goods and Services Tax (GST) — supply chain, it is possible that over AUD 200 million in new GST revenues could be generated per year."

Of the four options presented in the consultation document, we note that none offer a risk proportionate regulated adult consumer market. Instead, the continue on the path of medicalisation with increased pressure on the current Medicare system and the Australian Customs and Border patrols to limit the flow of nicotine into the country.

Nor do any of the options presented include an education programme for the over 98,487 medical practitioners in Australia to be educated on how to help their patients make the switch off of combustible tobacco - or even suggest using nicotine vaping products.

NONE of the options presented are reasonable nor feasible from an enforcement standpoint and will only continue to cause more harm to the population and increased costs to the government in terms of budget blowouts for overtime for Customs and Border Patrol as well as Health department inspectors and Police.

We continue to propose a fifth option - that Australia adopt a regulatory framework similar to the one currently in place in New Zealand for a consumer market with robust enforcement of regulations based on science and evidence.

Caveat 1: Restrict the sale of nicotine, in both freebase and salts, to 36mg/ml. Amounts higher than that should be available as a pharmacy only medicine prescribed by an authorised medical practitioner.

Caveat 2: Restrict the sale of disposable vapes to pharmacies and tobacconists. These above will limit access to high nicotine disposable vapes, which are the product of choice for youth who look to vape for the "buzz".

A regulated consumer market would give Australia the control necessary in product quality and quantity of retailers in the community. It would also allow for the products to be



"adult only" no different than alcohol and combustible cigarettes - which are both readily available in the open market for adult consumption.

The other salient point that is that if the manufacturing of Nicotine based products in Australia was accepted that would also bring revenue from the licencing of the facilities & shops.

Conclusion:

The further pursuit of the medical model for nicotine vaping has failed Australia. It has failed the communities where illicit markets have developed and products that have no quality control or production standards are readily available. The fact that the product that is most deadly to the population - combustible tobacco- is readily available at any general retailer is a mockery of public health.

If the concern is the loss of tobacco excise as adults switch to nicotine vaping, one needs only to look at the Llewellyn report to see that the Australian government can collect even more in GST revenue in a consumer nicotine market than they have on tobacco excise in years. Yet, all current products sold already contain a 10% GST component - not taking into consideration that *each* component of the current model attracts the 10% GST including freight, packing, printing, manufacturing, facility rental and all other subsequent charges.

If the concern is truly about youth access, the only way to address it is to regulate appropriately, with harsh fines and licence revocations for retailers who fail to abide by the law. In New Zealand both the smoking *and* vaping amongst Year 10 students has fallen. Drastically in the case of the former, and for the first time, in the latter group. As was expected, and is expected to continue in a downward trend.

If the concern is truly about public health, then Australia needs to only look across the Tasman to New Zealand for an example of a consumer framework that works, as over 150,000 Kiwis have switched off combustibles and onto safer nicotine products in the past year alone.

Australia needs to decide if their policy decisions around nicotine are about science, evidence and facts to promote and maintain the health of her people, or if they instead are choosing money over health, in terms of tobacco excise and other funds that they may receive for pursuing a draconian policy that has already shown itself to be a failure.



It is our hope that Australia errs on the side of public health, wellbeing and upholding the right to health and harm reduction that that they are mandated to, as a signatory to the Framework Convention on Tobacco Control.

We thank you for this opportunity to participate in this consultation.

Sincerely,

Nancy E Loucas, Executive Coordinator
On behalf of the member organisations of CAPHRA

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The Subversion of Public Health: Consumer Perspectives

Nancy E. Loucas Executive Coordinator Coalition of Asia Pacific (Tobacco) Harm Reduction Advocates

October 2022



EXECUTIVE SUMMARY: 2BACKGI 2INTRODU	JCTION:
3M 4WHO Q&A on Electronic cigarettes - 25 Ma 4Are e-cigarettes dar	-
	6
Do e-cigarettes cause lung injuries?	8
Are e-cigarettes more dangerous than combustible smoking?	9
Are ENDS addictive?	10
Are second hand ENDS emissions dangerous?	12
What role do ENDS play in smoking cessation?	14
Other Disinformation:	16
1. Are E-cigarettes a "gateway" to smoking in Youth?	16
2. There is no "Youth Vaping Epidemic"	17
3. Renormalisation of Smoking:	18
4. Myth about Flavours - They only exist to entice Youth:	19
5. What about Pregnant Women and Vaping?:	20
6. Second hand Vapour contains toxic chemicals?:	21
WHO Report on the Global Tobacco epidemic: Addressing new and emerging products. Preamble to the WHO FCTC:	20The
Articles of the Treaty	29
DISCUSSION:	33
Concerns over Legitimacy:	33
Nicotine E Liquid is not the Enemy:	33
Smoke and Mirrors - creating problems where none exist:	34
Your Money or Your Life:	34
Where there is Smoke, there is Death:	35
CONCLUSION:	33



EXECUTIVE SUMMARY:

In this document we review the information from the World Health Organisation (WHO) on their approach and guidance for safer nicotine products (SNP), specifically on e-cigarettes. (E-cigarettes are also called "vapes", ENDS, ENNDS. For the purposes of this document we will use the term e-cigarette.)

The aim of this review is to provide information and evidence that has not been included in any of the guidance publicly provided by the WHO to signatories and delegates of the Framework Convention on Tobacco Control (FCTC) on safer nicotine products (SNP).

It is hoped that the information contained in this review assists with pragmatic and objective policy discussions, decisions and regulations that are risk proportionate and will greatly assist the aim of reducing the harms of combustible and unsafe tobacco products globally as is the aim of the FCTC Treaty.

BACKGROUND:

Almost all of the adult consumers of e-cigarettes (and other reduced risk products) have been purposely excluded from the discussion around their use of the products and the impacts of policy implementations - from the WHO FCTC all the way down to the local level. It should be noted that this behaviour on the part of the WHO FCTC and *some* government and public health officials are contradictory to the principles that the WHO and the FCTC were based upon - specifically article 1d of the (FCTC) Treaty.

This has been done, we believe, to disenfranchise the adult consumers of these products as they are evidence of their efficacy and the value of innovation towards tobacco control. Many of these professionals have resorted to blatant disrespect of the consumer voice and some have made unfounded accusations that consumers and consumer advocates of Tobacco Harm Reduction are no more than tobacco company operatives trying to subvert Article 5.3 of the treaty.

The behaviour of some, not all, of the public health researchers who refuse to engage is in direct non-compliance against the ten ethical principles common across scientific disciplines. They are duty to society; beneficence; conflict of interest; informed consent; integrity; non-discrimination; nonexploitation; privacy and confidentiality; professional competence; and professional discipline.¹

Many of the officials and public health researchers who refuse to acknowledge the evidence of how these products can assist with their efforts, are operating from a "quit or die" mentality that has been ingrained in tobacco control since time immemorial.

¹ https://www.rand.org/pubs/research_reports/RR2912.html



Science *is* about innovation and progress, especially when it comes to human health. The COVID-19 pandemic, EBOLA and Monkeypox is showing all of us that we must think in an innovative and pragmatic manner to protect and save human lives.

INTRODUCTION:

Tobacco use sickens and kills millions of people every year. Over 8 million people die from a tobacco-related disease annually. The number of annual deaths can be expected to keep growing even once rates of tobacco use are in decline, because tobacco kills its users and people exposed to its emissions slowly. World Health Organization (WHO) Member States adopted the WHO Framework Convention on Tobacco Control (WHO FCTC) in 2003, which lays out specific, *evidence-based actions* that all Parties to the Convention should take to reduce demand for tobacco.²

The programmes and policies put into place by FCTC signatories since its inception in 2003 have proven effective in those countries where there have been resources to effectively implement tobacco controls. The global smoking rate has declined drastically across most signatory countries and as of 2020, only 22.3% of the global population used tobacco.³ In 1990 that figure was 59.8% of the global population used tobacco.⁴ Declines have been largest in the higher socio demographic countries, falling by more than 40% in some high-income countries, and also in several Latin American countries, notably Brazil, where prevalence has fallen by 70% since 1990.⁵

In low and middle income countries (LMIC's) the use of combustible and unsafe oral tobacco rates have not declined as dramatically. As such, the focus has been on working with those signatories in LMICs to reach the stated goal - "by 2030 reduce by one-third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being." 6

Funding Considerations:

However, it seems that the WHO FCTC and some signatory countries realise that at the current rate of decline in smoking, they may have worked their way out of relevance and need as "tobacco control". This is especially true for those governments who are directly involved in the manufacture and distribution of tobacco and those governments who rely heavily on tobacco excise (tax) to bolster their annual budgets.

Public health researchers rely on funding grants from pharmaceutical company profits, whose nicotine replacement therapy products are losing ground in the battle against combustion, impacting their bottom line. Funding programmes are also provided by local governments who use tobacco excise as money for public health research. As less people smoke, less excise is collected and the pool of funding shrinks.

⁶ https://www.euro.who.int/__data/assets/pdf_file/0020/340193/TOBACCO-CONTROL-AND-THE-SUSTAINABLE-DEVELOPMENT-GOALS_Edited.pdf



² https://www.who.int/publications/i/item/9789240032095

³ https://www.who.int/news-room/fact-sheets/detail/tobacco

⁴ https://tobaccocontrol.bmj.com/content/31/2/129

⁵ ibid.

Philanthropic Involvement:

In 2007, US billionaire Michael Bloomberg created "The Bloomberg Initiative to Reduce Tobacco Use" and has, to date, donated over 1.1 billion US dollars to this cause in the past decade. In 2016, Bloomberg was first appointed as a Global Ambassador for Non Communicable Diseases (NCDs) - a position he still holds at WHO. In 2018, it became apparent that the focus of FCTC changed from combustible and unsafe oral tobacco to nicotine, based upon concerns over access outside the pharmaceutical model and youth use of e-cigarettes.

This is the point where, we believe, WHO FCTC lost track of their mandate. We believe that this is why e-cigarettes, as of 2020 are now classified as "tobacco products" and demonised by the WHO. This is an atrocity of great proportion as these products are being ignored for their life saving potential for the remaining 1.1 billion people who currently smoke in 2022.

The Way Forward

Richard Feynman⁹, who was a Nobel Prize winning physicist had many thoughts on science, and the method by which people performed their research. In the first instance he said "The idea is to try to give all the information to help others to judge the value of your contribution; not just the information that leads to judgement in one particular direction or another." Dr. Feynman also famously said "It doesn't matter how beautiful your theory is, it doesn't matter how smart you are. If it doesn't agree with the experiment, it's wrong. In that simple statement is the key to science."

METHOD:

We begin our review with the <u>WHO Q&A on Electronic cigarettes</u> that was updated on 25 May 2022. This document is a summary of what is contained in the <u>WHO Report on the Global Tobacco epidemic: Addressing new and emerging products</u> from 27 July 2021.

For the former document, we provide links to scientific research that WHO FCTC has chosen to not consider in their review of the evidence. There is also commentary from public health experts on the document to support the scientific research that has been excluded.

For the latter document, we review for what it does *not* contain relative to the treaty itself, as well as commentary on some of the more contentious information contained therein.

⁹ https://www.nobelprize.org/prizes/physics/1965/feynman/biographical/



4

 $^{^{7}\} https://www.bloomberg.org/public-health/reducing-tobacco-use/bloomberg-initiative-to-reduce-to-bacco-use/bloomberg-initiative-to-reduce-to-bacco-use/bloomberg-initiative-to-reduce-to-bacco-use/bloomberg-initiative-to-reduce-to-bacco-use/bloomberg-initiative-to-bacco-$

⁸ https://www.who.int/news/item/27-09-2018-who-director-general-reappoints-michael-r-bloomberg-as-who-global-ambassador--for-noncommunicable-diseases-and-injuries

WHO Q&A on Electronic cigarettes - 25 May 2022

References for above (Clickable Links):

- WHO report on the global tobacco epidemic, 2021. Geneva: World Health Organization, 2021
- Ghebreyesus TA. (2019). Progress in beating the tobacco epidemic. Lancet. (published online July 26)
- WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1015). Licence: CC BYNC-SA 3.0 IGO
- FCTC/COP6 10 Rev 1 (2014) -WHO. Electronic nicotine delivery systems. Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, sixth session
- FCTC/COP7/11 (2016) WHO. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Seventh session
- E-cigarettes are harmful to health (2020)
- WHO report on the global tobacco epidemic, 2021. Geneva: World Health Organization, 2021



1. Are e-cigarettes dangerous?

- a. E-cigarette emissions typically contain nicotine and other toxic substances that are harmful to both users, and non-users who are exposed to the aerosols second-hand.
- b. The consumption of nicotine in children and adolescents has deleterious impacts on brain development, leading to long-term consequences for brain development and potentially leading to learning and anxiety disorders.
- c. Nicotine is highly addictive, and some evidence suggests that never-smoker minors who use ENDS can double their chance of starting to smoke tobacco cigarettes later in life.
- d. Evidence reveals that these products are harmful to health and are not safe.
- e. ENDS use can also expose non-smokers and bystanders to nicotine and other harmful chemicals.
- f. Electronic delivery systems have also been linked to a number of physical injuries, including burns from explosions or malfunctions, when the products are not of the expected standard or are tampered with by users.

RESPONSE¹⁰

- 1a. **This statement contains no useful information**. There is little evidence that the emissions are or are likely to be a cause of serious harm, and certainly nothing comparable to cigarettes.
- 1b. These claims about effects on the brain are largely false and rely on a few experiments done on rodents. The effects of nicotine on the brain would be seen in the brains of generations of mature adults who started using nicotine as adolescents by smoking. No research supports this and believe me, the research would be very well known if there was any evidence.
- 1c. This statement is true but highly misleading. The use of ENDS does not *cause* cigarette smoking (a "gateway effect"). Far more likely is that those same influences that incline young people to smoke also incline them to use ENDS (these factors might include genetics, family circumstances, mental health, school environment, delinquency, risk-taking etc). This is known as 'common liability'. It also means that ENDS are more likely to be beneficial to the young people who use them because they may be diverting them away from smoking.
- 1d. **This argument is greatly overstated**. There is some evidence of *effects* on the body from ENDS use but this is not surprising given that nicotine is a stimulant. Because nearly every adult ENDS user is a current or former smoker, it is nearly impossible to isolate the effects of ENDS use from the effects of prior smoking.
- 1e. The answer misunderstands basic toxicology, that "the dose makes the poison" and the quantity of exposure is what matters. Vaping in public places exposes users to vapour aerosol. Nicotine exposure is minimal because most is absorbed in the body of the ENDS user (there is no equivalent of the burning tip releasing sidestream smoke). Toxic exposure is much lower because vapour aerosol is much less toxic than cigarette smoke. Finally, vapour aerosol dissipates and breaks down much more rapidly than cigarette smoke. The result is that vapour exposure is unlikely to be more than a matter of nuisance and etiquette.

 $^{^{10}\} https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/$



1f. The answer is pure nonsense. I don't know of any cases of skin being 'burnt' by the liquid or any reason why it would cause burns. So this claim is a complete mystery. Nicotine ingested in large doses can cause poisoning - but it is also an emetic (causes vomiting) and so severe incidents are rare and treatable. There are normal precautions for dealing with anything hazardous - medicines, cleaning agents, alcohol - that mitigate risks of accidental exposure: child-resistant containers, warning labels, and advice on what to do. There have been a few cases of battery explosions, but the numbers harmed in this way are a tiny fraction of those injured or killed in smoking-related fires.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

- SRNT 15 on Vaping Misinformation to WHO FCTC (2021):
 https://www.natlawreview.com/article/new-paper-authored-15-past-presidents-srnt-argue-balanced-approach-to-e-cigarette
- The latest Cochrane review (2022): https://www.cebm.ox.ac.uk/research/electronic-cigarettes-for-smoking-cessation-cochrane-living-systematic-review-1)
- Vaping misrepresentations (2022)
 https://www.nature.com/articles/s41415-022-4409-1
- Is Vaping more harmful than combustible tobacco? (2021)
 https://www.cancerresearchuk.org/about-cancer/causes-of-cancer/smoking-and-cancer/is-vaping-harmful
- Association of Vaping-related Lung Injuries with Rates of E-cigarette and Cannabis Use...(2020)
 https://sci-hub.st/https://onlinelibrary.wiley.com/doi/10.1111/add.15235#
- Gateway research not valid (2020)
 https://onlinelibrary.wiley.com/doi/10.1111/add.15246
- Gateway Effect Disproved (2021): https://tobaccocontrol.bmj.com/content/30/2/212
- Vaping supports long term abstinence from smoking (2020): https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-020-00418-8
- Analyzing Trajectories of Acute Cigarette Reduction Post-Introduction of an E-Cigarette (2022)

https://pubmed.ncbi.nlm.nih.gov/35742698/

• Nicotine without Smoke: Fighting the Tobacco Epidemic (2019) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31884-7/fulltext



 A scoping review of studies on the health impact of electronic nicotine delivery systems (2022)

https://link.springer.com/article/10.1007/s11739-021-02835-4

2. <u>Do e-cigarettes cause lung injuries?</u>

a. There is growing evidence that ENDS could be associated with lung injuries and in recent times e-cigarette and vaping have been linked to an outbreak of lung injury in the USA. This is described by the United States Centers for Disease Control and Prevention (CDC) as e-cigarette or vaping associated lung injury (EVALI).

RESPONSE¹¹

This is a shameful and outright falsehood. There is no 'growing evidence' that ENDS could cause lung damage of the type seen in the United States between June and December 2019. On the contrary, since July 2019, there has been growing and now conclusive evidence that this outbreak has nothing at all to do with ENDS (i.e. nicotine delivery systems).

Some actual facts missing from WHO's Q&A fact sheet:

- Vitamin E acetate is the cause of the severe lung injuries seen so far: this substance *cannot* be added to nicotine e-liquids it is not soluble in the excipients used in nicotine liquids.
- No nicotine e-liquids tested following outbreaks of the lung injury have contained suspect ingredients.
- The supply chain for nicotine e-liquids in the United States is legal, regulated and does not substantially overlap with the THC vape supply chain. There is a vanishingly small chance that a completely independent problem with nicotine e-liquids would emerge at the same time, in the same place with the same symptoms as the cases caused by additives to THC vapes. Using the well-established epidemiological techniques used for, for example, isolating causes of food poisoning, it should have been possible to eliminate ENDS as a possible cause in August at the latest.
- The confusion was caused by, and perhaps promoted by, focussing on testimonies from lung injury victims claiming to have used only nicotine liquids and not THC. However, these accounts are obviously unreliable because of the legal status of THC and the user's risk of committing a crime or facing problems with employment, education or family. There has been no conclusive case where nicotine liquids were established as the cause of the injury.
- CDC now (January 2020) focusses its advice on avoiding THC vapes and Vitamin E acetate, not ENDS it maintains its customary reserve about ENDS (but no more than that).

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

• Vape pen lung injury: Here's what you need to know https://www.leafly.com/news/health/vape-pen-lung-disease-advice-consumers

¹¹ https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/



 CDC is Concealing and Suppressing Information on Youth Marijuana Vaping to Over-hype Harms of E-Cigarettes

http://tobaccoanalysis.blogspot.com/2020/

 Association of vaping-related lung injuries with rates of e-cigarette and cannabis use across US states

https://sci-hub.st/https://onlinelibrary.wiley.com/doi/10.1111/add.15235#

3. Are e-cigarettes more dangerous than combustible smoking?

a. Both tobacco products and ENDS pose risks to health. The safest approach is not to use either. The levels of risk associated with using ENDS or tobacco products are likely to depend on a range of factors, some relating to the products used and some to the individual user. Factors include product type and characteristics, how the products are used, including frequency of use, how the products are manufactured, who is using the product, and whether product characteristics are manipulated post-sale.

RESPONSE¹²

3a. The *question itself* is a scandal. No respectable scientist believes that ENDS are even close to the risk of smoking. So the question is designed to introduce "anchoring bias" - establishing the idea that the question on everyone's mind is whether ENDS are more dangerous than cigarettes or about the same, thus suggesting parity of risk is the best case for ENDS. Implying that is deeply unethical and could have serious health consequences if it causes people to abandon ENDS for cigarettes or not to switch.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

- NASEM: Public Health Consequences of E-Cigarettes https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes
 - NASEM: Public Health Consequences of E-Cigarettes (Release): https://www.youtube.com/watch?v=vifAY4YcVbQ&t=1978s
 - NASEM: Public Health Consequences of E-Cigarettes (Slides): https://nap.nationalacademies.org/resource/24952/NASEM-E-Cigs-Webinar-Slides.pdf
- Nicotine without Smoke: Tobacco Harm Reduction: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction
- Health Impact of E-Cigarettes...(2017)
 https://www.nature.com/articles/s41598-017-14043-2

¹² https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/



4. Are ENDS addictive?

a. Nicotine is highly addictive. A non-smoker who uses ENDS may become addicted to nicotine and find it difficult to stop using ENDS or become addicted to conventional tobacco products.

RESPONSE¹³

4a. The answer is gross oversimplification. First, "addiction" is a loaded and pejorative term. In professional communication, such language needs to be carefully defined. It usually means some sort of additional harm (disease, mental impairment, loss of employment, family breakdown) arises because of compulsive behaviour. In fact, WHO itself avoids the term "addiction" and uses the preferable term: dependence syndrome. According to WHO itself, diagnosis of dependence depends on:

Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

Whether nicotine is dependence-forming depends also on how it is delivered - how quickly it reaches the brain and the peak level it reaches in the blood. This is what experts refer to as the pharmacokinetics or "PK" and this is a function of the delivery system and in the case of tobacco smoke, possible other reinforcers. We do not see WHO warning about nicotine replacement therapy, for example. This is because NRT products (patches, gum etc) are designed not to have dependence forming characteristics, or to minimise what pharmaceutical regulators call "abuse liability".

But here's the catch: this is why NRTs are not very effective at helping smokers quit smoking. Harm reduction supporters take a different approach. They recognise that nicotine is a legal drug and unlikely to be banned outright, but widely used in its most dangerous form (smoking). They are looking for the 'reward' provided by vaping to be equivalent to or at least competitive with smoking, so as to help users switch by choice. Trying to suppress this amounts to protection of cigarette trade from competition.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

- Abuse Liability of Abuse Liability of Vuse Solo Relative To Combustible Cigarettes And Nicotine Gum
 https://assets.researchsquare.com/files/rs-1062121/v1/fb8f5195-4cce-470f-9e09-e752fae3c931.pdf?c=1642705044
- Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4920051/
- Clinical laboratory assessment of the abuse liability of an electronic cigarette

¹³ https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/



 Vapers exhibit similar subjective nicotine dependence but lower nicotine reinforcing value compared to smokers

https://www.sciencedirect.com/science/article/abs/pii/S0306460320308662

- Dependence on e-cigarettes and cigarettes in a cross-sectional study of US adults https://pubmed.ncbi.nlm.nih.gov/32196810/
- Then and now: Consumption and dependence in e-cigarette users who formerly smoked cigarettes

https://pubmed.ncbi.nlm.nih.gov/28780356/

 Development of a Questionnaire for Assessing Dependence on Electronic Cigarettes Among a Large Sample of Ex-Smoking E-cigarette Users

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838001/

5. Are second hand ENDS emissions dangerous?

a. The aerosols generated by ENDS typically raises the concentration of particulate matter in indoor environments and contain nicotine and other potentially toxic substances. ENDS emissions therefore pose potential risks to both users and non-users.

RESPONSE¹⁴

5a. Glycol is not a chemical itself, but a *class of chemicals*. The ethylene glycol used in anti-freeze is a completely different substance to the propylene glycol used in vaping liquids. Two minutes spent consulting the internet would have clarified this.

There are three reasons why indoor emissions of vapour aerosol are far less risky than second-hand smoke.

- 1. <u>The quantity emitted.</u> Most of the inhaled vapour is absorbed by the user and only a small fraction is exhaled (15% or less, depending on the constituent). In contrast, about four times as much environmental tobacco smoke comes directly from the burning tip of the cigarette than is exhaled by the smoker. There is no equivalent of this "sidestream smoke" for vaping.
- 2. <u>The toxicity of the emissions</u>. Tobacco smoke contains hundreds of toxic products of combustion that are either not present or present at very low levels in vapour aerosol. Vapour emissions do not have toxins present at levels that pose a material risk to health.
- 3. <u>The time that the emissions remain in the atmosphere</u>. Environmental tobacco smoke persists for far longer in the environment (about 20-40 minutes per exhalation). The vapour aerosol droplets evaporate in less than a minute and the gas phase disperses in less than 2 minutes.

No case has so far been made that this amounts to a meaningful risk to bystanders, rather than a nuisance. It is not a reason for ENDS use to be allowed everywhere, but also not a reason to ban it

¹⁴ https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/



everywhere by law. The correct balance of responsibilities is to allow property owners or managers to decide where their customers, clients, employees, visitors etc can use ENDS.

None of this factual and policy-relevant information is conveyed by WHO - rather, it is obscured by WHO's absurd generalisations and elementary errors.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

- Evaluation of Second-Hand Exposure to Electronic Cigarette Vaping under a Real Scenario:
 Measurements of Ultrafine Particle Number Concentration and Size Distribution and
 Comparison with Traditional Tobacco Smoke
 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6958336/
- Secondhand Exposure to Vapors From Electronic Cigarettes https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565991/
- Expert reaction to study looking at second hand nicotine vaping in the home and respiratory symptoms in young adults
 https://www.sciencemediacentre.org/expert-reaction-to-study-looking-at-second-hand-nicotine-vaping-in-the-home-and-respiratory-symptoms-in-young-adults/
- Vaping in England: evidence update February 2021 https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021
- Evaluation of Chemical Exposures at a Vape Shop https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf
- Fine particles in homes of predominantly low-income families with children and smokers: Key physical and behavioral determinants to inform indoor-air-quality interventions

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177718



6. What role do ENDS play in smoking cessation?

a. To date, evidence on the use of ENDS as a cessation aid is inconclusive. In part due to the diversity of ENDS products and the low certainty surrounding many studies, the potential for ENDS to play a role as a population-level tobacco cessation intervention is unclear.

RESPONSE¹⁵:

6a. In this answer WHO ignores or dismisses the actual evidence with a sweeping generalisation. The only way WHO could support a claim like this is if it ignores the extensive available evidence or sets an impossibly high standard for certainty that it doesn't apply to its preferred methods or to anything else.

There are now four strands of evidence that suggest e-cigarettes are effective in helping people to quit smoking:

- 1. evidence from randomised controlled trials, notably, Hajek et al 2019, which showed vaping to be about twice as effective as NRT; "E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support."
- 2. observational studies (watching what happens when people use e-cigarettes) for example, Jackson et al 2019; "Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England."
- 3. population data (unusually rapid reductions in smoking prevalence and cigarette sales), for example, Zhu S-H et al, 2018. "The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions."
- 4. the thousands of testimonials of users who have struggled to quit using other methods. See, for example, CASAA (12,500 testimonials) and, before dismissing 'anecdotes', make sure you read Carl V Phillips on why Anecdotes ARE scientific data

None are decisive in themselves. But all four sources point towards e-cigarettes displacing smoking. You could also add "common sense". An alternative way of taking nicotine with a fraction of the health risk and stigma, combined with other attractive features, should be *expected* to displace smoking in the normal ways that technology evolves. It would require strong evidence for the idea that ENDS somehow increases smoking or leaves it unaffected. No such evidence exists.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made by WHO in their guidance.

- Nicotine without smoke: Tobacco harm reduction https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction
- Can electronic cigarettes help people stop smoking, and do they have any unwanted effects when used for this purpose?

¹⁵ https://clivebates.com/fake-news-alert-who-updates-its-post-truth-fact-sheet-on-e-cigarettes/



https://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-do-they-have-any-unwanted-effects-when-used

- Effectiveness of the electronic cigarette: An eight-week Flemish study with six-month follow-up on smoking reduction, craving and experienced benefits and complaints https://pubmed.ncbi.nlm.nih.gov/25358095/
- Electronic cigarettes for smoking cessation https://pubmed.ncbi.nlm.nih.gov/34519354/
- Electronic Cigarettes as Smoking Cessation Tool: Are we there? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5480094/
- Effectiveness of e-cigarettes as aids for smoking cessation: evidence from the PATH Study cohort, 2017-2019
 https://tobaccocontrol.bmj.com/content/early/2022/01/11/tobaccocontrol-2021-056901
- Analysis of common methodological flaws in the highest cited e-cigarette epidemiology research

https://www.researchgate.net/publication/359454346_Analysis_of_common_methodological_flaws_in_the_highest_cited_e-cigarette_epidemiology_research

- E-cigarettes to Augment Stop Smoking In-person Support and Treatment With Varenicline (E-ASSIST): A Pragmatic Randomized Controlled Trial https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/ntac149/6615413
- A Pragmatic Randomized Comparative Trial of e-Cigarettes and Other Nicotine Products for Quitting or Long-Term Substitution in Smokers https://academic.oup.com/ntr/article-abstract/24/7/1079/6470892?redirectedFrom=fulltext
- Electronic cigarettes versus nicotine patches for smoking cessation in pregnancy: a randomized controlled trial https://www.nature.com/articles/s41591-022-01808-0
- A Randomized Pilot of a Tailored Smoking Cessation Quitline Intervention for Individuals Who Smoke and Vape

https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntac129/6586250?redirectedFrom=fulltext

 A pilot randomised controlled trial of abrupt versus gradual smoking cessation in combination with vaporised nicotine products for people receiving alcohol and other drug treatment

https://www.sciencedirect.com/science/article/abs/pii/S0306460322000946?via%3Dihub

• E-Cigarette Provision to Promote Switching in Cigarette Smokers With Serious Mental Illness—A Randomized Trial

https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntac082/6562456?redirectedFrom=fulltext



Other Disinformation:

1. Are E-cigarettes a "gateway" to smoking in Youth?

Vaping by adolescents and young adults is a legitimate concern as there is a risk that some may start smoking and that electronic cigarette (EC) use may have adverse effects in the developing lungs of adolescents. This commentary provides updated information on vaping patterns among adolescents and young adults in the United States, as well as the impact of EC usage on respiratory health.

EC use had surged greatly among high school students and young adults over the last decade but fortunately has declined significantly since its peak in 2019. During the same time period, smoking rates have constantly fallen to new low record levels. These trends argue against EC use as a gateway to smoking.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "gateway theory".

A Close Look at Vaping in Adolescents and Young Adults:

https://www.jaci-inpractice.org/article/S2213-2198(22)00584-0/fulltext#.YrSKpuVt0Vk.linkedin

• Clearing the haze - ASH NZ Year 10 Survey

 $\frac{\text{https://www.drugfoundation.org.nz/news-media-and-events/clearing-the-haze-new-stats-give-us-a-clearer-picture-on-youth-vaping/#:~:text=Out%20of%20the%2042.7%25%20of,the%20two%20require%20different%20approaches.}$

• Vaping is not a Gateway:

https://www.newscientist.com/article/2311701-vaping-probably-isnt-a-gateway-to-smoking/

Does Gateway theory justify bans?:

https://athra.org.au/wp-content/uploads/2020/03/Mendelsohn-CP-Hall-W.-Does-the-gateway-theory-justify-a-ban-on-nicotine-vaping-in-Australia.-International-Journal-of-Drug-Policy-2020.pdf

How not to be duped by gateway effect claims:

https://clivebates.com/how-not-to-be-duped-by-gateway-effect-claims/

Gateway research not valid:

https://onlinelibrary.wiley.com/doi/10.1111/add.15246

• Gateway Effect Disproven:

https://tobaccocontrol.bmj.com/content/30/2/212

Flavours and Gateway:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275248/



2. There is no "Youth Vaping Epidemic"

According to the CDC, the youth vaping rate in the United States has been in steady decline since 2020. *CDC data has shown that youth vaping has plummeted by 60% over the past 2 years*. Only 3.1 percent of high-school age and 0.3% of middle-school age students used e-cigarettes daily.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "the youth vaping epidemic".

- CDC National Youth Tobacco Survey 2022 https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm
- Use of E-cigarettes among young people in the UK: https://ash.org.uk/wp-content/uploads/2021/07/Use-of-e-cigarettes-among-young-people-in-Great-Britain-2021.pdf
- Stats showing youth vaping is on decline/as is smoking: https://www.jaci-inpractice.org/article/S2213-2198(22)00584-0/fulltext?fbclid=IwAR3Q6Md_Vw2e46zELQL3MGQba-OU82XaPe0F6GkDS8ywg194bMas7R6Yclk#relatedArticles
- Brad Rodu on the "epidemic" that wasn't: https://rodutobaccotruth.blogspot.com/2022/06/campaign-for-tobacco-free-kids-sustains.html?fbclid=lwAR3-bCH1SY1lyteuYB8JKchrbdbTyxSx5ChCRyGD4rnoK5fLi2yVupFDA-0



3. Renormalisation of Smoking:

"Policies to denormalize tobacco smoking in society and historic reductions in tobacco consumption may be undermined by this new 'gateway' product to nicotine dependency".

The above concern has not held up to analysis or research. Youth as young as 7 know that vaping is not smoking.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "the renormalisation theory".

 Government and public health responses to e-cigarettes in New Zealand: vapers' perspectives

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885311/

• UK Study on renormalisation:

https://tobaccocontrol.bmj.com/content/29/2/207

- The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7
- Vapers and vaping: E-cigarettes users views of vaping and smoking https://www.tandfonline.com/doi/full/10.1080/09687637.2017.1296933

4. Myth about Flavours - They only exist to entice Youth:

There has been a lot of talk about how flavoured vaping has enticed youth to vape. There has been no real discussion or concern about the fact that flavours are what helps adults to switch off combustibles to e-cigarettes.

When it comes to flavours and youth, we must address the primary beneficiaries of flavoured vapes, the adults who need them to switch off combustible tobacco.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "flavours entice youth theory".

Myths about Flavours:

https://www.clivebates.com/documents/NLFlavoursResponseJan2021.pdf

• Flavours and Gateway:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275248/

• Effects of electronic cigarette e-liquid flavouring on cigarette craving https://tobaccocontrol.bmj.com/content/early/2022/05/08/tobaccocontrol-2021-056769



• The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking...

https://academic.oup.com/ntr/article/22/10/1831/5843872

5. What about Pregnant Women and Vaping?:

You may have heard that nicotine is harmful to pregnant women and the babies they are carrying. With the blessing of their respective governments, pregnant women in the UK (and also in NZ) are supported to get off ciggies and onto vape as the harm to themselves and the babies is 95% LESS than smoking.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "vaping is dangerous for pregnant women and babies".

• Vaping is not harmless, but is likely to be less harmful than smoking while pregnant.

https://vapingfacts.health.nz/the-facts-of-vaping/vaping-and-pregnancy.html

• Current evidence on e cigarettes indicates they are much less risky than smoking. Cigarettes deliver nicotine along with thousands of harmful chemicals. E cigarettes allow you to inhale nicotine through a vapour rather than smoke. By itself, nicotine is rather harmless.

https://www.nhs.uk/pregnancy/keeping-well/stop-smoking/

6. Second hand Vapour contains toxic chemicals?:

There is an urban myth/idea that second hand aerosols from vapes contain potentially harmful substances such as formaldehyde, cancer-causing chemicals, and heavy metals such as cadmium, chromium, lead, manganese, and nickel. Users breathe in these toxic contaminants, and others nearby risk second-hand exposure.

For reference, please refer to the following: The references below come from medical doctors, researchers and government funded agencies. All of these refute the claims made about "second hand 'vape aerosol' in an indoor environment."

- Association of electronic cigarette use with lead, cadmium, barium, and antimony body burden: NHANES 2015-2016
- "Blood lead levels, and urinary cadmium, barium, and antimony levels were similar between participants who used e-cigarettes and participants who did not."
- Are Metals Emitted from Electronic Cigarettes a Reason for Health Concern? A Risk-Assessment Analysis of Currently Available Literature

"Based on currently available data, overall exposure to metals from EC use is not expected to be of significant health concern for smokers switching to EC use, but is an unnecessary



source of exposure for never-smokers. Metal analysis should be expanded to more products and exposure can be further reduced through improvements in product quality and appropriate choice of materials."

Section Discussion

The WHO has continued to fail the smoking population in three major ways.

First, by focussing solely on supply and demand reduction and <u>not addressing harm</u> <u>reduction</u>, even though it too is endorsed in Article 1, item d of the World Health Organization Framework Convention on Tobacco Control (FCTC). Article 1d is supported by many scientists and policy experts world-wide. It is a complement, not an alternative to established tobacco control approaches and works by giving smokers additional and more appealing options to quit smoking. ¹⁶ Policy guidance and implementation needs to be based on scientific evidence and facts that are objectively presented, peer reviewed and support the WHO mandate outlined in Article 1d of the FCTC charter.

Secondly, by not objectively reviewing all the available science that is available on the subject and not heeding calls to engage with pro tobacco harm reduction experts to evaluate the ENTIRE body of evidence and facts and come to an objective analysis that provides guidance based on facts.

Dr. Robert Beaglehole was on the staff of the World Health Organization in 2000 and between 2004 and 2007 directed the Department of Chronic Disease and Health Promotion and helped draft the FCTC treaty. Dr. Ruth Bonita, was WHO Staff as director of NCD Surveillance from 1999-2007 where she put her energies into developing a standardised step-wise approach to surveillance of the risk factors that predict NCDs.

They have come out in a commentary titled "Tobacco control: getting to the finish line" ¹⁷ published in the Lancet in response to the 2021 WHO report. ¹⁸ They commence with the statement that "Tobacco Control is not working for most of the world" and "Globally, the overall number of tobacco users has barely changed." Furthermore, they make it very clear that "The missing strategy in WHO and FCTC policies is harm reduction. Most people smoke because they are dependent on nicotine. Tobacco harm reduction reduces the harm caused by burnt tobacco by replacing cigarettes with much less harmful ways of delivering nicotine; these alternatives have great potential to disrupt the cigarette industry."

"Unfortunately, WHO and the FCTC Conference of Parties reject harm reduction. This opposition is not grounded in 21st century technological advances, and is unduly influenced by vested interests who promote nicotine abstinence. This opposition privileges the most harmful products—cigarettes."

¹⁸ https://www.who.int/publications/i/item/9789240032095



The Subversion of Public Health: Consumer Perspectives

19

¹⁶ https://apps.who.int/gb/archive/pdf_files/WHA56/ea56r1.pdf

¹⁷ https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00835-2/fulltext

In an article by 15 former presidents of the Society for Research on Nicotine and Tobacco (SRNT) published in the American Journal of Public Health entitled "<u>Balancing Consideration</u> <u>of the Risks and Benefits of E-Cigarettes.</u>" addresses each item in the <u>WHO Q&A on E-cigarettes.</u>²⁰

They state that "Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality."

This article also acknowledges that "Scientists differ in their views of the relative risks and benefits of vaping nicotine, and of their implications. Many, including this article's authors, believe that vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking's toll. Our objective is to encourage more balanced consideration of vaping within public health and in the media and policy circles."

And lastly, the WHO does a great disservice to all people who smoke, by continuing to create division amongst the ranks of tobacco control experts, as noted by Clifford Douglas, former vice president of Tobacco Control at the American Cancer Society and founder of the Center for Tobacco Control, in a commentary he published²¹ where he pleads with fellow tobacco control and harm reduction advocates that "<u>It is Time to Act with Integrity and End the Internecine Warfare Over E-Cigarettes."</u> and focus on the real issue "The primary target of tobacco control should be ending the unnecessary suffering and premature death caused by cigarettes and other combustible tobacco products, as prioritized in a major report from the American Cancer Society in 2018²²." While this commentary was aimed at the FDA in the US, it holds true for the entire tobacco control advocacy and expert community as the source of the issues lies at the feet of the WHO FCTC.

WHO Report on the Global Tobacco epidemic: Addressing new and emerging products.

Background:

Please keep in mind that this document is the basis for the WHO E-cigarette Q&A from May 2022. We have already provided a detailed overview of the information contained therein, and therefore we will only address omissions and glaring disinformation in the report in this section.

The eighth <u>WHO report on the Global Tobacco Epidemic</u> tracks the progress made by countries in tobacco control since 2008 and, for the first time, presents data on electronic nicotine delivery systems, such as 'e-cigarettes'. This report was published in July 2021.

²² https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21455



20

¹⁹ https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2021.306416

²⁰ https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes

²¹ https://drive.google.com/file/d/1C1nk1XEZ8WhnOXtCGTgHdegomc9HOuko/view

The data presented in this report advocates for stricter legislation of e-cigs, asserting there is no proof they help smokers quit their habit, are harmful to health and could even be a gateway to tobacco addiction for young people.

The Report Itself:

Before we even get to the actual content of the report, we are given colourful text pages with messages such as: "Electronic Nicotine Delivery Systems (ENDS) are addictive and not without harm."; "ENDS should be strictly regulated for maximum protection of public health." and "Children and adolescents who use ENDS can double their risk of smoking cigarettes."

Using the MPOWER graphic in a report about new and emerging products that are not combustible tobacco, confirms the new modus operandi, i.e. all nicotine products are tobacco products.

Monitor tobacco use

Protect people from tobacco smoke

Offer help to quit tobacco use

Warn about the dangers of tobacco

Enforce bans on tobacco advertising and promotion

Taise taxes on tobacco products



This is confirmed in the foreword where there are statements from Dr Tedros Adhanom Ghebreyesus Director-General of the World Health Organization:

"..And globally, smoking prevalence among people aged over 15 years has fallen from 22.7% to 17.5%.

This is encouraging progress. At the same time, we must remain vigilant to the challenges posed by new products such as electronic nicotine delivery systems and heated tobacco products.

The WHO report on the global tobacco epidemic 2021: addressing new and emerging products highlights how these products are promoted aggressively as "safer" or "smoke-free" alternatives to conventional cigarettes. Although their full risks remain unknown, the impact of nicotine delivery devices is clear...

...All countries have the obligation to protect the health of their people by beating back the scourge of tobacco, whatever form it takes."

And a statement from Michael Bloomberg, WHO Global Ambassador for Noncommunicable Diseases and Injuries & Founder, Bloomberg Philanthropies:

"...More than 1 billion people around the world still smoke. And as cigarette sales



have fallen, tobacco companies have been aggressively marketing new products - like e-cigarettes and heated-tobacco products - and lobbying governments to limit their regulation. Their goal is simple: to hook another generation on nicotine. We cannot let that happen.

This report brings a special focus to these new products and what we can do to protect kids from them. Around 80 countries have taken steps to address the dangers of ecigarettes, but they still remain unregulated in much of the world.

This report is a call to action and an outline for building on the progress we have made. Fighting tobacco use is truly a team effort, and as far as we have come, much more progress is still needed. Together, we can keep pushing forward, and save many more lives."

As you can see the WHO FCTC has changed focus from tobacco to nicotine and considers non-tobacco products as now being tobacco and therefore subject to the same treatment as tobacco products. According to Bloomberg, anyone who has an interest in the regulation and use of these products is a tobacco company operative.

Yet, within the report, on page 32, WHO states "ENDS were first developed by companies independent of the tobacco industry, but tobacco manufacturers have since entered the ENDS market. The early growth of the ENDS market was driven largely by companies independent of traditional tobacco companies…"

On page 24, the report provides an outline of Key FCTC provisions, <u>according to WHO the key articles are Articles 4 - 22.</u> It is interesting to note that **neither** *the preamble* **nor** *Articles 1-5* are found within this document as "key FCTC provisions". These items are the guiding principle and definition of terms for the FCTC and yet it is excluded.

Let's review the Preamble to the WHO FCTC: (Emphasis is ours.)

The Parties to this Convention,

- Determined to give priority to their right to protect public health,
- Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response,
- Reflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke,
- Seriously concerned about the increase in the worldwide consumption and production of cigarettes and other tobacco products, particularly in developing countries, as well as about the burden this places on families, on the poor, and on national health systems,



- Recognizing that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases,
- Recognizing also that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,
- Acknowledging that there is clear scientific evidence that prenatal exposure to tobacco smoke causes adverse health and developmental conditions for children,
- Deeply concerned about the escalation in smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages,
- Alarmed by the increase in smoking and other forms of tobacco consumption by women and young girls worldwide and keeping in mind the need for full participation of women at all levels of policy-making and implementation and the need for gender-specific tobacco control strategies,
- Deeply concerned about the high levels of smoking and other forms of tobacco consumption by indigenous peoples,
- Seriously concerned about *the impact of all forms of advertising*, *promotion and sponsorship* aimed at encouraging the use of tobacco products,
- Recognizing that cooperative action is necessary to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting,
- Acknowledging that tobacco control at all levels and particularly in developing countries and in countries with economies in transition requires sufficient financial and technical resources commensurate with the current and projected need for tobacco control activities,
- Recognizing the need to develop appropriate mechanisms to address the long-term social and economic implications of successful tobacco demand reduction strategies,
- Mindful of the social and economic difficulties that tobacco control programmes
 may engender in the medium and long term in some developing countries and
 countries with economies in transition, and recognizing their need for technical



- and financial assistance in the context of nationally developed strategies for sustainable development,
- Conscious of the valuable work being conducted by many States on tobacco control and commending the leadership of the World Health Organization as well as the efforts of other organizations and bodies of the United Nations system and other international and regional intergovernmental organizations in developing measures on tobacco control,
- Emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,
- Recognizing the need to be alert to any efforts by the tobacco industry to
 undermine or subvert tobacco control efforts and the need to be informed of
 activities of the tobacco industry that have a negative impact on tobacco control
 efforts,
- Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,
- Recalling also the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,
- Determined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,
- Recalling that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care,
- Recalling further that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health.

The adult consumers of safer nicotine products, such as e-cigarettes, advocate for access



and choice for other adults who smoke and use unsafe tobacco products. Their motivation and aim are nearly identical to those listed in the Preamble to the WHO Framework Convention on Tobacco Control.

We too are seriously concerned about the consumption of cigarettes and unsafe oral tobacco products and the burdens this use places on families. We are all people who formerly smoked, we understand the impacts on a very personal level in our own lives.

Our health was impacted by our use of cigarettes, and for many of us, the diseases and ailments that we suffered when we were using cigarettes have all but disappeared since we switched to safer nicotine products. We know they work, and we want others to have, what we consider, the gift of health that these products have provided for us.

As the primary stakeholders in this discussion, we realise that our lives are the evidence of the effectiveness of these products and our lived experiences, while anecdotal, are just as relevant as any experiment performed in a laboratory. To be excluded from the discussion, by means of unfounded accusations of industry collusion, not only goes against the guiding principles of the treaty but also the "participation of civil society is essential in achieving the objective of the Convention and its protocols."

If our demand that the WHO FCTC follows its own mandate to "to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations" is considered a threat, then the problem lies within the interpretation and motivation of the current WHO FCTC regime not wanting to follow their own mandate.

<u>Article 1 of the Treaty provides Definitions of the terms used within the treaty and is</u> comprised of six sections:

Article 1a: "illicit trade" means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity

Article 1b: "regional economic integration organization" means an organization that is composed of several sovereign states, and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters

Article 1c: "tobacco advertising and promotion" means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly

Article 1d: "tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke

Article 1e: "tobacco industry" means tobacco manufacturers, wholesale



distributors and importers of tobacco products

Article 1f: "tobacco products" means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.

Article 1, items a-c are self explanatory. The bolded items (1d, 1e and 1f) are clear in their aims.

Article 1d includes "harm reduction strategies" which has been absent from any policy guidance issued from WHO for years.

Article 1e defines "tobacco industry" to mean manufacturers, wholesale distributors and importers of tobacco products. In the past five years, WHO FCTC and some of its signatory countries and delegates have interpreted that to include consumers of safer nicotine products and have not only excluded them from the discussion, development of policy and regulations, but also accused them of being "tobacco company operatives", citing Article 5.3 as the justification. (We will cover article 5 below).

Article 1f defines "tobacco products" as products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.

Article 2 of the Treaty outlines the <u>Relationship between this Convention and other</u> <u>agreements and legal instruments</u>. It is self-explanatory and states:

In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law.

Article 3 of the Treaty outlines the Objective. It is self-explanatory and states:

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

The bolded/italicised words above are self-explanatory.

Keeping in mind that Article 4 of the treaty is considered "key" and outlines the <u>Guiding Principles</u> of the treaty, let us review **items 1 and 7**:



To achieve the objective of this Convention and its protocols and to implement its provisions, the Parties shall be guided, *inter alia*, by the principles set out below:

- 1. Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.
- 7. The participation of civil society is essential in achieving the objective of the Convention and its protocols.

Article 4.1 is clear that every person should be **informed** of the health consequences of exposure to tobacco smoke and that measures should be contemplated to **protect all persons from tobacco SMOKE.**

Article 4.7 is of specific interest to the public and consumers of safer nicotine products as it is the MANDATE that the participation of civil society is ESSENTIAL in achieving the objective of the treaty and its protocols.

The inclusion of nicotine equivalent to smoke and the exclusion of civil society, in reference to the consumers and advocates of safer nicotine products, who are directly affected by the policy guidelines and programmes, goes against the intent of Article 2, and the objective of Article 3 and the mandate of Article 4.

Article 5 of the treaty outlines <u>General Obligations</u> of signatory countries and their delegates.

- 1. Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.
- 2. Towards this end, each Party shall, in accordance with its capabilities:
 - (a) establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and
 - (b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.



- 3. In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.
- 4. The Parties shall cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are Parties.
- 5. The Parties shall cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.
- 6. The Parties shall, within means and resources at their disposal, cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.

Article 5 is where we finally see **nicotine** mentioned under **item 2b.**

"(b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in *developing appropriate* policies for preventing and reducing tobacco consumption, <u>nicotine addiction</u> and exposure to tobacco smoke.

Research has proven that nicotine is no more addictive than caffeine.²³ In 2015, the Royal Society for Public Health (UK) stated that "public confusion over nicotine to be addressed as a way of encouraging smokers to use safer forms of the substance. Tobacco contains nicotine along with many other chemicals, but nicotine by itself is fairly harmless.

Nicotine is harmful in cigarettes largely because it is combined with other damaging chemicals such as tar and arsenic, and as a highly addictive substance getting hooked on nicotine is one of the prime reasons why people become dependent on cigarettes. Electronic cigarettes and Nicotine Replacement Therapy (gum, lozenges, and patches) contain nicotine but don't contain the harmful substances found in cigarettes.

The other item of note in this section is item 3.

"In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."

Article 5.3 has been used not only by signatory governments, but also by private academic and research institutes to exclude consumers from participation. They have done this by, in some cases inferring and in other cases, publicly accusing consumers, consumer advocates, consumer advocacy groups and organisations of being "tobacco industry

²³ https://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html



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operatives" without any proof or evidence to support the supposition.

We can only presume that the exclusion of the preamble and the articles mentioned above were done with nefarious intent to continue the exclusion of civil society, outside of "approved non-governmental organisations" who may question the validity and effectiveness of the work that is being done and the policy guidance being proposed by WHO FCTC and its members.

DISCUSSION:

The WHO continues to completely ignore credible third-party scientific evidence, including Cancer Research UK and Action on Smoking and Health (ASH), of the harm reduction potential afforded by such products; as well its own data and statistics outlined in the report on youth uptake of e-cigarettes and daily use from 2019²⁴ and 2021²⁵. All of which points to the WHO Tobacco Free Initiative (TFI) bowing to the pharmaceutical industry whose Nicotine Replacement Therapies (NRT) are not meeting the needs of those who wish to stop smoking, where ENDS are meeting those needs and succeeding in abstinence from combustible tobacco.

The WHO FCTC and Michael Bloomberg's refusal to acknowledge the concerns of former WHO employees and experts in the field of Tobacco Control, who have no conflicts of interest such as affiliations with either the pharmaceutical or tobacco industries - and are deeply concerned by the path that WHO FCTC is taking towards the scientific evidence.

Concerns over Legitimacy:

What WHO FCTC are failing to acknowledge, is that this behaviour is putting their own expertise and legitimacy into question. This is especially relevant as the WHO handling of both Ebola and COVID has, in recent times, been put under the spotlight and proven to be less than stellar.

An independent panel to review the COVID 19 response, set up by the World Health Organization²⁶, said the combined response of the WHO and global governments to COVID-19 was a "toxic cocktail". The WHO should have declared a global emergency earlier than it did, its report said, adding that without urgent change the world was vulnerable to another major disease outbreak. More than 3.3 million people around the world have now died of Covid. Deaths that could have been prevented had WHO acted sooner. According to Naomi Grimley, global health correspondent for the BBC, "The most eye-catching line of this report is that the pandemic was the 21st Century's "Chernobyl moment" and its assertion that the world wasted time in February 2020 while the virus took hold."²⁷

²⁷ https://www.bbc.com/news/world-57085505



²⁴ New Nicotine Alliance UK. (August, 2019). World Health Organisation's tobacco report will only perpetuate smoking - NNA. Retrieved from https://nnalliance.org/nnanews/news/310-who-tobacco-report-30-july-2019

²⁵ https://ash.org.uk/wp-content/uploads/2021/07/Use-of-e-cigarettes-among-young-people-in-Great-Britain-2021.pdf

²⁶ https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

Nicotine E Liquid is not the Enemy:

There have been many "public health" announcements and media campaigns put out by various interests in the region (and worldwide) promoting and promulgating the many misconceptions surrounding nicotine as used in e-cigarette devices. For years the pharmaceutical industry has invested millions of dollars in research, development and marketing of Nicotine Replacement Therapies (NRT) to be utilised by combustible tobacco smokers to "kick the habit". This same pharmaceutical grade nicotine is exactly what is used by reputable e liquid manufacturers for use in e-cigarette devices.

Smoke and Mirrors - creating problems where none exist:

It is disconcerting that the WHO Global report on the Tobacco Epidemic is, once again, openly funded by Bloomberg Philanthropies, who continues to not only fund the report itself, but also to justify the billions of dollars in donations his organisation feeds through his "Bloomberg **Initiative to Reduce Tobacco Use"** globally for "tobacco control guidance".

This campaign has extended far beyond the borders of the USA and is being targeted in many of the Lower and Middle Income countries globally where unsafe tobacco consumption remains high and where the use of e-cigarettes and safer nicotine products could save millions of lives.

Your Money or Your Life:

Michael Bloomberg has presented himself as the saviour of youth and harm from flavoured nicotine e-liquid in the open market by continuing to utilise his network of partners of Bloomberg Philanthropies (read: people they fund) and his extensive media contact networks to promulgate not only "Fake News" regarding a non-existent global "Youth Vaping Epidemic" but also about a "Vaping Illnesses and Death Epidemic." 'proven' via 'scientific studies' that are not replicable inside a laboratory utilising ethical scientific methods. Up to including funding research that states that aerosol is the same as smoke. 28 A concept that has already been disproven in the laboratory.²⁹

Additionally, Bloomberg Philanthropies, through its network of "partners" has also dabbled in influencing policy in foreign countries, specifically LMIC's. In Asia, he was caught red handed in the Philippines³⁰³¹ and he continues on the same trajectory of treason in Bangladesh, Pakistan, Indonesia, Malaysia and Thailand - with the blessing of WHO FCTC. The same organisation that is tasked with treating health from a human rights perspective.

Marc Gunther, who is a journalist in the US, and who has no affiliations with any tobacco, vaping or libertarian organisations has been investigating the activities of Bloomberg Philanthropies and its "partners" in the field of Tobacco Control³². He publicly exposed how

³² https://medium.com/the-great-vape-debate/the-unchecked-power-of-philanthropy-e71e426b91b8



²⁸ https://pubmed.ncbi.nlm.nih.gov/35811880/

https://pubpeer.com/publications/EE000F6D5B8732A85FE0366654F95C?utm_source=Firefox&utm_medium=BrowserExtension&utm_campai gn=Firefox# on https://www.atr.org/bloomberg-exposed-foreign-meddling-tobacco-and-vaping-policy-philippines/

³¹ http://businessnewsthisweek.com/news/research-untangles-web-of-foreign-ngos-interference-in-philippine-policies/

some of the world's leading experts on tobacco and public health have been trying for months to meet with him and share evidence showing that his foundation's opposition to flavored ecigarettes is doing more harm than good. Bloomberg declined.³³

The experts, who attempted for months to arrange a meeting with Bloomberg to discuss, had sent a letter to make the arrangements. ³⁴ Since 2021, pro-harm reduction tobacco control and public health experts have sought to meet privately with philanthropist Michael Bloomberg and his foundation Bloomberg Philanthropies' anti-vaping leadership. 35 According to Jim McDonald, a harm reduction journalist, "... an interesting look at how Bloomberg responds to criticism from outside experts: he doesn't. In response, his minions offered little more than a recital of Bloomberg Philanthropies' greatest hits—the tobacco control talking points that serve as gospel for tens of thousands of anti-tobacco and anti-vaping activists around the world who are funded by the billionaire."36

This refusal to acknowledge any outside difference in opinion was conveyed perfectly by Marc Gunther - "Bloomberg Philanthropies used its money and influence to curb vaping, to be sure. But others who have worked for decades to reduce deaths from smoking say the ongoing campaign against e-cigarettes is misguided, built on unsound science, and likely to do more harm than good."37

Where there is Smoke, there is Death:

The ensuing global media storm over the "epidemics" of youth vaping and EVALI have created an environment in the general public, that promotes the anti nicotine agenda to the detriment of the millions of smokers and those who use safer nicotine products to stay away from combustion and unsafe oral tobacco use. The main takeaway was outlined clearly and succinctly by Prof Robert Beaglehole from Action on Smoking and Health New Zealand (and former director of chronic disease at the World Health Organisation): "The WHO's approach to vaping would protect the cigarette trade and cause more harm than good. Furthermore, the organisation was clinging to outdated ideas around smoking cessation and the rise of smoke-free nicotine products, particularly vaping, was the most disruptive influence on smoking in decades."38

According to Clive Bates, et al. "Because smoke free products are intended to displace smoking, there are many ways in which excessive regulation or taxation could cause more smoking and more harm to public health. In overview, the Royal College of Physicians (RCP) set out the challenge and danger of excessive regulation: 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

good

RNZ News. (2019, August 30). World Health Organisation's approach to vaping will do more harm than good - academic. Retrieved from a RNZ News. (2019, August 30). World Health Organisation's approach to vaping will-do-more-harm-than-good-academic. https://www.rnz.co.nz/news/national/397793/world-health-organisation-s-approach-to-vaping-will-do-more-harm-than-good-academic.



The Subversion of Public Health: Consumer Perspectives

³³ https://medium.com/the-great-vape-debate/michael-bloomberg-loves-data-except-when-he-doesnt-a6abb02d4d0a

³⁴ https://docs.google.com/document/d/1sztGoaTj_ZkaTWNZKOkU23zvZgCKrlg_lzry9jsKmxY/edit

³⁵ https://vaping360.com/vape-news/112873/bloomberg-refuses-proposed-discussion-of-vaping/

 $^{^{37}\} https://www.philanthropy.com/article/bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-against-vaping-could-it-do-more-harm-than-bloombergs-millions-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-an-effective-campaign-agains-funded-agains-funde$

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... it follows that regulators should be averse to interventions that may have the unintended effect of perpetuating smoking."39

Within scientific circles it is acknowledged and accepted that what causes harm in tobacco use is the combustion of leaf tobacco and the chemical reactions of the additives that form the negative health effects of tobacco and the tobacco aerosol residue (TAR). Professor Michael Russell's words "that people smoke for the nicotine, but die from the tar." can and should be heeded by WHO FCTC.

The WHO FCTC approach to smoke free alternatives is not only outdated, but is making fertile ground to create an even more insidious and very real public health crisis.

As outlined previously, there are no current global vaping epidemics. However, with punitive restrictions and bans being promoted as the way forward in dealing with safer nicotine products, there is good cause to believe that disruptive technologies such as safer nicotine products will go underground and to the black market with no product quality or purchase age requirements.

We are already seeing in countries such as Australia⁴¹ and in San Francisco, California⁴² where flavour bans have been implemented not only an increase in smoking but also product quality and underage access issues.

With a global black market there will be negative consequences that may well include a global NCD epidemic of illnesses and deaths.

Risk proportionate regulation will ensure that equipment and products within the disruptive technology category of alternative nicotine consumption products are safe to use and have proper controls on components and ingredients.

It is appalling to allow one group of individuals who are looking to make profits to control the narrative of tobacco harm reduction and influence the global public health community towards that end.

It is a violation of the human rights of all smokers and current users of safer nicotine products, to ban or restrict access to these products and it goes against the mandate of the WHO FCTC Article 1 that clearly outlines a two pronged approach to the global tobacco crisis that includes

⁴² https://gizmodo.com/san-franciscos-flavored-vape-ban-linked-to-more-teen-sm-1846968389



32 The Subversion of Public Health: Consumer Perspectives

³⁹ Bates, C., Beaglehole, R., Laking, G., Sweanor, D., & Youdan, B. (2019, October 7). A Surge Strategy for Smokefree 2025. Retrieved from https://www.ash.org.nz/surge_strategy_smokefree2025. 40 https://pubmed.ncbi.nlm.nih.gov/1859935/

⁴¹ https://www.abs.gov.au/statistics/health/health-conditions-and-risks/smoking/latestrelease#:~:text=In%202020%2D21%2C%20one%20in,the%20rate%20peaked%20at%2013.7%25.

a harm reduction approach⁴³. This is confirmed within Article 12 of the International Covenant on Economic, Social and Cultural Rights⁴⁴, which contends that international law supports a harm reduction approach to tobacco control.

It is criminal to allow the product that is known to kill people with certainty to be sold liberally on the free market, and ban or restrict access to safer alternatives for adult smokers.

CONCLUSION:

We take this opportunity, in closing, to remind all FCTC signatories and delegates of their responsibility as members of the WHO FCTC as outlined in the treaty itself.

RIGHTS AND RESPONSIBILITIES of WHO FCTC & Member Countries:

An individual's right to health is recognized as a fundamental international human right. Founded upon the non-derogable right to life, the Universal Declaration on Human Rights (UDHR) affirms that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including ... medical care and necessary social services. With appropriate regulations, you can help thousands of vapers and tens of millions of smokers in Asia Pacific, by simply telling them the truth: although the best option is not using any nicotine containing products, switching to a regulated vape product is better than continuing to smoke.

Realise that smoking causes the vast majority of tobacco-related death and disease. Burning tobacco is the main cause of smoking related diseases, not nicotine or inhaling vapour. Tobacco use causes one million deaths per year in the Asia Pacific Region and smoking causes the majority. E-cigarettes provide smokers with an option to get away from smoking and could hasten the demise of the cigarette. We should all want to see that.

Recognise that vaping is dramatically safer than cigarettes and has helped millions quit smoking. Vaping is not smoking. It uses electronic devices to generate a nicotine-containing vapour without burning tobacco. Public Health England's annual reviews of all available evidence have consistently concluded that e-cigarettes are around 95% less harmful than smoking. Millions of people have switched from cigarettes to these significantly safer products. Governments charged with protecting public health should welcome that, not discourage it.

<u>Recall that harm reduction is at the core of international treaty obligations.</u> The Framework Convention on Tobacco Control defines 'tobacco control' as 'a range of supply, demand and harm reduction strategies that aim to improve the health of a population'.

<u>Regulate rather than ban.</u> Bans serve only to protect the cigarette industry. Concerns that vaping may appeal to youth or may serve as a 'gateway' to smoking are inconsistent with

[,]The%20States%20Parties%20to%20the%20present%20Covenant%20recognize%20the%20right,of%20physical%20and%20mental%20health.



ectives 33

⁴³ http://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf?sequence=1

⁴⁴ https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights#:~:text=Article%2012,-1.&text=1.-

the evidence: E-cigarettes have been gateways out of smoking for millions and have been accompanied by declining youth smoking rates. Instead of banning them, governments should regulate e-cigarettes to maximise the benefits of low risk alternatives while minimising the likelihood they will be used by youth or non-smokers.

<u>Rethink dogma.</u> Safer products should be encouraged, not attacked with the same vehemence as cigarettes or, worse, banned. Smokers' health and the Government's credibility is at stake, they should avoid being perceived as promoting the interests of cigarette and pharmaceutical industries, and smokers should not be forced to choose between deadly cigarettes and marginally effective nicotine replacement therapies.

The information contained in this review will hopefully assist with pragmatic and objective policy discussions, decisions and regulations that are risk proportionate and will greatly assist the aim of reducing the harms of combustible and unsafe tobacco products globally as is the aim of the FCTC Treaty.

Almost all of the adult consumer advocates and consumers of e-cigarettes (and other reduced risk products) have been purposely excluded from the discussion around their use of the products and the impacts of policy implementations. This has been done, we believe, to disenfranchise the adult consumers of these products as they are evidence of their efficacy and the value of innovation towards tobacco control.

Many of the officials and public health researchers who refuse to acknowledge the evidence of how these products can assist with their efforts, are operating from a "quit or die" mentality that has been ingrained in tobacco control since time immemorial.

Science *is* about innovation and progress, especially when it comes to human health. The COVID-19 pandemic, EBOLA and Monkeypox is showing all of us that we must think in an innovative and pragmatic manner to protect and save human lives.

Nancy E Loucas October 2022

