Prohibitionists at work: how the WHO damages public health through hostility to tobacco harm reduction

Gangsters celebrate their good fortune with drinks at a speakeasy during US alcohol Prohibition

This post examines how WHO and related institutions aggressively promote the prohibition of much safer alternatives to cigarettes, such as vaping and heated tobacco products. The effect, if not the intent, is to protect the cigarette trade from competition, to promote black markets, to stimulate harmful workarounds, to nurture criminal networks, to harm young people, and to prolong the epidemic of avoidable smoking-related disease. It's a reckless policy, built on misplaced righteousness, defended by bureaucratic inertia, sustained by group-think, and cultivated by elitist billionaire foundation money. It's a curse and a blight on public health, and government representatives should apply real-world policy disciplines and reject it.

The post is broken into six sections:

1. The problem of prohibition

WHO is following a prohibitionist agenda. Let's just put it out there: WHO is advocating for the prohibition of vaping and heated tobacco products anywhere it thinks it can get away with it (this post will show how in detail in section 4). In doing so, it is following a discredited war-on-drugs playbook that has utterly failed everywhere for decades, causing untold harm to health and welfare, large-scale violence and criminality, and profound injustice.

Prohibitions don't work. Consider the naïve world of the prohibitionist: an all-powerful state bans a product, enforcement is total, the banned product disappears, and the former users of the product do something virtuous instead. And that's the win. Yet, every stage of that reasoning is wrong. In the reality-based world, users denied banned products switch to another risk behaviour (perhaps smoking), a black market develops in whatever has been banned, young users become engaged in criminal enterprise, and consumers and producers find workarounds (DIY) that are often riskier than the prohibited products. Passing a prohibition law simply creates a *perturbation* in a market, changing who supplies what product and under what conditions. It may deter some users but it may engage others. Through criminalisation of supply, it may increase exposure to other illicit goods and services and provide finance for deeper criminality.

Here's what WHO had to say about the (now reversed) tobacco prohibition in Bhutan in its 2020 report, *The big ban: Bhutan's journey towards a tobacco-free society*

> *Today, the country is faced with a greater challenge, that of illegal traffic in*

> *tobacco and its products. So long as the demand within the country persists, it will continue to fuel the illicit market that has expanded since the ban of its sale in early 2000. Unfortunately, as studies indicate, Bhutanese youth are at the centre of this growing illegal trade in tobacco and its products.*
>
> *Dr Rui Paulo de Jesus*
> ***WHO Representative***

Have they learnt anything from this (and other prohibitions)? No, they have not.

But this is the worst form of prohibition. WHO's approach to tobacco is even more *reckless* than ordinary failed and blood-soaked drug prohibition: this is the prohibition of products that are much safer than the legal market norm, cigarettes, and will have significant *health benefits* for those who switch to them. Snus in Sweden and Norway provides proof of concept for tobacco harm reduction – with record low levels of smoking and commensurately low rates of smoking-related disease. Yet, snus also provides a case study in the prohibition mindset in tobacco control – despite a mountain of evidence showing snus has been highly beneficial at the individual and population level, the European Union continues to prohibit the product outside Sweden [see letter to EU about the policy of banning snus]. Should we trust tobacco control officials, academics and activists to be evidence-based, professionally competent and ethical? Not if they pursue prohibition of much safer products while leaving the most dangerous widely available and easily accessible.

Like the prohibition of clean needles. By analogy, WHO's approach to tobacco would be like supporting the prohibition of clean needles so that intravenous drug users are forced to use dirty needles. No one would ever do this to IV drug users, of course, but by analogy, that is what WHO is advocating for smokers. The sinister logic of this position is that if the harm and risk are great enough, then the user will be frightened into abstinence – the *quit or die* proposition. In this threatening world-view, the harm is the point – the driver of abstinence. In reality, the causes of substance use run deep and people discount long-term risks, so we don't end up with abstinence, we end up with a lot of harm – people dying, not quitting. If you've ever wondered why abstinence-only activists appear gleeful when there is news, often fake news, of new or greater harms found with smoking or vaping, then this is why: harm gives them their agency, harm creates their

role, harm legitimises their involvement. Harm *reduction* does the opposite. Without harm, the case for abstinence and intervention is diminished (see coffee) and so harm reduction threatens their primary interest.

Negligent policymaking. It's not as though this is saying something groundbreaking – it's economics 101 – and you would have to be clueless or professionally negligent not to be aware of these issues with prohibition. Yet, WHO has no policy analysis whatsoever to support its prohibition stance – *none whatsoever* (ask them to produce it!). It just celebrates vaping prohibitions as a win and moves on. WHO has not expressed the slightest interest in the *evaluation* of the prohibition policies now in place, though it is happy to count them and promote them. It shows no interest in the likely harmful unintended consequences of the policies it is promoting or whether they work.

Justifying prohibition.. *oh no, it's the tobacco industry!* No effort has been made to assess vaping or HTP prohibition as a public health policy in terms of its detriments and benefits. The main rationale and PR talking point used by advocates of prohibition is that tobacco companies make the products, and therefore, as a matter of principle, the products must be bad and prohibiting them must be good. The reasoning is infantile and counterproductive. Unless you think nicotine use is about to disappear after 6,000 years and 1.2 billion current users are about to stop, then the public health challenge is to make nicotine use much less harmful (by eliminating combustion). It takes absurd and convoluted reasoning to believe – as many activists and WHO appear to – that the world will be better if tobacco companies only sold the most dangerous forms of nicotine, cigarettes. It's like saying oil companies should not migrate to renewables. The aim should be to shift "the merchants of death" into products that do far less harm – a direction that several companies, to varying degrees, want to take. Tobacco control activists and WHO, through advocacy for prohibition of low-risk alternatives, are pushing for the opposite – the maintenance of cigarette oligopolies. A far better approach would be to use risk-proportionate regulation to provide both consumer protection and incentives to shift markets from high-risk to low-risk nicotine products.

Prohibition flourishes in the groupthink of the Bloomberg propaganda complex – in which WHO is now firmly embedded. One of Bloomberg Philanthropies' most lavishly funded proxies, The Union, calls for "*prohibition of the sale of e-cigarettes and heated tobacco products in low- and middle-income countries [LMICs]*" (see

here). Note that 80% of the world's smokers are in LMICs – so this is saying 'quit or die' to about 800 million people and millions more to come. These bossy Paris-based imperialists declare: '*Where bans are best: Why LMICs must prohibit e-cigarettes and heated tobacco product sales to truly tackle tobacco'* and make their case in just 1,300 words under 10 headings – none of which is "*What could possibly go wrong?*" and most of which do not withstand a few seconds of scrutiny. You can read a critique of The Union paper by the consumer network INNCO here: *Why Bans of Low-Risk Nicotine Alternatives to Smoking in Low- and Middle-Income Countries (LMICs) Will Do More Harm Than Good.*

Credible experts support tobacco harm reduction. Despite efforts to position tobacco harm reduction as the devil's work acting through its corporeal emissary, the tobacco industry, harm reduction does in fact command significant support in the public health expert community. For example, fifteen past presidents of the Society for Research on Tobacco and Nicotine wrote a paper for the *American Journal of Public Health* urging policymakers to take a more balanced approach to risks and opportunities:

> *While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind. That is not happening.*
>
> *Balfour DJK, Benowitz NL, Colby SM, Hatsukami DK, Lando HA, Leischow SJ, et al. Balancing Consideration of the Risks and Benefits of E-Cigarettes. Am J Public Health . 2021 Aug 19. [link]*

Prior to COP-9, 100 independent experts signed a letter to COP delegates calling for WHO and the FCTC to take a more progressive to tobacco harm reduction:

> *We recognise there is uncertainty as to the benefits and risks associated with the evolving marketplace of non-combustible tobacco products over the longer term, and we recognise there is a continuum of risk in these products. We are also duly cautious about the involvement of the tobacco industry. However, we must also consider the substantial body of evidence we do have and not allow excessive caution or residual uncertainties to deny smokers promising options to switch away from the combustible products that we know with certainty are*

> *lethal. Regrettably, WHO has been dismissive of the potential to transform the tobacco market from high-risk to low-risk products. WHO is rejecting a public health strategy that could avoid millions of smoking-related deaths.*

See full letter text and signatories (PDF) English, Français, Español, Deutsch

Despite predictable efforts to smear this initiative as the work of the industry (e.g. see this and this), the signatories include the current and former editors of two leading scientific journals (*Nicotine and Tobacco Research* and *Addiction*, respectively), the chair and a member of US FDA's Tobacco Products Scientific Advisory Committee (TPSAC), three former WHO senior scientific staff, current and former deans of prestigious schools of public health, the former chief executive and former senior officials of the American Cancer Society, expert witnesses in litigation against tobacco companies and many others with great experience and achievement in public health and tobacco control science and policy. It would be better if delegates gave them a hearing rather than uncritically accepting or repeating disparaging but false activist claims at face value.

2. Prohibition starts with confusion about objectives

2.1 The objective of the FCTC really all about harm reduction

The objective of the FCTC is expressed in Article 3 of the treaty [link]

> *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.*

This convoluted framing muddles up the aim, the means to achieve the aim, and a vague attribution of causes. As expressed, it does not recognise the reality that

some tobacco products are much less risky than others and that low-risk tobacco products (snus, heated tobacco) could substitute for high-risk tobacco products (there is extensive proof of concept for harm reduction in Sweden and Norway, for example). Nor does it recognise non-tobacco consumer nicotine products (vaping, pouches). So aspects of this objective – the proposed means to achieve the ends – are internally contradictory with the aim itself. However, contradictions of this nature should be resolved by reference to the overriding primary objective, which is expressed at the start of the clause:

> *The objective … is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke*

2.2 This should lead to a laser-like focus on smoked tobacco.

The actual objective expressed above essentially establishes *a broad harm reduction agenda* because it refers to *harms* (health, social and economic). So those people who say they are against harm reduction are basically in the wrong room. Because the overwhelming cause of the harms described here comes from smoked tobacco, it follows that *smoked tobacco* should be the primary focus of the FCTC.

For a more complete discussion see: Kozlowski L. *Policy Makers and Consumers Should Prioritize Human Rights to Being Smoke-Free Over Either Tobacco- or Nicotine-Free: Accurate Terms and Relevant Evidence*. *NTR*, 2019 [link][PDF] which includes the diagram below:

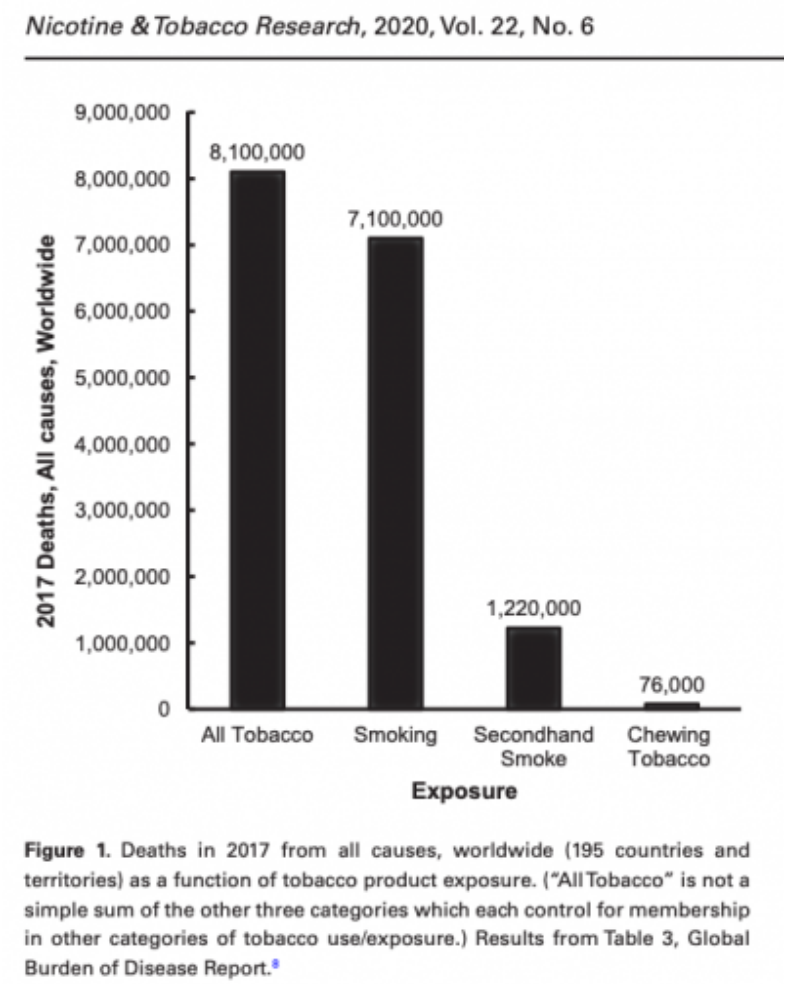


Figure 1. Deaths in 2017 from all causes, worldwide (195 countries and territories) as a function of tobacco product exposure. ("All Tobacco" is not a simple sum of the other three categories which each control for membership in other categories of tobacco use/exposure.) Results from Table 3, Global Burden of Disease Report.[8]

Smoking dominates tobacco-related disease

Professor Kozlowski's final remark in this paper is right on the mark:

> *How can tobacco control maintain its credibility if it fails to treat the tragedy of smoked tobacco in proper proportion to the lesser, in some cases dramatically lesser, harms from non-combusted products and non-tobacco, nicotine products? More accurate words and greater reliance on product-relevant evidence should be important when battling appalling epidemics and pursuing human rights to health.*

2.3 Objectives other than harm-reduction inevitably lead to more harm

The prohibitionists and abstinence-only activists think their way is the purer way. But they are wrong. Unless policymakers are focused on harm reduction, *there will be more harm*. It means more cancer, heart disease and COPD – and the war-on-drugs prohibition activists need to own that additional burden.

This is because with different goals, trade-offs will be made differently and these will detract from reducing harm in the name of, for example, attaining a nicotine-free society. If this is made a priority, no value will be placed on reducing harm by switching from high-risk to low-risk nicotine and all nicotine products will be treated equally, even though they vary by one to three orders of magnitude in risk. Remember, the 'nicotine-free society' advocates are prioritising their dislike of a relatively mild stimulant over other people dying in agony of cancer and living in misery with COPD. They can't escape this pro-cancer pro-disease outlook, but they somehow get away with it by claiming they are focused on youth. In practice, they are harming youth too.

Pursue these alternative goals and we end up with this kind of madness:

> *"It is important to prevent people from switching from #smoking to #snus or other new #tobacco products that keep emerging on the market. These products, too, are highly dangerous to health," says @IlkkaOksala the chair of the working group to develop tobacco&nicotine policy.*
>
> *— Tobacco Free Finland (@TobaccoFreeFin) May 31, 2018*

The FCTC aim is about reducing harm. It should not be diverted from this essential goal by aspiring for a tobacco-free or nicotine-free society, destroying the tobacco industry, or some other ideological 'war-on-drugs' goal. Yet these have become *goals of expedience* for many tobacco control abstinence-only activists. The inevitable consequence *will be more harm*.

2.4 The harms that arise from tobacco control policies must be considered in an integrated approach

A focus on smoked tobacco is not an ethical license to do anything a regulator wants to. A significant omission is any recognition that *tobacco policies* can cause harm – and responsible governments naturally take care not to inflict harm on the citizens that vote for them. For example, the FCTC objective mentions the economic harms of tobacco. But tobacco taxes can be economically painful and regressive, and under WHO guidelines should account for at least 70% of the

price. Most of the economic harm of tobacco is imposed by governments and by design. Social effects might include the stigma and alienation generated by anti-smoking campaigns and 'denormalisation' approaches, which stigmatise and alienate by design. Measures taken to reduce the appeal of vaping can protect cigarette sales, cause harm to health and reinforce exploitative cigarette oligopolies. For some people, nicotine may have therapeutic value and there may be harm from denying them a benefit. Harms can also arise from inhibiting people from exercising their autonomy and volition or degrading their experience or something they like – you don't have to be a libertarian to understand that. Not everything in life is subordinated to maximising life expectancy.

The FCTC approach to harm reduction should be broad and integrated across the range of harms arising from tobacco and nicotine use and take full account of the negative or unintended effects of the policies used for tobacco control.

3. How the WHO, FCTC Secretariat and COP influence the FCTC without changing the text

3.1 FCTC works mainly through encouragement and exhortation

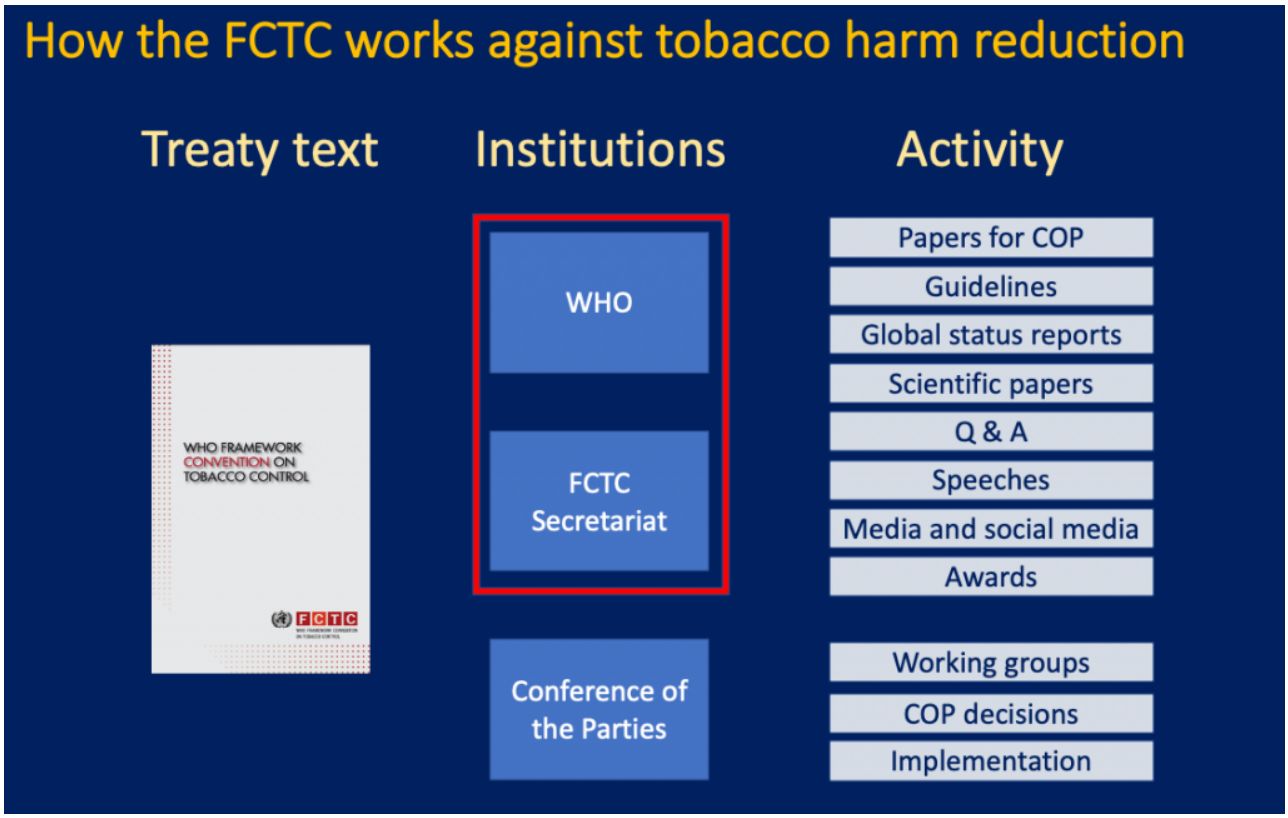
The FCTC itself is a *framework*. There is very little the FCTC *requires* parties to do in national law. It is best understood as a device for encouraging action and normalising particular policies. This is well illustrated in the case of tobacco taxation in the FCTC at Article 6. This is shown below with fudging language shown in red and firm language in blue:

> *FCTC Article 6*
> *1. The Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons.*
> *2. Without prejudice to the sovereign right of the Parties to determine and establish their taxation policies, each Party should take account of its national health objectives concerning tobacco control and adopt or maintain, as appropriate, measures which may include:*

(a) implementing tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption; and
(b) prohibiting or restricting, as appropriate, sales to and/or importations by international travellers of tax- and duty-free tobacco products.
3. The Parties shall provide rates of taxation for tobacco products and trends in tobacco consumption in their periodic reports to the Conference of the Parties, in accordance with Article 21.

The point is that there is a treaty text here if a government wants to use it for justification of taxes, and there are guidelines to back it up (WHO technical manual on tobacco tax policy and administration, 2021), but these are not hard requirements. The only firm requirement ("shall") is part 3, to *provide information* on rates of taxation and consumption. So what happens about taxation will be determined more by the dynamics and role of the FCTC and WHO – the policies that the FCTC normalises. The FCTC is a 'soft-power' instrument by design.

The policies normalised by the FCTC depend on the norms set by the institutions that make the FCTC work – the WHO, the FCTC secretariat and the Conference of the Parties and activities they undertake. The activity shapes the implementation of the FCTC and provides what policy analysts call an "authorising environment" (approval from an authoritative body that can help to justify introducing a policy).



3.2 The FCTC does not require prohibition and could and should be interpreted to support tobacco harm reduction

So far, no amendments have been made to the FCTC text itself, including language to address vaping and heated tobacco products. Consequently, the main FCTC text represents a view of tobacco control formed over the period it was negotiated. That was from the first working group meeting in October 1999 to the completion of the final text in June 2003. *This is a long time ago and pre-dates the emergence of vaping, the modern generation of heated tobacco products, and novel nicotine pouches.*

Though tobacco harm reduction is mentioned within the definition of tobacco control in Article 1.d of the FCTC [link], this was not a significant source of discussion or negotiating effort when the FCTC text was drawn up and has not found any expression subsequently (emphasis added)

> *1.d. 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;*

This language has not been operationalised, but it could be: *it just needs the Parties, with encouragement from WHO, to recognise the value of this strategy.* But in practice, the opposite has happened.

3.3 Using the FCTC to express instinctive hostility to innovation

However, the same flexibility also allows the FCTC to be hostile to innovation that emerged long after the text was settled. The static nature of the FCTC text does not stop the Convention from creating a hostile global approach to 'ENDS' (vaping products) or other recent innovations, even though some of these fall outside the literal scope of the FCTC. There is nothing in the FCTC text that suggests that vaping products should be prohibited, but a great deal of activity, notably by WHO, has gone into supporting prohibition and prohibition of reduced-risk products is self-evidently WHO preferred option. The late great Calestous Juma captured the instinctive bureaucratic hostility to innovation in his book, *Innovation and its Enemies*:

> *Claims about the promise of new technology are at times greeted with skepticism, vilification or outright opposition—often dominated by slander, innuendo, scare tactics, conspiracy theories and misinformation.*
>
> *The assumption that new technologies carry unknown risks guides much of the debate. This is often amplified to levels that overshadow the dangers of known risks.*
>
> *Juma C. Innovation and Its Enemies: Why People Resist New Technologies. Oxford, New York: Oxford University Press; 2016. [link]*

That feels like a very apt description of the bureaucratic reaction to low-risk alternatives to cigarettes.

The section below examines how the activity surrounding the FCTC is promoting and normalising prohibition.

4. Ten ways in which the activity of the WHO and FCTC institutions promote prohibition

There are many ways in which COP, WHO and the FCTC Secretariat negatively influence policy on tobacco harm reduction and encourage harm to public health. Ten ways are listed below:

4.1 Decisions of the COP

These decisions are consensus statements reached by the Parties and agreed upon at COP meetings. They are generally non-binding position-taking (e.g. "invites parties to consider…"), but they have the effect of 'normalising' favoured policies, in particular outright prohibition. For example, there are multiple hostile decisions on ENDS and tobacco harm reduction (examples below). The decisions are strongly influenced by the papers presented to the delegates and often initially drafted by WHO or the FCTC Secretariat. The process of reaching COP decisions is strongly subject to 'anchoring bias' – i.e. they closely resemble whatever text they started with. By holding the pen initially, WHO or the Secretariat shape the decisions of the COP, and these could be quite different if WHO wanted them to be.

Here are some examples:

COP-6 in 2014 (emphasis added):

> *INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health; 4. URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS;*
>
> *FCTC/COP6(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems, October 2014. [link]*

COP-7 in 2016:

> *INVITES Parties to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives;"*
>
> *FCTC/COP7(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems, 12 Nov 2016. [link]*

COP-8 in 2018:

> *to regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products, as appropriate to their national laws, taking into account a high level of protection for human health;*
>
> *FCTC/COP8(22) Novel and emerging tobacco products, 6 October 2018 [link]*

Paragraph 5 of this document essentially applies all FCTC provisions to heated tobacco products as if they were cigarettes, without assessing whether this would be potentially harmful to public health by reducing switching from high-risk to low-risk products. This is the 'Plan B' where outright prohibition is not possible – prohibit whatever you can and regulate what's left as though it is no different to cigarettes.

4.2 Papers to support COP meetings

These decisions of the COP do not come out of thin air. They are mostly formulated as ready for rubber-stamping by the Secretariat or WHO based on papers for the COP published 60 days before the meetings.

The WHO or Secretariat prepare documents on issues on the agenda for COP meetings, sometimes in response to decisions made at prior COPs. There have been papers on ENDS at:

COP-6 [FCTC/COP/6/10] This was the last time WHO attempted anything approaching even-handedness

> *ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased.*

> *Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to denormalize tobacco use.*

COP-7 [FCTC/COP/7/11] Though this WHO document contained some discussion of possible benefits, the payload was delivered in the "Regulatory options". This used a linguistic formulation to imply that the prohibition of ENDS was the default regulatory option – this choice of language is not accidental. Paragraphs 29 and 30 start:

> *Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options:*

See comment on this from Jeannie Cameron.

COP-8 [FCTC/COP/8/10] This paper is by the FCTC Secretariat. It pursues the prohibition agenda more forcefully, for example by providing a table of countries that have prohibited ENDS. It does not debate the merits and obviously unintended consequences of prohibition or give equivalent weight to other regulatory approaches. It is done in the guise of objective reporting, but the framing and emphases suggest the underlying aim is to normalise prohibition.

> *Data gathered by WHO for the WHO Report on the Global Tobacco Epidemic 2017 using legislation in place by December 2016 illustrate that ENDS were banned in 30 of the 195 WHO Member States globally (about 15%).*

COP-9 [FCTC/COP/9/9] is supposed to be a "*Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products […]*" by WHO. It apparently overlooks the vast body of evidence considered by the US FDA in determining that the iQOS heated tobacco product is "*appropriate for the protection of public health*" [FDA summary PDF] and that communicating its greatly reduced toxic exposures is "*appropriate to promote public health*" [FDA summary PDF]. Instead, this unserious document repeatedly intimates that harm reduction is no more than a tobacco industry conspiracy:

> *Regulators should not allow themselves to be distracted by tobacco and related industry tactics or the aggressive promotion of these products. To this end, it is evident that tobacco control policies must be forcefully protected from the*

> *influence of the nicotine and tobacco industries in line with Article 5.3 of the WHO FCTC and its Guidelines for Implementation.*

The paper continues the prohibitionist theme but also sets out Plan B, should prohibition not be possible: that heated tobacco products should be regulated as if they are the same as cigarettes, for example, with graphical health warnings (of what?). Again, an excellent way of supporting and defending the cigarette trade.

COP-9 also provides a supposedly technical paper [FCTC/COP/9/10] by the FCTC Secretariat on '*Challenges posed by and classification of novel and emerging tobacco products*' in which an implausible fictional account of combustion is used to claim that the aerosol from heated tobacco products is actually "tobacco smoke".

> *The aerosols emitted by HTPs thus fall under the definition of smoke. Since the source of this smoke is a tobacco product, the emissions of most novel and emerging tobacco products – including HTPs – are tobacco smoke.*

There is no actual scientific basis for this – it is a thinly disguised and crude gambit to support a WHO/Secretariat policy position that these products are no different to cigarettes and should be treated the same by policymakers, even though this patently false and would function as a regulatory protection of the cigarette trade.

We see the FCTC steadily advancing a prohibition agenda through these papers – though uncritically and without considering unintended consequences. The parties appear to go along with it.

4.3 Implementation guidelines

These are guidance documents, sometimes approved by decisions of the COP, that provide advice on the implementation of the Articles of the FCTC – for example, the WHO technical manual on tobacco tax policy and administration. What this says about ENDS and HTPs will influence how the vague terms of Article 6 (see above) are implemented. This is subject to very little scrutiny or consultation – certainly not by the people affected by it. For tobacco harm reduction, perhaps the most notable is the Guidelines for implementation of Article 5.3 [link]. Article

5.3 is about keeping the tobacco industry at a distance from policymaking – but the guidelines go *much* further and far beyond the original FCTC article. The guidance hangs on this 'principle':

> *Principle 1: There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.*

Article 5.3 itself does not say anything that justifies the 'principle' above. It is in fact a reasonable statement about containing excessive corporate influence – an idea that could be applicable in any treaty (substitute oil industry and climate change, for example):

> *5.3. 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.*

In the vast scope-creep between the wording of Article 5.3 itself (agreed in 2003) and the guidelines on implementation (2008), the guidance implicitly rules out tobacco harm reduction. If you think (as I do) that it should be *a goal of policy* to align the industry's interests with tobacco harm reduction this principle makes no sense. But if you are an anti-vaping activist that subscribe to this 'irreconcilable conflict' principle, you *have to* conclude that tobacco harm reduction is in a fundamental and irreconcilable conflict with public health, even if it is highly beneficial for public health. No justification is required, just a reference to this principle. Absurdly, this principle had already been falsified by the extensive evidence about snus experience already available at the time it was agreed. But the point is that this principle is how prohibitionists want the world to be, not how it is.

Many perverse consequences arise from the over-zealous application of that principle – all work against innovation, all reinforce the cigarette trade. I have discussed this here: *The irreconcilable conflict principle*. November 2020.

4.4 WHO tobacco regulation advisory committee "TobReg"

The WHO Study Group on Tobacco Product Regulation (often known as 'TobReg')

is a long-standing scientific advisory committee and has produced useful reports in the past. However, its advice is a product of the group's membership, and this has changed over time. The TobReg report published in 2021 has a strong prohibitionist theme. It contains multiple recommendations, and here are three of the most egregious:

> *to apply the most restrictive tobacco control regulations to heated tobacco products (including the device), as appropriate within national laws, taking into account a high level of protection for human health;*
>
> *to ban all commercial marketing of electronic nicotine delivery systems, electronic non-nicotine delivery systems and heated tobacco products, including in social media and through organizations funded by and associated with the tobacco industry;*
>
> *to prohibit the sale of electronic nicotine delivery systems and electronic non-nicotine delivery systems in which the user can control device features and liquid ingredients (that is, open systems);*
>
> *WHO study group on tobacco product regulation: Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group, May 2021 [link]*

Though there are many pages of ponderous scientific discussion in this report, there is no credible *policy analysis* to support any of the statements above – in particular, no consideration of whether the recommendation for ENDS and HTPs amount to protection and promotion of the cigarette trade. There is no discussion of what effect these policies would have on current or potential users of these products. Policy recommendations are just something *asserted* by this committee as if they follow automatically from their interpretation of the science. The likely behavioural responses to these policies – what actually matters – are never analysed or justified with evidence.

In order to have maximum 'influencing' impact, the report recommendations were summarised in a paper for the February 2021 Executive Board of WHO before the main report had been published – a disgraceful practice, in my view – though apparently, no one objected to this unsourced policy shopping list. See paper [EB148/27 paragraph 26-32, which list the main recommendations of the TobReg report above. These recommendations are *extremely contentious* but were provided to

the Executive Board without any supporting evidence or indication that these measures would be controversial, have a weak evidence base and would be vulnerable to damaging unintended consequences.

4.5 Scientific papers

The WHO or the Secretariat can commission advice on scientific or regulatory issues, and the Parties can request technical papers via COP Decisions. Science can be procured to order through the choice of the scientist contracted to provide it.

WHO staff also produce papers for scientific journals. The Director-General wrote a commentary for *The Lancet* in 2019. His piece was packed with misleading science and flawed reasoning, making multiple misleading and contested statements drawing on flawed or debunked studies:

> *Although tobacco and related industries promote these products as tools for quitting, the evidence does not support their use as part of population-based cessation strategies. The aerosols of ENDS contain toxic chemicals that are harmful to both users and non-users and are, therefore, products that come with health risks of their own. And in combination with smoking, which is the practice with the majority of ENDS users, the health effects of two or more products are combined. ENDS on their own are associated with increased risk of cardiovascular diseases and lung disorders and adverse effects on the development of the fetus during pregnancy. For adolescents, the addictive nature of nicotine can lead to dependence and may harm adolescent brain development, including reduced activity in the prefrontal cortex. Use of ENDS could also lead to a new generation of nicotine and tobacco users, as seen in some countries, especially given how these products are marketed to young people. Although the specific level of risk associated with ENDS has not yet been conclusively estimated, ENDS are undoubtedly harmful, should be strictly regulated, and, most importantly, must be kept away from children. It is also incorrect to think that heated-tobacco products are the answer, as they simply move tobacco users from one harmful tobacco product to another.*
>
> *Ghebreyesus TA. [Director General WHO] Progress in beating the tobacco epidemic. Lancet 2019 394(10198):548–549. [link].*

The Director General's paper was criticised for its hostility to innovation and failure to provide a reasoned analysis of risks (which are negligible) and

opportunities (substantial).

> *Vaping and other smoke-free products have the potential to reduce the enormous harm of smoked tobacco products. The stakes of getting policy responses to smoke-free products wrong are high, especially if such restrictions stop millions of the world's smokers accessing safer alternatives. It is disappointing that in its latest tobacco report, WHO clings to outdated orthodoxy when it could embrace innovation. Equating smoke-free products with cigarettes only serves to protect the stranglehold of the cigarette trade on the world's nicotine users and will nullify the potential of modern tobacco harm reduction strategies.*
>
> *Beaglehole R, Bates C, Youdan B, Bonita R. Nicotine without smoke: fighting the tobacco epidemic with harm reduction Lancet. 2019 394(10200):718–720. [link]*

But perhaps the most forceful take-down of WHO science happened for COP-7 (2016) by the independent experts at the UK Centre for Tobacco and Alcohol Studies. The main points raised in the summary and full UKCTAS critique are as follows:

- *Positioning ENDS as a threat rather than opportunity*
- *Failure to quantify risk*
- *Inadequate comparisons with smoking*
- *Misrepresenting second hand ENDS vapour risks*
- *Discounting the evidence that ENDS do help smokers quit*
- *ENDS marketing can be anti-smoking advertising*
- *Flavours are essential to the appeal of ENDS as alternative to smoking*
- *Mischaracterisation of the ENDS market and role of tobacco transnationals*
- *Unjustified support for ENDS prohibition*
- *Policy proposals made with no supporting policy analysis*
- *No assessment of unintended consequences*
- *Transparency and quality*

Britton J, Bogdanovica I, McNeill A, Bauld L. UKCTAS Commentary on WHO Report on Electronic Nicotine Delivery Systems and Electronic Non-nicotine Delivery Systems UKCTAS, 26 October 2016. [link][report PDF]

Critique of FCTC COP-7 paper on ENDS FCTC/COP/7/11 [link]

4.6 Global Tobacco Regulators Forum

WHO convenes a forum for tobacco regulators, the Global Tobacco Regulators Forum (GTRF). The secretive closed forum is funded by the US Food and Drug Administration (FDA). FDA has an exceedingly heavy-handed approach to the regulation of alternatives to cigarettes, which is collapsing into litigation chaos, so it is unclear what anyone can learn from that benighted agency.

However, the WHO uses this forum to influence regulators. Though its proceedings are kept secret, leaked papers prepared by WHO EMRO regional office revealed the promotion of regulatory proposals for vaping and heated tobacco products that are extremely hostile through this forum. See Clive Bates, *Leaked papers: WHO to intensify its pointless and destructive war against innovation – expect many dead*, 9 September 2019. [link] The two leaked papers repeatedly refer to prohibition.

> *This side-by-side text advices WHO Member States in the Eastern Mediterranean Region on options to consider in relation to ENDS/ENNDS (e-cigarettes). [link]*
>
> *Member States can consider regulatory options such as 1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)*

> *This side-by-side text advises Member States in the Eastern Mediterranean on options to consider in relation to HTPs. [link]*
>
> *Member States can consider regulatory options such as 1. Banning the importation, sale, and distribution of HTPs*

4.7 Advocacy by the FCTC Secretariat and WHO

The FCTC Secretariat and WHO signal their policy preferences in many ways through various forms of advocacy. This advocacy includes speeches, that falsely position harm reduction as merely a strategy of Big Tobacco and ignore the significant public health support for the concept both in tobacco control and in other areas of public health.

> *As known to many of us, the youth are the favorite target of the tobacco industry,*

> *especially through the novel and emerging tobacco products that are flooding the markets. We must act now. That is why, youth will be the focus of the ninth session of the Conference of the Parties to the WHO FCTC*
>
> *Dr Adriana Blanco Marquizo, Head of FCTC Secretariat. 15 year of the entry into force of the WHO Framework Convention on Tobacco Control. 5 March 2020 [link]*

Advocacy includes social media posts celebrating prohibition:

> *WHO congratulates #India 🇮🇳 for banning #ecigarettes. pic.twitter.com/L5kfhmELnO*
>
> *— WHO South-East Asia (@WHOSEARO) September 18, 2019*

Web resources such as the E-cigarette Q&A promote prohibition and hostility to harm reduction.

> *What are the policy options for regulating ENDS?*
>
> *How a country approaches ENDS will depend on factors particular to its situation. ENDS are currently banned in over 30 countries worldwide. In others they are regulated as consumer products, as pharmaceutical products, as tobacco products, other categories or totally unregulated.*
>
> *Where they are not banned, WHO recommends that ENDS be regulated.*

The original version of the E-cigarette Q & A was so deeply wrong and flawed that even WHO found it necessary to replace it within a few days – see my review: World Health Organisation fails at science and fails at propaganda – the sad case of WHO's anti-vaping Q&A. These activities are all purposefully hostile to vaping and tobacco harm reduction and designed to bolster the case for prohibition..

4.8 World No Tobacco Day

World No Tobacco Day (31 May every year) has become an annual exercise in foolishness. Never more so than this year, when WHO went on the attack against

the use of e-cigarettes as a method for stopping smoking [see absurd press release: Quit Tobacco To Be A Winner. In this initiative, WHO promotes gimmicks for which there is no supporting evidence for successful quitting (see the risibly robotic and easily dumbfounded, digital stop-smoking advisor Florence, for example). But WHO then goes to war with something that does actually work – vaping.

> *The tobacco industry has continuously attempted to subvert these life-saving public health measures. Over the last decade, the tobacco industry has promoted e-cigarettes as cessation aids under the guises of contributing to global tobacco control. Meanwhile, they have employed strategic marketing tactics to hook children on this same portfolio of products, making them available in over 15,000 attractive flavours.*
>
> *The scientific evidence on e-cigarettes as cessation aids is inconclusive and there is a lack of clarity as to whether these products have any role to play in smoking cessation. Switching from conventional tobacco products to e-cigarettes is not quitting*

As WHO hasn't troubled to engage in the actual evidence, let me provide a summary courtesy of Professor Kenneth Warner in May 2021, a former President of the Society for Research on Nicotine and Tobacco, and resident at the University of Michigan.

> *Evidence from six completely different sources demonstrates that vaping is increasing smoking cessation.*
>
> 1. *Randomized controlled trials. The Cochrane Review, the gold standard of scientific credibility, says there is "moderate certainty evidence" that vaping increases smoking cessation more effectively than do nicotine replacement therapy products.*
> 2. *Population studies find e-cigarettes increasing smoking cessation, especially when people use e-cigarettes frequently.*
> 3. *As e-cigarette sales rise, cigarette sales fall. Econometric studies confirm the two products are substitutes.*
> 4. *Other studies have found that policies intended to decrease youth vaping have increased youth smoking. Another study found that a tax on e-cigarettes in Minnesota increased adult smoking and decreased*

smoking cessation.

5. *Multiple simulation analyses have concluded that the potential benefit of vaping for adult smoking cessation substantially outweighs any risk that vaping might increase youth smoking.*
6. *Swedish men's substituting snus, a smokeless tobacco product, for cigarettes demonstrates the potential for lower-risk products to dramatically reduce tobacco-produced diseases.*

Tragically, public health organizations that focus exclusively on the potential risks of vaping for young people – risks that, frankly, have been grossly exaggerated – are likely to be damaging the health of the public.

Kenneth Warner, PhD
Avedis Donabedian Distinguished University Professor Emeritus of Public Health,
Dean Emeritus of Public Health
University of Michigan

David Abrams, Ray Niaura, David Sweanor and I wrote a detailed critique of WHO's World No Tobacco Day 2021 offerings – you can read our letter here: World Health Organisation must stop its baseless and irresponsible attack on tobacco harm reduction. This is the table of contents:

Of course, WHO never replied, and it never argues its case. It doesn't have to because the FCTC parties give it a free ride.

4.9 WHO report on the global tobacco epidemic – the not-so-hidden hand of Bloomberg

Every two years, WHO produces a status report on the 'global tobacco epidemic'. The 2021 report was dedicated to addressing the non-existent "threat" posed by vaping and other new and emerging products (the threat is from combustibles. Non-combustible products address the threat). This official WHO report is funded by the philanthropic foundation of New York financial services billionaire Michael Bloomberg and written with support from Bloomberg-funded staff[see report p.207]. It includes a foreword by Michael Bloomberg himself.

Mr Bloomberg is on record favouring outright prohibition of vaping. When interviewed by the New York Times as part of his Presidential primary campaign, Bloomberg explicitly called for the prohibition of vaping:

> *New York Times: Would you ban vaping products entirely?*
>
> *Michael Bloomberg: I think you can make a very good case to do so. It would be great if the President did that.*
>
> *Michael Bloomberg, Candidates Up Close: Should Vaping products Be Legal? New York Times (video interview), 25 January 2020. [link]*

Unsurprisingly, this Bloomberg-funded, supported and partially-authored WHO report comes out in favour of prohibition, using approving language like the following:

> *Where a ban on manufacture, sale and distribution of ENDS is the preferred regulatory approach to protect the health of a country's population (in the wider context of tobacco control, and based on the specific domestic regulatory environment), countries should strictly implement the ban without any interference from the industry to ensure a high degree of protection for children and adolescents.*
>
> *The evidence from this report indicates that 32 countries currently ban the sale of ENDS, taking a strong stance on preventing the potential harms they pose to their populations.*

WHO report on the global tobacco epidemic 2021: addressing new and emerging products [link]

Having given its blessing to outright prohibition as a "strong stance", the report also sets out the next best things a prohibitionist might hope for. Here are some of its policy proposals (not an exhaustive list)

- *"Consider prohibiting the sale of ENDS that the user can modify (either its features or e-liquid ingredients)"*
- *"Strong graphic health warnings should be mandated for all ENDS products"*
- *"On 1 October 2021 Australia will become the first country in the world to ban the purchase or import of ENDS by consumers unless they have a valid doctor's prescription to do so."*
- *"Banning or restricting advertising, promotion and sponsorship of ENDS/ENNDS"*
- *"Prohibiting by law the use of ENDS and ENNDS in indoor spaces"*
- *"Banning or restricting the use of flavours"*
- *"Taxing ENDS/ENNDS at a level that makes the devices and e-liquids unaffordable to minors"*

There is a pattern here: all these measures involve treating vaping as strictly or more strictly than cigarettes. This is the prohibitionist 'Plan B' – *de facto* prohibition by incremental restrictions. The only surprise is the omission of limiting nicotine strength to a low level – a measure that would make many more compact and convenient vaping product designs ineffective as alternatives to cigarettes.

The 2019 report works hard to develop the idea that much safer products than cigarettes must be bad.

> *These products [ENDS, heated tobacco] are aggressively marketed or promoted as cleaner alternatives to conventional cigarettes, as smoking cessation aids, or as "reduced risk" products. They have proliferated in several markets around the globe and present a unique challenge to regulators.*
>
> *WHO Report on the Global Tobacco Epidemic, 2019. [Archive link]*

The point is that these products are cleaner, reduced-risk alternatives to

cigarettes that function as smoking cessation aids. There's no point in denying that unless you have a prohibition agenda. But these reports do have a prohibition agenda – they are the work of a complex of influences funded and motivated by a prohibitionist.

Thankfully, Bloomberg's operations are finally attracting scrutiny: see the Marc Gunther, *Bloomberg's Millions Funded an Effective Campaign Against Vaping. Could It Do More Harm Than Good?* Chronicle of Philanthropy, March 2021. [link]

> *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*

Every person, organisation and institution (including WHO) taking money from the vast Bloomberg influencing complex should be acknowledging and declaring a conflict of interest arising from the proprietor's support for prohibition. This applies especially to the network of supposed 'civil society' organisations that surrounds the COP and is allowed into the meetings as observers. *Sorry, you are not civil society organisations*, you are functioning as the paid agents of an elitist billionaire prohibitionist.

4.10 Awards for prohibition – the conclusive proof of WHO's anti-vaping prohibitionist drive

The clearest articulation so far of WHO's ideological hostility to low-risk alternatives is its awards, and the signals it sends with them. Take the 2021 Director General's Special Recognition Award [link] to India's former Health and Family Welfare Minister. This is the most prestigious WHO award for tobacco control activism.

And for what was the award conferred? The citation states:

> *Dr Harsh Vardhan received the award for spearheading the Government of India's legislation to ban e-cigarettes and heated tobacco products in 2019.*

He got the award for *passing a prohibition law*, but did anyone ask questions about the effect of imposing a prohibition? Did this work? Does prohibition ever work? What was the effect on smoking? What was the effect on India's vapers? Has a black market formed? Has it protected India's tobacco industry from competition and who gained from that? So many questions before this could be deemed an award-worthy win for public health, yet the questions are not even asked, let alone answered.

A year earlier, in the World No Tobacco Day Awards for 2020 [link], Finland was appropriately patronised for its exemplary hostility to e-cigarettes [link]

> *WHO is pleased with Finland's exemplary actions, which have helped to reduce the appeal of e-cigarettes among young people in particular. Finland has strictly regulated the use of e-cigarettes and prohibited characterising flavours in liquids for e-cigarettes.*

Of course, no assessment has been made of the effects of this policy, in particular, whether it has driven young people towards smoking, black market products or other harmful workarounds. That is because for WHO, *the prohibition policy is the goal*.

5. By obstructing harm reduction, the FCTC fails public health

What needs to change? The FCTC institutions and their ways of working need to change. These are the headline problems:

5.1 Insensitive to large differences in risk

There is no text in the FCTC that relates to or anticipates the rise of low-risk consumer alternatives to cigarettes. This starts with the scope of the FCTC, which does not include consumer nicotine products. However, the parties have determined that they should bring these products into the norm-setting process of the FCTC, and they are free to do this if they do it by consensus.

The lack of risk sensitivity is evident, even though smokeless tobacco products such as snus had an observable harm reduction effect that was clear at the time the text was finalised. The European Union ban on snus and the American activist position that there was no meaningful difference in risk contributed to this design failure. Then, as now, many tobacco control advocates simply did not wish to acknowledge that it was possible to use tobacco or nicotine with very low risks. This is because harm (arising from smoke inhalation) is the key winning argument against nicotine use.

As a result, there is no *architecture* in the FCTC that allows for differential measures according to radically different levels of risk. The FCTC text is always exhorting the parties to go as far as possible within the confines of national legislation or constitutional constraints. There is no text at all that reflects the pronounced difference in risk between combustible smoked products and smoke-free products (vaping, heated and smokeless tobacco and nicotine pouches). There is no recognition that policymakers should use different measures to reflect different risks.

5.2 Blind to unintended consequences of policies

As a result, there is also nothing that recognises that policies designed to restrict low-risk alternatives to smoking may have unintended and perverse consequences, as carefully outlined by the Royal College of Physicians in 2016:

> *if [a risk-averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer-friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)*

These considerations ("getting this balance right") do not find any expression in the FCTC text and no longer feature in COP decisions or papers.

5.3 Relies on junk science

The original concept of the FCTC was to generalise established policies for which the scientific and public health community broadly agreed. These are supposed to be effective and proportionate public health measures that every government ought to take in some form. The idea of the FCTC was to build collective action and a kind of common agenda and to square up to the tobacco industry.

However, for vaping and other harm reduction options, there is no consensus on what these policies should be or what the underlying science tells us. The FCTC and its institutions have instead become activists in trying to enforce one view of the science and policy agenda – one that owes more to ideology than to science or sound policymaking.

Many of the policy measures so far adopted or proposed are strongly contested – either because they have a contested science base (for example, claiming a gateway effect), they are prone to unintended consequences (for example, prohibitions causing relapse to smoking), or they encode particular priorities or objectives (for example, a focus on nicotine use rather than disease). So this is not about normalising and creating an authorising environment for established policies but promoting one side in a debate where the science and policy is disputed. The FCTC COP – a theatrical setting for health bureaucrats – is wholly unsuited to advancing new policies and measures that have not been tried, tested

or validated and for which the underpinning science is so contested by independent non-conflicted scientists.

5.4 Excludes pro-harm-reduction perspectives and builds a group-think bubble

Instead of recognising that the debate over harm reduction is polarised and polarising, the FCTC and its institutions have simply tried to exclude one side of this debate. It does this by its system for approving and excluding observers, the way it commissions scientific advice and who it chooses to listen to, and the overt biases in its COP papers and advocacy. The WHO is wide open to conflicts of interest, for example, through its support from Bloomberg Philanthropies. Michael Bloomberg is on record favouring outright prohibition of vaping – yet this hardly raises an eyebrow among the delegates to the COP meetings.

6. What delegates to the Conference of the Parties should do now

The October 2021 letter of 100 experts addressed to COP delegates made six recommendations (letter PDF English, Français, Español, Deutsch), and these deserve reiterating:

> *We recommend that Parties to the FCTC take a more questioning and assertive approach to WHO's advocacy on smoke-free alternative to smoking and undertake the following:*

- Make tobacco harm reduction a component of the global strategy to meet the Sustainable Development Goals for health, notably SDG 3.4 on non-communicable diseases.
- Insist that any WHO policy analysis makes a proper assessment of benefits to smokers or would-be smokers, including adolescents, as well as risks to users and non-users of these products.
- Require any policy proposals, particularly prohibitions, to reflect the risks of unintended consequences, including potential increases in smoking and other adverse responses.
- Properly apply Article 5.3 of the FCTC to address genuine tobacco

industry malpractice, but not to create a counterproductive barrier to reduced-risk products that have public health benefits or to prevent critical assessment of industry data strictly on its scientific merits.

- Make the FCTC negotiations more open to stakeholders with harm-reduction perspectives, including consumers, public health experts, and some businesses with significant specialised knowledge not held within the traditional tobacco control community.
- Initiate an independent review of WHO and the FCTC approach to tobacco policy in the context of the SDGs. Such a review could address the interpretation and use of science, the quality of policy advice, stakeholder engagement, and accountability and governance. The Independent Panel for Pandemic Preparedness and Response (IPPPR), initiated to evaluate the response to the COVID-19 pandemic, offers such a model.