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Director-General  
World Health Organisation  
Avenue Appia 20  
1202 Geneva  
Switzerland

31 May 2021

Dear Dr Adhanom Ghebreyesus

### **World Health Organisation must stop its baseless and irresponsible attack on tobacco harm reduction**

We write as long-standing advocates for measures to reduce the burden of death and disease caused by tobacco use. We stress that we have no conflicts of interest with respect to the tobacco, nicotine, or pharmaceutical industries.

The World Health Organisation puts the death toll from tobacco use at over eight million people annually and suggests an economic cost of US\$1.4 trillion in health care burdens and lost productivity. The burning question is what WHO and governments are doing about this. Our concern is that the response of the World Health Organisation is inadequate, based on flawed science and poor analysis, and compromised by special interests.

We were particularly concerned by aspects of WHO's press release of 19 May for World No-Tobacco Day (31 May), which quotes you personally.<sup>1</sup> We have provided the attached briefing on the problems raised in this press release and why it leads us to express concern about WHO's approach to tobacco and nicotine policy. The briefing is organised in nine sections:

1. WHO has the wrong analysis of the problem – the focus must be on *smoking*
2. WHO misrepresents risks and denies the value of switching from smoking to vaping
3. WHO ignores compelling evidence that vaping is displacing smoking
4. WHO fails to grasp the importance of flavours and how vaping works for smokers
5. WHO backs untested and inadequate smoking cessation measures
6. WHO has based its campaign on arcane special interests
7. WHO must disclose and be accountable for interim results
8. WHO has failed to understand a significant technology transition but is trying to block it
9. WHO should apply the *first-do-no-harm principle* – and stop what it is doing

If the approach outlined in the press release reflects WHO policy and that policy is implemented by WHO's members, then there will be more disease, more premature death, and an easy ride for the cigarette trade. Further, there will also be a vanishingly small chance of meeting the Sustainable Development Goal 3.4 to reduce non-communicable disease mortality by one-third by 2030.

We urge WHO to drop its opposition to tobacco harm reduction and rethink strategically.

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<sup>1</sup> WHO press release for World No Tobacco Day 2021: *Quit tobacco to be a winner*. 19 May 2021. [\[link\]](#)

WHO should now pause and reflect on the role it is playing and the damage it is causing through its dogmatic opposition to technologies that could greatly reduce the risks facing the world's one billion smokers.

We hope that by World No Tobacco Day 2022, WHO will have re-evaluated its strategy and switched to actively promoting tobacco harm reduction as a part of an aggressive strategy to address the intolerable health, welfare and economic burdens of smoking.

We would, of course, be glad to assist in a strategic rethink. We can provide detailed recommendations or more evidence to support our perspective as necessary.

Yours sincerely,

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The authors declare no conflicts of interest with respect to tobacco, vaping or pharmaceutical industries and confirm that no issues arise with respect to FCTC Article 5.3.

## Briefing: the flaws in WHO's approach to tobacco and disease

This briefing draws on excerpts from WHO's press release for World No Tobacco Day (31 May 2021) to discuss WHO's approach to tobacco policy.<sup>1</sup> These excerpts are highlighted in red.

### 1. WHO has the wrong analysis of the problem – the focus must be on *smoking*

The press release and WHO's materials refer specifically to quitting *tobacco*.

***Quit tobacco to be a winner***

*To truly help tobacco users quit, they need to be supported with tried and tested policies and interventions to drive down the demand for tobacco*

This framing neglects a critical insight – almost all of the global burden of tobacco-related death and disease is caused by *smoking*, the inhalation of products of combustion of dried and cured tobacco leaf, or exposure to secondhand smoke.<sup>2 3</sup> The most authoritative assessment suggests 98.9% of tobacco-related deaths are smoking-related.<sup>4</sup>

There are now many tobacco products (for example, heated tobacco products and low-nitrosamine snus) and non-tobacco nicotine products (vaping products and oral nicotine pouches) that do not involve combustion, do not create smoke, and therefore do not expose the user to toxicants produced in the combustion process. We do not claim these products are risk-free but are *much less risky* than smoked tobacco products, such as cigarettes. Lower risk does not simply make them a lesser public health problem: it means that when low-risk smoke-free products displace high-risk smoked products, there is a health gain for society and a contribution to meeting the SDGs.

One of the world's foremost regulators, the Food and Drug Administration of the United States, has declared a smokeless tobacco product and a heated tobacco product to be "appropriate for the protection of public health" after exhaustive evaluation.<sup>5</sup> On what basis does the WHO dispute this assessment? On what basis does WHO believe it would not apply to other smokeless and heated tobacco products? We have seen no reasoning from WHO that would cause US FDA to revoke or revisit its assessment.

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<sup>1</sup> WHO press release for World No Tobacco Day 2021: *Quit tobacco to be a winner*. 19 May 2021. [\[link\]](#)

<sup>2</sup> U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease. A Report of the Surgeon General. Atlanta, Georgia. 2010. [\[link\]](#)

<sup>3</sup> We are aware of traditional mixtures such as paan, gutkha, naswar and toombak that contain smokeless tobacco. These products are often made with poor production standards and can contain many additional hazardous ingredients including slaked lime, ash, hydrocarbons, betel leaf and areca nut. There are harm reduction opportunities for users of these products, but they are not discussed further here.

<sup>4</sup> Kozlowski LT. Policy Makers and Consumers Should Prioritize Human Rights to Being Smoke-Free over Either Tobacco- or Nicotine-Free: Accurate Terms and Relevant Evidence. *Nicotine Tob. Res.* 2020;22(6):1056–1058. [\[link\]](#) (Based on Global Burden of Disease 2017 assessment, *The Lancet*)

<sup>5</sup> US Food and Drug Administration. Pre-Market Tobacco Product Marketing Orders. [\[link\]](#)  
"PMTAs are evaluated based on several factors, including whether permitting the marketing of a new tobacco product would be appropriate for the protection of the public health, which is determined with respect to the risks and benefits of the product to the population as a whole, including users and non-users."

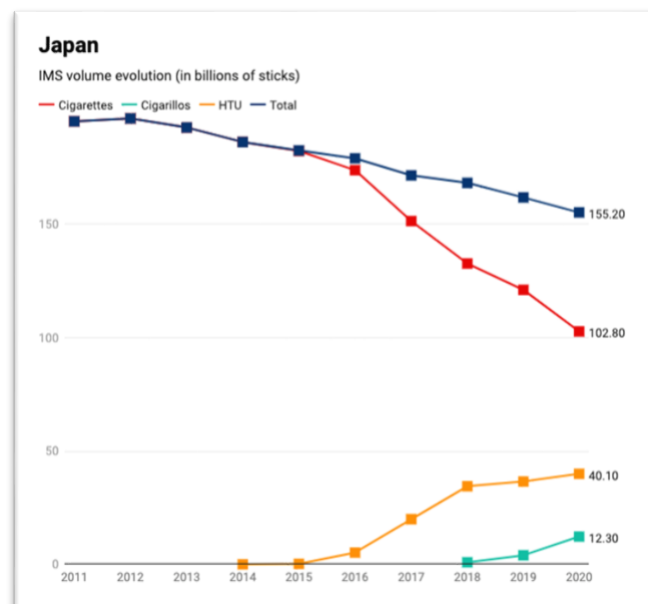
Sweden has the lowest rate of adult *smoking* found anywhere (7%) in the developed world, even though it has rates of *tobacco* use similar to the norm in other European countries.<sup>6</sup> This is because many tobacco users choose snus, a form of smokeless tobacco, instead of smoking. Because of its low smoking prevalence, Sweden has lower rates of smoking-related disease among men, the primary users of snus.

This highly beneficial effect of snus, a tobacco product, is well understood and documented.<sup>7</sup>

*All these effects suggest that the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe.*

In Norway, daily smoking prevalence among 16-24-year-old women fell from 17 per cent in 2008 to just one per cent in 2017<sup>8</sup> - an amazing transformation in just ten years - again because of the displacement of smoking by snus, a tobacco product.

In Japan, there has been a rapid and accelerated decline in cigarette volumes in the five years since the introduction of heated tobacco products. Low-risk heated tobacco products are “cannibalising” the market for cigarettes in a way that will work for health.



Source: Phillip Morris International<sup>9</sup>

If WHO wants to make a difference, it needs to focus on preventing *smoking*. Smoke-free tobacco and nicotine products displace smoking, and they are part of the solution, not part of the problem.

<sup>6</sup> European Commission, Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes, February 2021. Fieldwork August-September 2020 [\[link\]](#) Current adult smoking prevalence in Sweden = 7%. Daily smoking = 5%.

<sup>7</sup> Ramström L, Borland R, Wikmans T. Patterns of smoking and snus use in Sweden: Implications for public health. *Int J Environ Res Public Health* 2016;13(11) [\[link\]](#). Also see, Ramström L. Tobacco-related mortality Sweden & EU, 2020 Researchgate [\[link\]](#). based on Abbafati C, Abbas KM, Abbasi-Kangevari M, et al. Global Burden of Disease Study 2019. *Lancet* 2020;396(10258):1223–1249. m

<sup>8</sup> Statistics Norway, Tobacco Alcohol and Other Drugs, [\[link\]](#)

<sup>9</sup> Phillip Morris International. Case study: can innovative products like iQOS accelerate the declines of smoking, 18 May 2021 [\[link\]](#)

## 2. WHO misrepresents risks and denies the value of switching from smoking to vaping

WHO makes several statements about e-cigarette risks that are highly misleading.

*WHO Director-General Dr Tedros Adhanom Ghebreyesus [said]: “E-cigarettes generate toxic chemicals, which have been linked to harmful health effects such as cardiovascular disease & lung disorders.”*

The presence of a hazardous chemical does not make it dangerous. For example, there are at least 19 established carcinogens in a typical cup of coffee.<sup>10</sup> We do not, however, present coffee as a cancer risk.

E-cigarettes generate an aerosol that contains a mix of chemicals. However, the harmful chemicals present in cigarette smoke are either not present at detectable levels in vape aerosol, are present at much lower concentrations, or present at levels close to those found in non-smokers or former smokers. Extensive biomarker data confirms that vapers have greatly reduced exposure to harmful and potentially harmful constituents compared to smokers.<sup>11</sup> In 2018, Public Health England’s experts reviewed the available studies of biomarkers of exposure.<sup>12</sup> Based on their assessment of the biomarker and other evidence, PHE’s experts concluded:

*Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously*

The question is not whether hazardous chemicals are present (they are present almost everywhere), but whether the typical human exposures are sufficient to cause harmful effects. If so, the next question is whether the risk is significantly lower than smoking and if not, the question is how large the margin of safety is. There is no real doubt that e-cigarettes are much less harmful than cigarettes and, therefore, that significant harm reduction is possible when smokers switch.<sup>13</sup>

WHO argues that e-cigarettes cause cardiovascular disease. The evidence does not currently support this assertion, and there is good clinical trial evidence to show that switching to e-cigarettes improves cardiovascular outcomes in smokers who switch.<sup>14</sup> The flawed methodology<sup>15</sup> used to suggest that e-

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<sup>10</sup> Ames BN, Gold LS. The causes and prevention of cancer: Gaining perspective. In: Environmental Health Perspectives. Public Health Services, US Dept of Health and Human Services; 1997. p. 865–873. [\[link\]](#)

<sup>11</sup> Akiyama Y, Sherwood N. Systematic review of biomarker findings from clinical studies of electronic cigarettes and heated tobacco products. *Toxicol. Reports*. 2021;8:282–294. [\[link\]](#)

<sup>12</sup> McNeill A, Brose LS, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England [Internet]. London: 2018 [ [link](#) ] For biomarker studies see page 163 in the main report [\[PDF\]](#)

<sup>13</sup> Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. *Prev Med (Baltim)*. Academic Press; 2018 Jun 23; [\[link\]](#)

<sup>14</sup> George J, Hussain M, Vadiveloo T, et al. Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. *J Am Coll Cardiol* 2019;74(25):3112–3120. [\[link\]](#)

<sup>15</sup> Rodu B, Plurphanswat N. A re-analysis of e-cigarette use and heart attacks in PATH wave 1 data. *Addiction* 2020;115(11) [\[link\]](#)

cigarettes cause cardiovascular disease has led to the retraction of one influential paper.<sup>16</sup> The flawed methodology casts doubt on the scientific reliability of other papers cited by WHO.<sup>17</sup>

WHO makes a vague claim about e-cigarettes causing “lung disorders”. It is not clear what this refers to, and no source is provided. However, in its online E-cigarette Briefing<sup>18</sup>, WHO refers to:

*... 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)*

This US outbreak of lung injuries was *nothing* to do with nicotine vaping (or ENDS – Electronic Nicotine Delivery Systems), and it is misleading and irresponsible to imply that it is. This condition was caused by the addition of a cutting agent, Vitamin E Acetate, to illicit cannabis vape pens.<sup>19</sup> Vitamin E Acetate cannot be added to nicotine liquids<sup>20</sup>, and it would serve no economic or other useful purpose even if it could. Once the error was recognised, the practice stopped (even criminals do not want to kill their customers). The supply pipeline gradually emptied, meaning that lung injuries tapered away in early 2020, and CDC stopped its monitoring. There is no excuse for WHO to be implying this is a nicotine vaping risk in 2021.

E-cigarettes are much less risky than cigarettes. It is unethical and anti-scientific for WHO to deny smokers the health opportunities of switching from high-risk to low-risk products.

### 3. WHO ignores compelling evidence that vaping is displacing smoking

Much of the WHO press release is devoted to rejecting vaping as an alternative to smoking and an effective method for quitting smoking. The WHO press release states:

*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.*

This is not the case, and no reputable scientific agency could draw these conclusions from the available science or use the residual uncertainties to reject vaping as an alternative to smoking. It is irresponsible to suggest switching from conventional tobacco products to e-cigarette is somehow “not quitting”. That argument risks entrenching current smoking and promoting relapse. Switching to vaping means *quitting smoking*, and quitting smoking means avoiding nearly all the health risks. Avoiding as much health risk as

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<sup>16</sup> Bhatta DN, Glantz SA. Electronic Cigarette Use and Myocardial Infarction Among Adults in the US Population Assessment of Tobacco and Health. *J Am Heart Assoc* 2019;8(12):e012317. [\[link\]](#) RETRACTED.

<sup>17</sup> For example, Alzahrani T, Pena I, Temesgen N, Glantz SA. Association Between Electronic Cigarette Use and Myocardial Infarction. *Am J Prev Med* 2018;55(4):455–461. [\[link\]](#) was erroneously cited in Ghebreyesus TA. Progress in beating the tobacco epidemic. *Lancet* 2019;394(10198):548–549. [\[link\]](#) as if Alzahrani et al. established a causal link between vaping and MI – *it does not and cannot*.

<sup>18</sup> World Health Organisation, Tobacco: E-cigarettes 29 January 2020, Accessed 23 May 2021 [\[link\]](#)

<sup>19</sup> Blount BC, Karwowski MP, Shields PG, et al. Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI. *N Engl J Med* 2020;382(8):697–705. [\[link\]](#)

<sup>20</sup> Kozlovich S, Harvanko AM., Benowitz NL. Vitamin E Acetate is not Soluble in Nicotine E-liquids: Ingenta Connect. *Tob Regul Sci* 2021;7(2):130–134. [\[link\]](#)

possible is why smokers change their behaviour. There is no reason for WHO to devalue or declare their achievement in *quitting smoking* to be somehow illegitimate or ill-conceived.

There is abundant evidence that e-cigarette use is an effective alternative to smoking. To understand how e-cigarettes have the effect of displacing smoking at individual and population level, it is essential to look at the convergence of evidence from multiple sources. This convergence provides strong evidence that e-cigarettes are effective alternatives to smoking.

- *Randomised controlled trials.* Several recent trials show positive results.<sup>21 22</sup> The most substantial clinical trial to date showed e-cigarettes with approximately twice the smoking cessation efficacy of NRT<sup>23</sup>. There is an accumulating evidence base: the authoritative Cochrane Review now recognises evidence of efficacy and that e-cigarette compare favourably to nicotine replacement therapy.<sup>24</sup>

According to the Cochrane Review:

*More people probably stop smoking for at least six months using nicotine e-cigarettes than using nicotine replacement therapy (3 studies, 1498 people), or nicotine-free e-cigarettes (4 studies, 1057 people).*

*Nicotine e-cigarettes may help more people to stop smoking than no support or behavioral support only (5 studies, 2561 people).*

- *Observational data.* There is evidence that smokers who use e-cigarettes are more likely to quit smoking than those who do not.<sup>25 26</sup>
- *Population trends.* A further important factor is the *popularity* of vaping as a strategy for quitting smoking.<sup>27 28</sup> For a smoking cessation method to be effective for public health purposes, it has to be not only effective but also popular. There is evidence that as the prevalence of e-cigarette use

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<sup>21</sup> Eisenberg MJ, Hébert-Losier A, Windle SB, et al. Effect of e-Cigarettes plus Counseling vs Counseling Alone on Smoking Cessation: A Randomized Clinical Trial. *JAMA - J Am Med Assoc* 2020;324(18):1844–1854. [\[link\]](#)

<sup>22</sup> Pulvers K, Nollen NL, Rice M, et al. Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers: A Randomized Clinical Trial. *JAMA Netw open* [Internet] 2020 [cited 2021 Jan 18];3(11):e2026324. [\[link\]](#)

<sup>23</sup> Hajek P, Phillips-Waller A, Przulj D, et al. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. *N Engl J Med* 2019;380(7):629–637. [\[link\]](#)

<sup>24</sup> Hartmann-Boyce J, McRobbie H, Lindson N, et al. Electronic cigarettes for smoking cessation. *Cochrane Database Syst Rev* 2021. [\[link\]](#)

<sup>25</sup> Jackson SE, Kotz D, West R, Brown J. Moderators of real-world effectiveness of smoking cessation aids: a population study. *Addiction* 2019;114(9):1627–1638. [\[link\]](#)

<sup>26</sup> Kotz D, Brown J, West R. “Real-world” effectiveness of smoking cessation treatments: A population study. *Addiction* 2014 [\[link\]](#)

<sup>27</sup> Caraballo RS, Shafer PR, Patel D, Davis KC, McAfee TA. Quit Methods Used by US Adult Cigarette Smokers, 2014–2016. *Prev Chronic Dis* 2017;14(4):160600. [\[link\]](#)

<sup>28</sup> Public Health England, Health matters: stopping smoking – what works? 17 December 2019 [\[link\]](#) “E-cigarettes are currently the most popular stop smoking aid in England, with an estimated 2.5 million users”

increases in a population, smoking cessation activity also increases.<sup>29 30 31 32</sup> There is also evidence that vaping is a diversion from smoking for adolescents and that adolescents who vape are likely to have smoked otherwise, implying that even adolescent vaping has a harm reduction effect.<sup>33 34</sup>

- *Modelling studies.* Modelling studies based on the experience so far show very substantial public health potential even when parameterised with sceptical assumptions.<sup>35 36</sup>
- *Economic research.* Market data shows that e-cigarettes displace smoking, and these products are economic substitutes.<sup>37 38 39</sup>
- *Testimonials.* There is a large databank of positive user accounts of switching from smoking to vaping and experiencing health, welfare, and wellbeing benefits as a result.<sup>40</sup> These form part of the evidence base and align with the other, more formal scientific data above.

In April 2021, the Royal College of Physicians (London) published a detailed scientific assessment focussed on smoking cessation. The College concluded the following:<sup>41</sup>

*E-cigarettes are an effective treatment for tobacco dependency and their use should be included and encouraged in all treatment pathways. [...] E-cigarettes are included in standard protocols to treat tobacco dependency.*

*Media campaigns should also encourage switching from smoked tobacco to e-cigarettes and provide balanced information on other harm reduction options such as heated tobacco.*

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- <sup>29</sup> Beard E, West R, Michie S, Brown J. Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time-series analysis between 2006 and 2017. *Addiction* 2020;115(5):961–974. [\[link\]](#)
- <sup>30</sup> Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ*. 2017;358:j3262. [\[link\]](#)
- <sup>31</sup> Levy DT, Yuan Z, Luo Y, Abrams DB. The relationship of e-cigarette use to cigarette quit attempts and cessation: Insights from a large, nationally representative U.S. Survey. *Nicotine Tob Res* 2018; [\[link\]](#)
- <sup>32</sup> Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. *BMJ* [Internet] 2016 [cited 2020 Dec 3];354:i4645. [\[link\]](#)
- <sup>33</sup> Selya AS, Foxon F. Trends in electronic cigarette use and conventional smoking: quantifying a possible ‘diversion’ effect among US adolescents. *Addiction* 2020;add.15385. [\[link\]](#)
- <sup>34</sup> Sokol N, Feldman J. High school seniors who used e-cigarettes may have otherwise been cigarette smokers: evidence from Monitoring the Future (United States, 2009-2018). *Nicotine Tob Res* 2021; [\[link\]](#)
- <sup>35</sup> Levy DT, Borland R, Lindblom EN, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. *Tob Control* [Internet] 2018 [cited 2020 Dec 5];27(1):18–25. [\[link\]](#)
- <sup>36</sup> Mendez D, Warner KE. A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking. *Nicotine Tob Res* 2020; [\[link\]](#)
- <sup>37</sup> Pesko MF, Warman C. The Effect of Prices on Youth Cigarette and E-Cigarette Use: Economic Substitutes or Complements? *SSRN Electron J* 2017 [\[link\]](#)
- <sup>38</sup> Pesko MF, Courtemanche CJ, Maclean JC. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. *J Risk Uncertain* 2020;60(3):229–258. [\[link\]](#)
- <sup>39</sup> Cotti C, Courtemanche C, Maclean JC, Nesson E, Pesko M, Tefft N. The Effects of E-Cigarette Taxes on E-Cigarette Prices and Tobacco Product Sales: Evidence from Retail Panel Data. NBER Working Paper #26724. Cambridge, MA: 2020 [\[link\]](#)
- <sup>40</sup> See for example, the collection of over 13,000 user testimonials held by Consumer Advocates for Smoke-free Alternatives Association (CASAA). Available at: <https://casaa.org/testimonials/>
- <sup>41</sup> Royal College of Physicians (London). Smoking and health 2021: A coming of age for tobacco control? London. 29 April 2021 [\[link\]](#)



*To incentivise and signal the importance of substituting tobacco with less harmful forms of nicotine, the level of taxation applied to non-tobacco nicotine products should be proportionate to their harm relative to tobacco. To this end, tax on medicinal nicotine should be abolished and tax on electronic cigarettes reduced.*

*Health warnings on e-cigarette packs include a statement that e-cigarette vapour is likely to be substantially less harmful than tobacco smoke.*

*Use of non-tobacco nicotine, including e-cigarettes, is important as a means to support abstinence from smoking in public places, and in some circumstances also indoors.*

We cannot see why WHO draws an opposite conclusion to this eminent society, and we have not seen equivalent justification for WHO's hostile position towards e-cigarettes. Where is the evidence?

#### **4. WHO fails to grasp the importance of flavours and how vaping works for smokers**

*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.*

It is a matter of historical record that the tobacco industry did not create e-cigarettes. They are not marketed as cessation aids (e-cigarettes are not licensed medications with smoking cessation indications). E-cigarettes are alternatives to cigarettes for nicotine users, and that is how they are marketed. They are successful at causing smoking cessation because they appeal to smokers. One reason for their appeal is the wide variety of non-tobacco flavours, which help smokers migrate away from smoking. The reason that most approaches to smoking cessation do not work is two-fold: (1) they are not very effective among those who are motivated to quit and try them; (2) not many users try them. Vaping works by providing an appealing alternative to smoking that many smokers wish to try.

It is just plain wrong to assert that the diversity of flavours is targeted at youth. Adult smokers are by far the largest market for these products, and flavours are integral to the experience for smokers.<sup>42 43</sup>

Given that e-cigarettes are an economic substitute for smoking for both adults and adolescents, it would not be surprising to see *anti-vaping policies* cause an increase in *smoking*. This appears to have been the effect of the ban on flavoured products that came into effect in San Francisco in July 2018. Teen *smoking* appears to have increased sharply in San Francisco compared to equivalent districts between the 2017 and 2019 Youth Risk Behavior Surveillance System surveys – see figure from Friedman A (2021) below.<sup>44</sup>

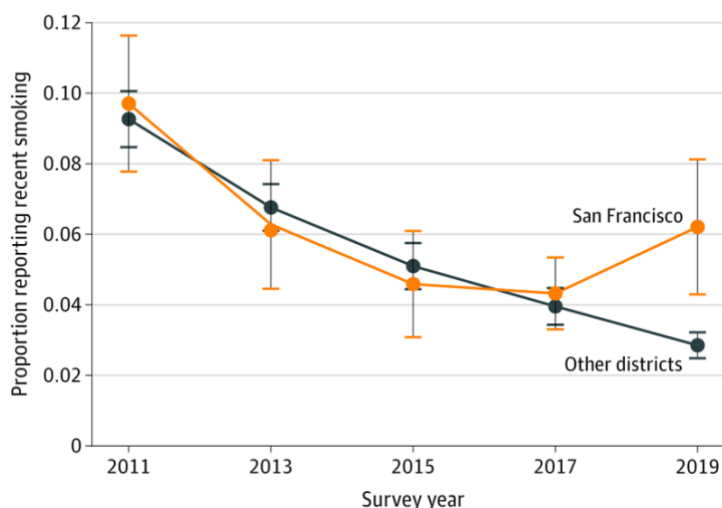
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<sup>42</sup> Gravelly S, Cummings KM, Hammond D, et al. The association of e-cigarette flavors with satisfaction, enjoyment, and trying to quit or stay abstinent from smoking among regular adult vapers from Canada and the United States: Findings from the 2018 ITC four country smoking and vaping survey. *Nicotine Tob Res* 2021;22(10):1831–1841. [[link](#)]

<sup>43</sup> Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* [Internet] 2018 [cited 2018 Jul 17];15(1):33. [[link](#)]

<sup>44</sup> Friedman AS. A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California. *JAMA Pediatr* 2021 [[link](#)]

Figure 1. Past-30-Day Smoking Trends Among High School Students Younger Than 18 Years



The idea that anti-vaping policies might cause more smoking may surprise WHO, but it should not because it is an *obvious* likely perverse consequence. Furthermore, the Royal College of Physicians warned about such harmful unintended consequences in 2016.<sup>45</sup>

*However, [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)*

The tobacco industry has entered the market for reduced-risk products for good reasons: smokers are turning to e-cigarettes to reduce their risks. It is better for tobacco companies and everyone else if nicotine use involves much less harm.

Tobacco companies have spent decades being “merchants of death”. Their transition to low-risk products should be welcomed and expedited by WHO, not condemned and obstructed.

## 5. WHO backs untested and inadequate smoking cessation measures

We agree with WHO that *smoking cessation* is a major priority. But unlike WHO, we believe it should be pursued by any method that works, including switching to smoke-free nicotine products. In rejecting this approach, WHO offers an extremely weak alternative package. The WHO press release states:

*That’s why WHO launched a year-long campaign for World No Tobacco Day’s – “Commit to Quit” theme. The campaign aims to empower 100 million tobacco users to make a quit attempt by creating networks of support and increasing access to services proven to help tobacco users quit successfully.*

*This will be achieved by scaling-up existing services such as brief advice from health professionals and national toll-free quit lines, as well as launching innovative services like Florence, WHO’s first digital health worker, and chatbot support programmes on WhatsApp and Viber.*

<sup>45</sup> Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. London: RCP; 2016. [\[link\]](#)

*To truly help tobacco users quit, they need to be supported with tried and tested policies and interventions to drive down the demand for tobacco.*

We can see no evidence that supports this strategy. “Florence” is a little more than an automated response system producing pre-programmed and formulaic replies that would alienate even the most obliging client.<sup>46</sup> What evidence supports the use of an automaton WhatsApp chatbot for smoking cessation: is there any evidence that receiving messages through such a cumbersome dialogue has any effect on smoking behaviour?<sup>47</sup> We are not aware of any.

Given that 80% of smokers are in low- and medium-income countries (LMICs), how does WHO expect “*scaling up of national toll-free quit lines*” to work where these either do not exist or require large budgets to encourage smokers to pick up the phone? How will “*brief advice from health professionals*” be delivered in LMIC health care settings, and who will instruct doctors and nurses to provide this advice?

While denying the effectiveness of measures that have worked for millions, WHO supports measures for which there is no supporting evidence (and unlikely ever to be any). Why?

## 6. WHO has based its campaign on arcane special interests

This campaign was launched on 8 December 2020 as a year-long effort to “help 100 million people quit tobacco”.<sup>48</sup> The press release launching the initiative included the following:

*WHO, together with partners, will create and build-up digital communities where people can find the social support they need to quit. The focus will be on high burden countries\* where the majority of the world’s tobacco users live.*

*WHO welcomes new contributions from partners, including private sector companies that have offered support, including Allen Carr’s Easyway, Amazon Web Services, Cipla, Facebook and WhatsApp, Google, Johnson & Johnson, Praekelt, and Soul Machines.*

Can WHO provide evidence that supports the role of these commercial enterprises in a WHO-fronted global smoking cessation initiative? On what evidence were Allen Carr’s Easyway self-help offerings selected for participation in this initiative?

For transparency reasons, it is important to know if any of these entities have a “pay-to-play” relationship with WHO – and we would be grateful for some accounting for any money involved. For example, has the pharmaceutical company Johnson & Johnson donated to the WHO or paid to be involved in this initiative?

We should expect to know who funds WHO’s World No Tobacco Day initiatives and its tobacco work more generally. Where is the financial disclosure?

## 7. WHO must disclose and be accountable for interim results

*The campaign aims to empower 100 million tobacco users to make a quit attempt by creating networks of support and increasing access to services proven to help tobacco users quit successfully.*

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<sup>46</sup> See “Florence”, WHO’s digital health worker [\[link\]](#)

<sup>47</sup> See the WHO WhatsApp Chatbot [\[link\]](#)

<sup>48</sup> WHO press release: WHO launches year-long campaign to help 100 million people quit tobacco, 8 December 2020. [\[link\]](#)

Given that World No Tobacco Day, 31 May 2021, is almost at the mid-point of the one-year campaign that started on 8 December 2020, there must be interim results by now, assuming the initiative is being monitored and evaluated. WHO should provide information on the use of the “Florence” and the WhatsApp bot services? WHO should provide data on the other commercial offerings included in this initiative, including progress in meeting the goal of 100 million people making quit attempts. WHO is pushing these untried techniques while aggressively opposing measures for which there is a good evidence base.

Where is the data that suggests WHO’s approach is working?

## **8. WHO has failed to understand a significant technology transition but is trying to block it**

Much of the WHO press release is devoted to criticising the tobacco industry. It draws on Article 5.3 of the FCTC.

*The tobacco industry is the single greatest barrier to reducing deaths caused by tobacco use. Their interests are irreconcilably opposed to promoting public health, and point to a critical need to keep them out of global tobacco control efforts. WHO FCTC Article 5.3 aims to do just that.*

This analysis is popular with tobacco control activists and funders. We are very well aware of the history of the tobacco industry and have played our part in holding these companies to account. But this view should not be accepted uncritically and without reference to what is happening today, not just the past.

We do not think that opposition to the industry should ever take priority over reducing severe diseases and premature death, should those two aims conflict. If “irreconcilable” opposition to the tobacco industry means rejecting products that are much less risky than cigarettes just because tobacco companies make them, then that is a major ethical failing.

The better way to understand the evolving nicotine marketplace is that it is undergoing a fundamental technology transition. It is moving from a market dominated by combustible tobacco products to one based on a variety of non-combustion nicotine products. Unless WHO believes nicotine, a relatively innocuous recreational drug, should be eradicated (a prohibition that would be certain to fail), then the question is how nicotine products should be made available with acceptable risk and within what regulatory environment.

This sort of technology transition is hardly unique. Other industries undergoing fundamental transitions include:

- *Automotive sector.* The auto industry is in the process of transition from the internal combustion engine to electrically power vehicles. This process involves niche companies (Tesla) but will be driven by changes at the major corporations like Toyota and Volkswagen.
- *Energy sector.* Companies are moving into lower carbon fuels and renewables as part of the response to climate change. The oil major Shell has declared it will achieve “net zero” greenhouse gas emissions by 2050.
- *Industrial gases.* The makers of ozone-depleting chemicals (refrigerants and foam blowing agents such as CFCs) such as DuPont led the way with innovations that dramatically reduced or eliminated ozone depleters.

These transitions all share several characteristics: the innovation is coming from both outside and within the established companies; the transition is not instantaneous, and the incumbent harmful technology continues to be deployed while transition evolves; there is considerable scepticism about the pace of change, and most governments and activists would like it to go faster; change is driven by a mix of regulatory pressure, legal liability, license to operate, investor confidence, corporate strategy, and what is technologically and economically achievable.

But *in not one of these cases* has any responsible agency done what WHO is doing in the case of tobacco. No agency has tried to obstruct a transition from high-risk to low-risk technology, denied that transition is necessary, or established a principle that change is impossible because of an “irreconcilable” conflict.

WHO is taking a moralising abstinence-only approach to addressing the gigantic health and economic burden of smoking and obstructing a market transition that would address the health problem through consumer choice and producer innovation.

## **9. WHO should apply the *first-do-no-harm principle* – and stop what it is doing**

A recent estimate put the use of safer nicotine products at 98 million people worldwide.<sup>49</sup> That remains a small fraction of the world total of smokers and a small fraction of the potential to displace smoking. Since 2014, the contribution of WHO and the FCTC Secretariat has been wholly negative: supporting and applauding prohibitions of low-risk alternatives, promoting disproportionate regulation and excessive taxation, publishing misleading information, and marginalising and excluding consumers and pragmatic public health experts who favour harm reduction.<sup>50</sup>

This needs to stop.

For tobacco harm reduction to work, all WHO needs to do is to cease opposing it and obstructing smokers from switching. Market forces, consumer demand, and innovation will drive low-risk alternatives to cigarette smoking because, unsurprisingly, *that is what people want* – they do not want cancer, cardiovascular disease, or respiratory conditions. The FCTC should focus on smoking and stop encouraging ill-conceived and evidence-free anti-vaping policies.

It would be a bonus if WHO started to promote the concept of tobacco harm reduction,<sup>51</sup> but that is not *necessary* for there to be a significant gain for public health.

WHO could help to reduce the burden of smoking-related disease by applying the *first-do-no-harm principle* and stopping its activities while it reflects on its responsibilities and accountability.

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<sup>49</sup> Burning Issues: Global State of Tobacco Harm Reduction 2020. London: Knowledge--Action-Change, 2020. [\[link\]](#)

<sup>50</sup> See Clive Bates, Evidence to All-Party Parliamentary Group on Vaping Inquiry into WHO and FCTC COP-9. March 2021 [\[link\]](#)

<sup>51</sup> Beaglehole R, Bates CD, Youdan B, Bonita R. Nicotine without smoke: fighting the tobacco epidemic with harm reduction. *Lancet*. 2019;394(10200):718–720. [\[link\]](#)

## Appendix: About the authors

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**Clive D. Bates** is Director of Counterfactual, a consulting and advocacy practise focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. From 2000, he was closely involved in the development of the Framework Convention on Tobacco Control as head of a leading non-profit tobacco control organisation and was instrumental in the establishment of the Framework Convention Alliance of supportive NGOs. In 2003, he joined Prime Minister Blair's Strategy Unit as a senior UK civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan. He started Counterfactual in 2013.

**Dr Raymond S. Niaura** is Professor, Department of Social and Behavioral Science NYU School of Global Public Health New York University. USA. He is a psychologist and an expert on tobacco dependence and treatment, as well as substance use and addiction to alcohol. For eight years, Dr Niaura was the Director of Science and Training at the Schroeder Institute (SI) for Tobacco Research and Policy Studies at the Truth Initiative and Professor, Health Behavior and Society, Bloomberg School of Public Health, The Johns Hopkins University. Dr. Niaura has previously taught and conducted research at Brown University, Johns Hopkins Bloomberg School of Public Health, the Georgetown Medical Center, and the School of Public Health at University of Maryland. He was also a former President of the Society for Research on Nicotine and Tobacco and is a Deputy Editor of the journal *Nicotine and Tobacco Research*. Dr Niaura has published over 400 peer-reviewed articles and book chapters.

**David T. Swenor JD** is Adjunct Professor of Law and Chair of the Advisory Board of the Centre for Health Law, Policy and Ethics at the University of Ottawa. He has worked on global tobacco and health issues for 40 years, helping set many global precedents in Canada. He has also worked globally on tobacco issues with the WHO, PAHO, World Bank and numerous other bodies and spoken and published widely. His interests extend to a wide range of topics, and in addition to his personal work, he funds numerous initiatives. He was the recipient of the Outstanding Individual Philanthropist award for Ottawa in 2016.