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Dear Dr. Adhanom Ghebreyesus

WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products

As academics and experts in the field of tobacco control (see page 6), we are concerned by the apparent support of WHO and the FCTC Secretariat for outright bans or over-regulation of low-risk alternatives to smoking. These low-risk products include e-cigarettes and other vaping products, heated tobacco products, modern smokeless tobacco and novel nicotine products. These products, collectively known as Alternative Nicotine Delivery Systems (ANDS), form the basis for the public health strategy of 'tobacco harm reduction'. They have one factor in common: they do not involve burning of tobacco leaf or smoke inhalation. It is *smoke* that causes the overwhelming burden of disease and there is no serious doubt that non-combustible products are far less harmful than cigarettes.

We regard *prohibition* of these products as unethical, unscientific, damaging to public health and an irrational protection of the cigarette trade. We regard *excessive regulation or taxation* of ANDS as counterproductive and harmful for similar reasons. Public health efforts should focus on driving out the cigarette trade, not protecting it and perpetuating smoking. The objective of the WHO is: "*the attainment by all peoples of the highest possible level of health*" [1]. In the 2018 United States Annual Review of Public Health, the authors recognised the transformative potential to realise that goal:[2]

> *A diverse class of alternative nicotine delivery systems (ANDS) has recently been developed that do not combust tobacco and are substantially less harmful than cigarettes. ANDS have the potential to disrupt the 120-year dominance of the cigarette and challenge the field on how the tobacco pandemic could be reversed if nicotine is decoupled from lethal inhaled smoke,*

ANDS products are integral to 'harm reduction', and harm reduction is integral to the definition of tobacco control, as specified in the Framework Convention on Tobacco Control,[3]:

> Article 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*; (emphasis added)

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1 WHO, Constitution of the World Health Organisation. Chapter One: Objective, Article 1 [link]

2 Abrams DB, Glasser AM, Pearson JL, Villanti AC, Collins LK, Niaura RS. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annu Rev Public Health*; 2018. [link]

3 WHO Framework Convention on Tobacco Control, 2003 [link]

There is now a substantial body of evidence evidence that these products are much safer than smoking. In a wide-ranging assessment, the United States National Academy of Sciences states:[4]

> *While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.*

In its ground-breaking 2016 report, the London-based Royal College of Physicians states:[5]

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

We have also seen no compelling evidence that these products attract significant numbers of young people who would not otherwise have smoked[6]. Claims of 'gateway effects' have invariably suffered from methodological weaknesses[7] [8]. Regular youth use is concentrated in young people who smoke[9] and there is evidence that young people use vaping products to reduce harm and to quit smoking[10]. Youth smoking has fallen unusually rapidly in the United States in recent years even as youth vaping has increased[11]. We see no evidence that vaping 'normalises' smoking. As expected, it appears to do the opposite by promoting alternatives to smoking, thereby *normalising smoking cessation*[12].

Millions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom[13], Sweden[14], the United States[15], and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018[16] following the introduction of heated tobacco products. That is a remarkable result that should engage everyone concerned with tobacco control and tackling non-communicable disease. But many have ignored it.

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

5 Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016 [link]

6 Kozlowski LT, Warner KE. Adolescents and e-cigarettes: Objects of concern may appear larger than they are. *Drug Alcohol Depend.* 2017 May;174(1 May 2017):209–14. [link][PDF]

7 Villanti AC, Feirman SP, Niaura RS, Pearson JL, Glasser AM, Collins LK, et al. How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor. *Addiction*. 2017 Oct 3; [link]

8 Phillips C V. Gateway Effects: Why the Cited Evidence Does Not Support Their Existence for Low-Risk Tobacco Products (and What Evidence Would). *Int J Environ Res Public Health* 2015;12:5439–64. [link]

9 Collins LK, Villanti AC, Pearson JL, Glasser AM, Johnson AL, Niaura RS, et al. Update to Villanti et al., "frequency of youth e-cigarette and tobacco use patterns in the United States: Measurement precision is critical to inform public health." Vol. 19, Nicotine and Tobacco Research. Oxford University Press; 2017. p. 1253–4. [link]

10 Shiffman S. Sembower MA. PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes, Poster SRNT, Florence March 2017 [link]

11 Wang TW, Gentzke A, Sharapova S, Cullen KA, Ambrose BK, Jamal A. Tobacco Product Use Among Middle and High School Students — United States, 2011–2017. MMWR Morb Mortal Wkly Rep 2018;67:629–633. [link]

12 Bates CD, Mendelsohn C, Submission 336 - Evidence to Standing Committee on Health, Aged Care and Sport (Australia) Inquiry The Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia Do vapour products reduce or increase smoking? A summary of published studies. 19 October 2017 [link]

13 Office for National Statistics (UK). Smoking habits in the UK and its constituent countries, 2017 data, 3 July 2018 [link]

14 Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [link]

15 National Center for Health Statistics, National Health Interview Survey, Early releases [link], Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 2006- 2017. [link]

16 Japan Tobacco, Japanese Domestic Cigarette Sales Results for March 2015 2016 2017 2018

The misplaced hostility of WHO to tobacco harm reduction

Although WHO backs harm-reduction in other areas of public health such as HIV/AIDS, sexual health and intravenous drug use, it has historically taken a hostile approach to the tobacco harm reduction strategy and ANDS. For example, comments in the China Daily[17] attributed to the previous Director General of the WHO called for prohibition of e-cigarettes:

> *Margaret Chan, the WHO's director-general, expressed concern and urged caution. "E-cigarettes will prompt young people to take up smoking. I recommend that national governments ban, or at least regulate, them," she said.*

We have since seen WHO and the FCTC secretariat embrace the concept of prohibition, for example in briefing materials for FCTC COP-7 in 2016[18] as if this policy is the norm or a default option. This WHO stance was subject to very strong and well-founded expert criticism[19]. In the papers for COP-8 to be held in October this year[20], we were disappointed to see more emphasis on ENDS prohibition, with repeated references to bans or applying the same regulation to the most harmful products, cigarettes. The position taken towards ANDS continues to be negative and unbalanced (see, for example, paragraph 27 and 28 of the COP-8 paper on ENDS [20]), which stress only risks but never opportunities and call for policies that would be the same as applied to cigarettes. In the case of heated tobacco products (HTPs), WHO describes all tobacco products as "harmful" without recognition that the difference in risk between tobacco products spans two orders of magnitude[21].

> *All forms of tobacco use are harmful, including HTPs. Tobacco is inherently toxic and contains carcinogens even in its natural form. Therefore, HTPs should be subject to policy and regulatory measures applied to all other tobacco products, in line with the WHO Framework Convention on Tobacco Control (WHO FCTC).*

This assertion makes no sense: why should regulators take an undifferentiated approach to the riskiness of the product when *health risk is the primary purpose of regulation* and the risks differ dramatically between different products? Yet the statements of WHO have influenced countries such as India, with 104 million smokers, to adopt policies that promote prohibition and aim to deny these low-risk options to its citizens[22]. There are now 30 countries that ban these products[20].

Given that many millions of smokers are now, as a matter of policy, deliberately discouraged from or denied the opportunity to switch from cigarettes to low-risk products, who will assume responsibility for those who continue to smoke, and perhaps die, as a result? Will the World Health Organisation accept this responsibility?

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17 China Daily, *Tougher controls urged for e-cigarettes*, 13 October 2015 [link]

18 FCTC/COP/7/11, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS): a report by WHO, August 2016 [link] – see especially WHO's policy proposals (para 29-32) which start by assuming prohibition is the norm.

19 UK Centre for Alcohol and Tobacco Studies (UKCTAS), Commentary on WHO report on ENDS and ENNDS, October 2016 [link][PDF] – note: report and summaries are available in all UN languages.

20 FCTC/COP/8/10, Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) 66 Report by the Convention Secretariat. 27 June 2018 [link] See table: "*Parties where ENDS are banned per Region*"

21 WHO Tobacco Free Initiative: Heated Tobacco Products (HTPs) information sheet. Accessed 30 August 2018. [link]

22 Government of India, Ministry of Health & Family Welfare, Advisory on Electronic Nicotine Delivery Systems (ENDS), including E-Cigarettes. Heat-Not-burn devices. Vape. e-Sheesha. e-Nicotine flavoured Hookah. and the like products. No-P-16012 /19/2017 -TC 28 August 2018 [link]

Putting the health goal first: a change of approach is essential

Under agreements made in 2013 to reduce non-communicable diseases (NCDs), the nations of the World Health Assembly committed to reduce smoking prevalence by 30% in relative terms by 2025, compared to 2010[23]. However, WHO's most recent assessment of the likely outcomes[24] suggests that this target will be missed in three-quarters (97 of 129) of the countries assessed. In 33 countries, smoking prevalence will rise on current trends. The target focus has now shifted to 2030 and the Sustainable Development Goals, specifically Goal 3 and Target 4[25]:

> *By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being*

Though the goalposts have shifted to 2030 and a less precise target, it is important to ask if anything has been learnt from the likely impending failure to meet the 2025 goal? Tobacco harm reduction would have made a difference: it is an important tool to address the epidemic of smoking-related disease and the overall burden of non-communicable disease. If WHO is serious about its role in achieving this goal, it should recognise that the fastest way to reduce premature mortality by 2030 is by *smoking cessation among adult smokers* by whatever means works. The strategy of tobacco harm reduction through use of ANDS is one of the most promising ways to achieve smoking cessation, precisely because it is so popular with smokers and requires a smaller, more manageable change of behaviour than necessary to achieve complete abstinence, yet with almost the same health benefits.

How to proceed: risk-proportionate regulation

The Royal College of Physicians has highlighted how excessively burdensome regulation (including prohibition) applied to ANDS such as e-cigarettes can actually lead to more smoking[26].

> *However, if [a risk averse, 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.*

We believe that the WHO and FCTFC Secretariat should be helping member countries and parties negotiate this difficult balance, not avoid it altogether by advocating prohibition or the same regulation that applies to cigarettes. A major UK parliamentary inquiry into e-cigarettes reported on 17 August, 2018[27]. The Members of Parliament concluded:

> *E-cigarettes present an opportunity to significantly accelerate already declining smoking rates, and thereby tackle one of the largest causes of death in the UK today. […] There should be a shift to a more risk-proportionate regulatory environment; where regulations, advertising rules and tax duties reflect the evidence of the relative harms of the various e-cigarette and tobacco products available.*

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23 World Health Assembly Resolution 66/8 Draft comprehensive global monitoring framework and targets for the prevention and control of non-communicable diseases, March 2013 [link]

24 World Health Organisation, WHO global report on trends in prevalence of tobacco smoking 2015. [link]

25 United Nations Sustainable Development Goals. [link]

26 Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 (Section 12.10 page 187) [link]

27 House of Commons Science and Technology Committee (UK) Inquiry into e-cigarettes. [Report and press notice] [PDF] 17 August 2018.

We agree with this conclusion. In every area of policy covered by the FCTC, the appropriate approach is to place the greatest burdens and restrictions on the most risky products, especially cigarettes, and use regulation to encourage smokers to switch to ANDS or to quit altogether. This would mean in practice:

- The highest taxes on cigarettes but lower tax or no tax on low-risk products, with tax differentials reflecting the likely difference in risk.
- Complete bans on promotion of cigarettes, but controls on content, target audience and placement of promotion for ANDS (given these function as smoking cessation adverts).
- Strong graphic health warnings and plain packaging for cigarettes, but for ANDS proportionate warnings about nicotine backed by clear communication of the comparative risks of smoking.
- Legally-mandated bans on smoking in enclosed public places, but policy on ANDS use would remain the responsibility of owners or managers of public places.
- Product regulation of cigarettes focussed on reducing aspects of product appeal, but prudent regulation via product standards to improve and standardise ANDS safety and quality.
- Public health agencies to give realistic information about risk and quitting smoking, not simply campaign to reduce ANDS use whatever the impact on smoking.

In your capacity as Director General and the most influential leader in global public health, we hope you will make a statement calling for an open mind about the potential for new technologies and innovations that can help people stop smoking. We hope you will insist on impartial expert advice and assessments to guide policy. We hope you will urge caution on those jurisdictions considering prohibition or excessive regulation of ANDS and remind them to take responsibility for the likely harmful unintended consequences of policies that deny smokers options to quit smoking.

Finally, we would welcome an opportunity to meet with you and appropriate members of your team to discuss these issues and the proper approach for WHO in more depth. Please let us know if this would be possible.

Yours sincerely,

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Dr. David B. Abrams is Professor, Department of Social and Behavioral Science NYU College of Global Public Health New York University. USA. He directed the Office of Behavioral and Social Sciences Research (OBSSR), National Institutes of Health. He has published over 280 peer-reviewed articles, is Principal Investigator on numerous NIH grants and served on the Board of Scientific Advisors of the National Cancer Institute. Dr. Abrams was President of the Society for Behavioral Medicine and recipient of their Distinguished Scientist, Research Mentorship and Service Awards; received the Cullen Memorial Award, American Society for Preventive Oncology for lifetime contributions to tobacco control; Research Laureate Award, American Academy of Health Behavior; and the Distinguished Alumni Award, Rutgers University. He authored the award-winning: *The Tobacco Dependence Treatment Handbook: A Guide to Best Practices.* His current focus is health promotion in populations and nicotine use from basic science to prevention, treatment, public health and health care practice, to policy.

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice 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 College 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. 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. Sweanor 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 more than 30 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.