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August 31, 2021

Dear Dr. Henning

Medical University of South Carolina Department of

Thank you for your letter of June 1, 2021, on behalf of Michael Bloomberg, replying to ours of May 13. We still hope that Mr. Bloomberg will respond positively to our request to meet. We certainly recognize and appreciate the contribution Mr. Bloomberg has made to public health and tobacco control specifically, but with the number of smokers in the world today and the devastating disease and deaths caused by smoking, we think the status quo, an annual global death toll of eight million, is unacceptable.

Given the experience in our group, we hope Mr. Bloomberg will welcome a discussion of evidence, even if that may be challenging to some of the assumptions that underpin hundreds of millions of dollars of his philanthropic expenditure. Some reflection on policy in this area could have the potential to alter the trajectory of preventable death and disease around the world.

We see considerable scope for alignment between MPOWER and tobacco harm reduction in meeting Sustainable Development Goal 3.4 to reduce non-communicable disease by one-third by 2030 compared to 2015. We know this is a high priority for Mr. Bloomberg as he begins his third term as WHO Global Ambassador for Non-Communicable Diseases and Injuries, but without new impetus in tobacco control, this target will remain out of reach.

We are concerned about efforts to shut down and even censor debate and discussion of best policy options at a time where the science on smoking harm reduction is still evolving. We remain concerned that Bloomberg Philanthropies may be doing more harm than good with some of its investments in tobacco control, particularly through its opposition to tobacco harm reduction. We are concerned that the foundation has misunderstood youth vaping, undervalued tobacco harm reduction, and has not adequately assessed perverse consequences arising from some of the policies for which it advocates.

In the spirit of constructive engagement and as you asked us to share data that is critical to this discussion or contradicts the position taken by Bloomberg Philanthropies, we have enclosed an issues paper that could form the basis for a constructive discussion. We do not claim a monopoly on knowledge in this field, we recognize that there is much controversy, and there are differing

perspectives within our own group. But we believe there are serious issues that demand further and deeper consideration, given human health outcomes at stake.

We hope you will also consider and engage with the assessment of evidence, policy implications, and possible unintended consequences in the newly published paper authored by fifteen past presidents of the Society for Research on Nicotine and Tobacco. Warner et al (2021) conclude.<sup>1</sup>

Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality. We review the health risks of e-cigarette use, the likelihood that vaping increases smoking cessation, concerns about youth vaping, and the need to balance valid concerns about risks to youths with the potential benefits of increasing adult smoking cessation.

We would like to reiterate our request to meet Mr. Bloomberg and to discuss these issues with him directly. We remain concerned that aspects of Bloomberg Philanthropies' tobacco control program could be doing more harm than good to the health of both adolescents and adults, both in the United States and globally. We look forward to hearing from you and hope for a constructive discussion.

We are copying this letter to Patricia Harris, Chief Executive at Bloomberg Philanthropies and to Howard Wolfson, Senior Adviser to Mr. Bloomberg.

Yours sincerely,

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<sup>&</sup>lt;sup>1</sup> Balfou DJK, Benowitz NL, Colby SM, Warner KE et al. Balancing Consideration of the Risks and Benefits of E-Cigarettes. *Am J Public Health* 2021;e1–e12. https://doi.org/10.2105/AJPH.2021.306416

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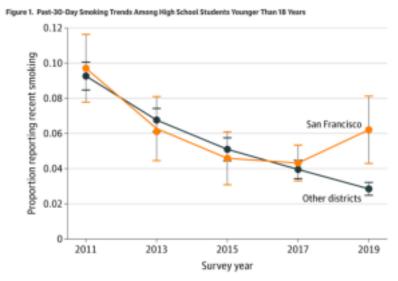
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# Bloomberg Philanthropies' approach to tobacco and nicotine policy an issues paper for discussion 30 August 2021

# 1. Unintended impact of e-cigarette flavor bans

Bloomberg Philanthropies has committed \$160 million to secure nicotine e-liquid flavor bans in the United States. <sup>2</sup> One of the few studies that have evaluated nicotine use before and after a flavor ban found *a sharp rise in adolescent smoking*. The increase observed in San Francisco was not replicated in districts that had not imposed a flavor ban.<sup>3</sup> The figure from Friedman (2021) is shown below:



Given that Bloomberg Philanthropies has committed \$160 million to secure flavor bans of the type implemented in San Francisco, the observed sharp and anomalous increase in teen smoking in San Francisco should be a reason for a thorough and urgent re-evaluation of the evidential basis for this campaign. It should not, however, be a surprise. It is consistent with what is known about the interaction between smoking and vaping. The interaction between youth smoking and vaping presents a significant conceptual challenge to the Bloomberg-funded campaign – the harms from only small increases in smoking would easily overwhelm any health gains from reduced vaping among adolescents

who would never have otherwise used nicotine over the longer term.

That opens a further question: what assumptions are made about how young people (and adults) will respond to an e-cigarette flavor ban? One possibility is that they will simply stop vaping or never start and do nothing else instead, which is assumed to be the result Bloomberg Philanthropies hopes to achieve. However, many young users may simply switch to the products not banned. It is plausible that a

flavor ban may promote a resurgence of smoking (see the San Francisco example, cited above). But this is not the only possible perverse outcome: a ban may also cause:

- the formation of a black market in poor quality illicit flavored products (see Omaiye et al. 2021: "Restriction of JUUL flavours may have inadvertently caused a migration of users to a potentially more harmful product")<sup>4</sup>
- cross-border trade in prohibited products that are legally available in other jurisdictions the development of a new flavors market using food or aromatherapy flavorings increase in home mixing and informal suppliers with attendant safety risks
  - increased contact between young people and criminal supply networks as customers or low level vendors with multiple adverse consequences that flow from such engagement
  - the accelerated development of synthetic nicotine products that fall outside FDA's jurisdiction

Given Bloomberg Philanthropies is spending \$160 million on a campaign to ban flavors, how confident is the foundation about the likely behavioral responses – both among suppliers and consumers – that such interventions are likely to trigger? Because smoking is so much more dangerous than vaping, it only requires a small fraction of vapers to smoke instead of vaping for the intervention to cause more harm than good. This remains a concern about the public benefit of the foundation's investments in this field.

## 2. Youth vaping and smoking behaviors are connected

There is no disagreement about the desired goal of preventing nonsmokers, especially youth from using tobacco or nicotine. However, prevention of youth uptake cannot be done without also considering the consequences for smokers – both adult *and adolescent*. A sophisticated understanding of the interaction between smoking and vaping is necessary before advancing policies, such as e-cigarette flavor bans. E cigarettes function as *substitutes* for cigarettes for both adolescents and adults. While there was a substantial increase in adolescent e-cigarette use between 2017 and 2019, it is important to be clear that most adolescent use was *infrequent*, and *frequent* use was highly concentrated in young people who had a prior history of tobacco use. This means that vaping can disrupt pathways that lead to smoking, a much more damaging youth risk behavior. Recent analysis suggests that e-cigarettes create a

<sup>&</sup>lt;sup>2</sup> Bloomberg Philanthropies, Bloomberg Philanthropies Launches New \$160 Million Program to End the Youth E-Cigarette Epidemic, 10 September 2019 [access]

<sup>&</sup>lt;sup>3</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 [access]

diversion from adolescent smoking.<sup>78</sup> This is consistent with observed US adolescent population trends,

which have seen a sharp decline in smoking as vaping has risen. By 2020, youth smoking prevalence was far below the level expected when the Healthy People 2020 target for past-month adolescent cigarette use was set at 16.0 percent. In 2020, cigarette prevalence was just 4.6 percent and any-combustible tobacco use was 9.4 percent.

2

Though most may wish for adolescents not to use nicotine, not to smoke, not to drink, not to use illicit drugs, not to have sex, and not to do anything that puts them in any danger, adolescence is a time of risk taking— whatever adults might wish. The approach of 'just-say-no' has never been an effective public health strategy. It is pragmatic, therefore, to be open to harm reduction *at all ages*. <sup>12</sup> Like Bloomberg Philanthropies, no-one in public health wants young people to use nicotine, but the primary concern is minimizing overall harm, including and especially among young people who have a high risk taking propensity and would be inclined to smoke. The use of nicotine is not *safe*, but the most troubling outcome would be for use to progress to a lifetime of cigarette smoking and the attendant health consequences – but the evidence suggests the opposite effect, that vaping diverts from smoking.

The Bloomberg response letter asserts that: "the federal government has not been effective at overseeing the marketing and sale of these products in a way that is sufficient to prevent a new generation of kids from becoming addicted to nicotine." It is also important not to treat all nicotine use as synonymous with nicotine addiction, especially as most of the adolescent use has been infrequent. Despite the increases in e-cigarette use, there has not been a commensurate increase in dependence.<sup>13</sup>

Some of the claims made about nicotine and damage to the human brain are not substantiated in the multiple generations of adults who consumed nicotine as smokers during adolescence. These claims rely primarily on unrepresentative studies of acute nicotine exposure in rodents or associations prone to confounding or reverse causation. <sup>14</sup> In the UK, nicotine replacement therapy is approved for smoking cessation in children aged 12 or over. <sup>15</sup>

**3. Flavor bans will not address underlying demand for tobacco or nicotine** The Bloomberg reply letter points out "Other data show that young people often cite flavors as a reason for using

<sup>&</sup>lt;sup>4</sup>The restrictions on Juul flavored products have led to a rise in Puff Bar products, but a recent analysis showed these to be potentially more harmful than the Juul equivalents. Omaiye EE, Luo W, McWhirter KJ, Pankow JF, Talbot P. Flavour chemicals, synthetic coolants and pulegone in popular mint-flavoured and menthol-flavoured e-cigarettes. *Tob Control* [Internet] 2021 [cited 2021 Jul 2];0:tobaccocontrol 2021-056582. [access] https://tobaccocontrol.bmj.com/lookup/doi/10.1136/tobaccocontrol-2021-056582

<sup>&</sup>lt;sup>5</sup>The substitution effect is clear from analysis that examines the impact on demand for e-cigarettes and cigarettes when taxation or restrictions are placed on e-cigarettes. Please see "Economics of E-cigarettes: Background, Theory, and Evidence" by Michael Pesko [access]. We are willing to summarise this literature should there be interest.

<sup>&</sup>lt;sup>6</sup>Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios* 2020 [access]

<sup>&</sup>lt;sup>7</sup>Selya AS, Foxon F. Trends in electronic cigarette use and conventional smoking: quantifying a possible 'diversion' effect among US adolescents. *Addiction* 2021;add.15385. [access]

<sup>&</sup>lt;sup>8</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 [access]

e-cigarettes". When young people are asked, their stated motivations for vaping mention

3

flavors but also include various forms of harm reduction<sup>16</sup> A CDC survey found that curiosity was the main reason given by adolescents for e-cigarette use, with flavors a distant third. It is conceivable that large-scale activist campaigns increase curiosity and effectively advertise vaping to young people. How would Bloomberg Philanthropies know if its campaign was raising awareness of and interest in vaping?

If Bloomberg Philanthropies is going to be guided by what young people say, then it should anticipate a substantial increase in smoking to arise from a successful campaigns to ban flavors Researchers asked 18–34-year-olds what they would do if non-tobacco flavors were banned:

If restricted to tobacco flavors, 39.1% of e-cigarette users reported being likely (very/somewhat) to continue using e-cigarettes (30.5% not at all likely); **33.2% were likely to switch to cigarettes** (45.5% not at all). Considering complete vape product sales restrictions, equal numbers (~39%) were likely vs. not at all likely to switch to cigarettes. (Emphasis added)

Such an increases would be consistent with the observed effects in San Francisco and analysis showing that e-cigarettes function as a substitute for cigarettes and youth vaping displaces youth smoking.

Non-tobacco flavors are *not necessary* for there to be widespread use of tobacco products. Large numbers of young people have been willing to use products with authentic tobacco flavor over many decades. Just ten years ago, past-30-day combustible tobacco prevalence was 21.8% of high school students, and it has been higher in the past. This implies that the underlying drivers of tobacco and nicotine use are stronger and deeper than the recent availability of non-tobacco flavors in e-liquids.

## 4. Smoking and vaping have deeper underlying causes

It is important to avoid basing policy on weak assumptions about cause and effect. It is true but trivially obvious that flavors do make the products more appealing – and this is one reason they are effective in displacing smoking and positive for public health. However, the reasons that young people choose to smoke or vape are far more complicated than a single product characteristic. For example, Nicksic et al.

<sup>&</sup>lt;sup>9</sup>Levy DT, Warner KE, Cummings KM, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control* 2019;28(6):629–635. [access]

<sup>&</sup>lt;sup>10</sup> Healthy People 2020. Target TU-2.2 Reduce use of cigarettes by adolescents from 19.5% in 2009 to 16 percent in 2020 [access] <sup>11</sup> Gentzke AS, Wang TW, Jamal A, et al. Tobacco Product Use Among Middle and High School Students — United States, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1881–1888. [access] Past-30-day smoking prevalence among high school students.

<sup>12</sup> Kozlowski LT. Minors, moral psychology, and the harm reduction debate: The case of tobacco and nicotine. *J Health Polit Policy Law* 2017;42(6):1099–1112. [access]

<sup>&</sup>lt;sup>13</sup> Jackson SE, Brown J, Jarvis MJ. Dependence on nicotine in US high school students in the context of changing patterns of tobacco product use. *Addiction* 2021;116(7):1859–1870. [access]

<sup>&</sup>lt;sup>14</sup> Polosa R, Russell C, Nitzkin J, Farsalinos KE. A critique of the US Surgeon General's conclusions regarding e-cigarette use among youth and young adults in the United States of America. *Harm Reduct J* 2017;14(1):1–10. [access]

<sup>&</sup>lt;sup>15</sup> National Institute for Health and Care Excellence (UK) British National Formulary for Children: *Smoking cessation* [access] *Nicotine* [access] Accessed August 12, 2021

(2019) examined the reasons given for youth vaping. The authors: 18

...found two overarching factors, "alternative to cigarettes" and "larger social environment", which combine sub-categories to explain main motivators of e-cigarette use

They listed 13 factors influencing e-cigarette adoption, which included a weak effect of flavor appeal but also several harm reduction motivations. Nicksic et al. (2019) report:

Items that loaded highly onto the "alternative to cigarettes" factor for youth and adults included using in places where cigarettes prohibited, less harmful to me and others, help quit smoking, no smell, and more acceptable. The "larger social environment" factor included people in the media use e-cigarettes, people who are important use them, enjoy socializing while using, and appealing advertising.

There is extensive literature on the risk factors for *smoking* initiation that points towards deeper causes than those stated by young people when asked. For instance, Wellman et al. (2016) published a systematic review of risk factors for smoking onset:<sup>19</sup>

Ninety-eight conceptually different potential predictors were identified in 53 studies. An increased risk of smoking onset was consistently (i.e., in four or more studies) associated with increased age/grade, lower SES, poor academic performance, sensation-seeking or rebelliousness, intention to smoke in the future, receptivity to tobacco promotion efforts, susceptibility to smoking, family members' smoking, having friends who smoke, and exposure to films, whereas higher self-esteem and high parental monitoring/supervision of the child appeared to protect against smoking onset.

It is not possible, therefore, simply to attribute the cause of adolescent vaping to flavors or to assume that banning flavors will stop teenagers vaping, smoking, using nicotine, or using another substance. Removing one possible factor (flavors) will not remove the others. The residual drivers will mean that young people will seek out alternative risk behaviors, including smoking, vaping workarounds, the black market, and possibly other substance use. The essence of policy in this area is to understand the way simple-sounding interventions may cause unintended consequences.

# 5. Gateway effects

<sup>&</sup>lt;sup>16</sup> Ambrose BK, Day HR, Rostron B, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *JAMA* [Internet] 2015;314(17):1871–3. [access]

<sup>&</sup>lt;sup>17</sup> Shiffman S., Sembower MA, PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes. Poster SRNT 2017, Pinney Associates [access]

<sup>&</sup>lt;sup>18</sup> Nicksic NE, Snell LM, Barnes AJ. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. *Addict Behav.* 2019 Jun 1;93:93–9. [access]

The underlying causes described above (characteristics of the individual and their circumstances, rather than the products they use) also provide a credible alternative explanation to a gateway effect, namely confounding by common causes or 'common liabilities'<sup>20</sup>. The Bloomberg Philanthropies letter asserts that "youth who use these products are at greater risk of trying cigarettes and becoming smokers." However, that statement is too easily misinterpreted: correlation is not causation. These associations arise because the individuals involved share common characteristics (genetic, behavioral, mental health, family, community) that incline them to both smoking and vaping, not because the vaping caused the smoking.<sup>21 22 23</sup> As discussed earlier, the population trends support the idea that youth vaping *displaces* 

smoking, not that it increases smoking via a gateway effect. The assertion of a gateway effect from vaping to smoking is a persistent misrepresentation by Bloomberg-funded entities.

# 6. Ensuring accurate communications about product risks

Bloomberg Philanthropies raises legitimate concerns about any irresponsible marketing of e-cigarettes and other tobacco products. FDA should be expected to use its powers to ensure that companies act lawfully and responsibly target their marketing at smokers. There are examples of unacceptable commercial practices, but to our knowledge, there is no systematic study of the scale and impact of improper marketing by e-cigarette companies, and many are law-abiding and responsible. It is difficult, therefore, to draw broad conclusions about the extent of this, whether it is ongoing, and to what extent, if any, it is responsible for the rise in youth vaping. Not all teenage substance use is driven by advertising: US 12<sup>th</sup> grade past-30-day cannabis prevalence has consistently been around 20 percent for the past 25 years, <sup>24</sup> but with virtually no advertising. FDA's scientific review process and assessment of whether products are "appropriate for the protection of public health" will add further protections – though it is notable that Bloomberg-funded organizations are trying to circumvent the scientific review process by asserting their campaign goals as 'principles' that FDA should adopt. <sup>25</sup>

While e-cigarette manufacturers fall under FDA and Tobacco Control Act jurisdiction, claims made by tobacco control organizations are protected free speech. But that must not be a license for public interest non-profits to be reckless or irresponsible in their claims. There is widespread misinformation about the risks arising from vaping compared to smoking and that this may be adversely affecting risk perceptions and holding back transitions from high-risk to low-risk products. <sup>26</sup> Four examples follow:

I. Risk communication. The following statement from Bloomberg Philanthropies suggests that the

<sup>&</sup>lt;sup>19</sup> Wellman RJ, Dugas EN, Dutczak H, et al. Predictors of the Onset of Cigarette Smoking: A Systematic Review of Longitudinal Population Based Studies in Youth. *Am. J. Prev. Med.* 2016;51(5):767–778 [access]

<sup>&</sup>lt;sup>20</sup> Vanyukov MM, Tarter RE, Kirillova GP, et al. Common liability to addiction and "gateway hypothesis": Theoretical, empirical and evolutionary perspective. *Drug Alcohol Depend* [Internet] 2012;123:S3–S17. [access]

<sup>&</sup>lt;sup>21</sup> Chan GCK, Stjepanović D, Lim C, et al. Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e cigarette use and future smoking initiation. *Addiction*. 2020;add.15246. [access]

<sup>&</sup>lt;sup>22</sup> Kim S, Selya AS. The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors. *Nicotine Tob Res* 2020; [access]

<sup>&</sup>lt;sup>23</sup> Hall W, Chan G. The "gateway" effect of e-cigarettes may be explained by a genetic liability to risk-taking. *PLOS Med* 2021;18(3): [access]

foundation believes that e-cigarettes are as risky or riskier than traditional cigarettes:<sup>27</sup>

E-cigarette companies have promoted unsubstantiated health claims about their products as healthier than traditional cigarettes, when, in fact, e-cigarettes are uniquely dangerous for kids due to nicotine's impact on their developing brains.

This is not an appropriate risk-communication. That e-cigarettes are much safer than cigarettes is beyond reasonable doubt, even if there is an expert debate about *how much* safer and with what metrics safety should be assessed. E-cigarettes are not "uniquely dangerous" for anyone and there are many substances and behaviors that are considerably more dangerous for adolescents, including cigarette smoking. More than 70,000 Americans died from drug-involved overdoses in 2019, including

illicit drugs and prescription opioids, an approximately doubling in the last ten years.<sup>28</sup> The statement above is misleading and would cause harm if user behavior was guided by it.

II. EVALI. When announcing its campaign to ban e-cigarette flavors, Bloomberg Philanthropies stated:

New initiative launches on heels of 33 states investigating more than 450 cases of lung illnesses associated with vaping, many of which involve teens and young adults.

This refers to what CDC termed "e-cigarette, or vaping, product use-associated lung injury (EVALI)". *EVALI has nothing to do with nicotine vaping* – its cause was a cutting agent, Vitamin E acetate, used in THC vapes that cannot be added to nicotine liquids and would serve no purpose if it could.<sup>29</sup> Many tobacco control organizations have misrepresented the cause of EVALI, and this has led to adverse changes in relative risk perceptions in the United States.<sup>30</sup> It has been used tactically as a misleading basis to call for restrictions on e-cigarettes such as flavor bans at the State level. This confusion persists and little has been done to rectify it.

**III. Vaping and intelligence quotient (IQ).** Mr. Bloomberg stated on national television that vaping causes a lifelong loss of intelligence.<sup>31</sup>

**Michael Bloomberg**: Just think if your kid was doing this and ends up with an IQ ten or fifteen points lower for the rest of his or her life.

**Interviewer:** Is that demonstrated?

Matthew Myers (Campaign for Tobacco-Free Kids): science shows it has a negative impact on

<sup>&</sup>lt;sup>24</sup> Monitoring the Future, 2020 Data from In-School Surveys of 8th-, 10th-, and 12th-Grade Students – data tables [access] Table 3: Trends in 30-Day Prevalence of Use of Various Drugs in Grades 8, 10, and 12 [access]

<sup>&</sup>lt;sup>25</sup> Campaign for Tobacco Free Kids, As E-Cigarette Makers Face Critical September 9 Deadline, Leading Health Groups Urge FDA Not to Allow Sale of Any Flavored Products, August 10, 2020. [access]

Huang J, Feng B, Weaver SR, Pechacek TF, Slovic P, Eriksen MP. Changing Perceptions of Harm of e-Cigarette vs Cigarette Use Among Adults in 2 US National Surveys From 2012 to 2017. *JAMA Netw open* 2019;2(3):e191047. [access]

<sup>&</sup>lt;sup>27</sup> See Bloomberg Philanthropies, *E-cigarettes*, accessed June 30, 2021 [access]

brain development. It's hard to measure those kinds of things.

Mr. Myers corrected Mr. Bloomberg on air because there is no basis for the claim about loss of IQ. The claims made about impaired brain development are contested and, at best, have a weak scientific basis.

**IV. Overstating youth vaping**. In the 30 July 2021 episode of Bloomberg Philanthropies Podcast, *Follow the Data*, the presenter states at 5:43:<sup>32</sup>

...if we look at some of the statistics, last year, in 2020, almost 39% of high school students and 20% of middle school students, were frequent users of e-cigarettes.

This is not true. Those percentages refer to the proportion of *e-cigarette users* who were frequent users, not all students. The correct figures would be 8% and 1.1% for high school and middle school student

respectively. Also, for more truthful context, most of these frequent users are past or current smokers.<sup>33</sup> These young people may well be benefiting from vaping instead of smoking.

At this stage, it has not been possible to conduct a more complete audit of misleading or exaggerated claims made by tobacco control groups, including Bloomberg Philanthropies and its partners, but this appears to be a significant problem in misshaping risk perceptions and misdirecting informed consumer choice. In acting in the public interest, Bloomberg Philanthropies and its partners should uphold the highest standards of truthfulness in communications.

Finally, it is essential to keep in mind that cigarettes and other combustible nicotine products are ubiquitously available, far more harmful, and still used by one in ten (9.4 percent) high school students.<sup>34</sup> Smoking remains the dominant youth tobacco and nicotine use problem.

## 7. Adult vaping as a harm reduction strategy

The discussion above concentrates on Bloomberg Philanthropies' focus on *teenage vaping* and unintended consequences arising from flavor bans, notably to *adolescent smokers*. But the foundation should give more intensive consideration to the welfare of *adult smokers*. Adult smokers, on average, are more likely to suffer various forms of social and economic disadvantage, and adult smoking is a significant driver of health disparities.<sup>35</sup> Adult smokers in middle age or older constitute the sub population at most immediate risk of serious diseases and premature death. They are the population

<sup>&</sup>lt;sup>28</sup> NIDA, Overdose death rates (1999-2019), accessed August 10, 2021 [access]. NIDA reports 4,777 overdose deaths in 15-24 year-olds [access], but these statistics are incomplete.

<sup>&</sup>lt;sup>29</sup> Bates C. The outbreak of lung injuries often known as "EVALI" was nothing to do with nicotine vaping. *Qeios* 2021 [access] <sup>30</sup> Dave D, Dench D, Kenkel D, Mathios A, Wang H. News that takes your breath away: risk perceptions during an outbreak of vaping-related lung injuries. *J Risk Uncertain* 2020;60(3):281–307. [access]

<sup>&</sup>lt;sup>31</sup> CBS This Morning, Michael Bloomberg Blames FDA for teen vaping epidemic, 10 September 2019 (at 3:18) [video]

<sup>&</sup>lt;sup>32</sup> Bloomberg Philanthropies, Follow the data podcast, July 31, 2021 [access]

that benefits most immediately and substantially from *smoking* cessation. A recent evidence paper from the Tobacco Treatment Network of the Society for Research on Nicotine and Tobacco endorsed harm reduction approaches and argued for focus on reducing the use of *combustible* tobacco.<sup>36</sup>

Strategies used for combustible product cessation may be adapted for novel products, and treatment recommendations for [tobacco use disorder] should be made within the context of a harm reduction framework wherein alternative product use may be the desired outcome.

It is incorrect to assert that the diversity of flavors is targeted at youth or that youth use "is overwhelmingly dominated by child-friendly flavors" unless circular logic is employed. Bloomberg funded groups like the Campaign for Tobacco-Free Kids started by referring to flavors like 'Gummy Bear' and 'Cotton Candy' as child-friendly.<sup>37</sup> However, they later redefined child-friendly to include fruit, dessert, and other flavors widely used by adults. This occurred following sharp growth in the sale of Juul products, which had age-neutral flavor descriptors like menthol, mint, mango, cucumber, or crème.

Adult smokers are by far the largest market for these products, and flavors are integral to the experience for smokers.<sup>38</sup> Surveys suggest that adults like dessert, fruit, and candy flavors more than tobacco flavors.<sup>39</sup>

The use of e-cigarette flavors also predicts for adult smoking cessation<sup>40 41</sup> and Li et al (2021) concluded "Use of fruit and other sweet-flavored e-liquids is positively related to smokers' transition away from cigarettes."<sup>42</sup> There is also compelling evidence that the rise of Juul in the United States was very effective in helping adults to switch completely away from cigarettes.<sup>43</sup>

There is now an abundance of evidence that smoke-free products such as e-cigarettes displace smoking for adults, and modeling suggests very substantial overall public health gains arising from the introduction of vaping products. Levy et al. (2021) conclude:<sup>44</sup>

The [smoking and vaping model] projects that under current patterns of US NVP [nicotine vaping product] use and substitution, NVP use will translate into 1.8 million premature smoking- and vaping-attributable deaths avoided and 38.9 million life-years gained between 2013 and 2060.

Mendez and Warner (2020) ran models with multiple combinations of assumptions coded into 360 scenarios, with conclusions that highlight synergies with MPOWER-based tobacco control:<sup>45</sup>

<sup>&</sup>lt;sup>33</sup> Jarvis M, Jackson S, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey 2017-2019 reveal about high school e-cigarette use in the USA? *Qeios* 2020 [access]

<sup>&</sup>lt;sup>34</sup> Gentzke AS, Wang TW, Jamal A, et al. Tobacco Product Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1881–1888. [access]

<sup>&</sup>lt;sup>35</sup> CDC, Current cigarette smoking among adults in the United States [access] and Tobacco-related disparities [access]

<sup>&</sup>lt;sup>36</sup> Palmer AM, Toll BA, Carpenter MJ, et al. Reappraising Choice in Addiction: Novel Conceptualizations and Treatments for Tobacco Use Disorder. *Nicotine Tob Res* 2021 [access]

<sup>&</sup>lt;sup>37</sup> See, for example: Campaign for Tobacco Free Kids, The Flavor Trap, March 17, 2017. [access]

The combination of assumptions produces 360 possible scenarios. 357 (99%) yield positive estimates of life-years saved (LYS) due to vaping by 2100, from 143 000 to 65 million. Most scenarios result in millions of individuals quitting smoking due to vaping.

Vaping is highly likely to reduce smoking-produced mortality. Still, vaping is not "the" answer to the public health crisis created by smoking. Rather, it may well be a tool to add to the armamentarium of effective tobacco control measures.

Such models are illustrative, but they do show very significant public health benefits and, therefore, great potential harms if these benefits are put at risk by well-intentioned but ultimately harmful policy interventions. Our confidence in tobacco harm reduction comes from multiple sources: clinical trials, observational studies, population data trends, market data and stock analyst insights, economic analyses and natural experiments, and thousands of user testimonies. A foundation spending heavily on tobacco control advocacy has a responsibility to assess the impact of its proposed measures on *adult smoking* and to be clear about what detriment to adult health it considers to be worthwhile to justify the claimed (though contested) benefits to adolescent health.

9

# **8.** Medicalization of e-cigarettes may due may do more harm than good The Bloomberg Philanthropies response letter states:

Our course of action is driven by the belief that neither adults nor youth are well served by the current situation where products that appeal to youth are widely available, minimally regulated, and e-cigarette manufacturers have little incentive to produce products that both minimize the potential for youth abuse and are effective at helping smokers quit. The efforts we have

<sup>&</sup>lt;sup>38</sup> Gravely 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. [access]

<sup>&</sup>lt;sup>39</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* 2018;15(1):33. [link]

<sup>&</sup>lt;sup>40</sup> Jones DM, Ashley DL, Weaver SR, Eriksen MP. Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016-2017. *Tob Regul Sci* 2019;5(6):518–531. [access]

<sup>&</sup>lt;sup>41</sup> Friedman AS, Xu S. Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation. *JAMA Netw Open* 2020;3(6):203826. Available from: https://jamanetwork.com/

<sup>&</sup>lt;sup>42</sup> Li L, Borland R, Cummings KM, et al. How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys. *Nicotine Tob Res* [Internet] 2021 [cited 2021 Jul 4]; Available from: https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/ntab033/6149939

<sup>&</sup>lt;sup>43</sup> Prakash S, Xu Y, Goldenson NI, Wissmann R, Gougelet R, Shiffman S. Transitions in smoking among adults newly purchasing the JUUL system. *Am J Health Behav* 2021;45(5):546–562. [access]

Levy DT, Tam J, Sanchez-Romero LM, et al. Public health implications of vaping in the USA: the smoking and vaping simulation model. *Popul Health Metr* 2021;19(1):19. [access]

<sup>&</sup>lt;sup>45</sup> Mendez D, Warner KE. A Magic Bullet? The Potential Impact of E-Cigarettes on the Toll of Cigarette Smoking. *Nicotine Tob Res* 2020 [access]

supported have sought to encourage the FDA Center for Drug Evaluation and research (CDER) to support innovation to help more smokers quit and to create a regulatory environment that encourages and facilitates responsible companies' efforts to develop new, more effective tobacco cessation medications and tools.

There is a good case to extend the range of CDER-approved smoking cessation products, in particular to help build confidence in the health care sector. This was envisaged in FDA's 2017 nicotine strategy, <sup>46</sup> but progress has been slow. However, this should not be at the expense of products that compete directly with cigarettes, which are available as consumer products. An exclusive focus on CDER-approved products misunderstands the way vaping products displace smoking for most adults (and for adolescent smokers). They are a consumer alternative to cigarettes with many of the same attributes but much lower risk. <sup>47</sup> They do not function for most users in the same way as smoking cessation medications, which, while efficacious in RCTs, have not had much success at the population level, and by some accounts are unlikely to contribute to significant progress going forward. <sup>48</sup> The problem with the medical model proposed in the Bloomberg response is that it may make the products *less* appealing to smokers as alternatives to smoking while requiring them to want to quit, admit that they need medical help, and commit to quit abruptly and completely. While quitting rates with NRT decline over time, there is some evidence that smoking to vaping switching rates *increase* over time as users transition from dual use to complete switching. <sup>49</sup>

Adoption of lower-risk noncombustible products is driven by a different mindset for most smokers, and many report eventually switching completely even if they did not have the initial intention to quit – so called accidental guitters. According to Notley and colleagues;<sup>50</sup>

Our data demonstrates that e-cigarettes may be a unique harm reduction innovation for smoking relapse prevention. E-cigarettes meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related aspects of tobacco addiction. Some vapers reported that they found vaping pleasurable and enjoyable—being more than a substitute but actually preferred, over time, to tobacco smoking. This clearly suggests that vaping is a viable long-term substitute for smoking, with substantial implications for tobacco harm reduction.

A move to mandatory medicalization of these products would have the unintended effect of protecting the cigarette trade by removing a satisfying alternative and direct competitor to cigarettes from the

<sup>&</sup>lt;sup>46</sup> FDA, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, July 27, 2017 [access] <sup>47</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)* 2018;117:88–97. [access]

<sup>&</sup>lt;sup>48</sup> Rosen LJ, Galili T, Kott J, Rees V. Beyond "Safe and Effective": The urgent need for high-impact smoking cessation medications. *Prev Med* 2021 (May):106567. [access]

<sup>&</sup>lt;sup>49</sup> Selya AS, Shiffman S, Greenberg M, Augustson EM. Dual use of cigarettes and JUUL: Trajectory and cigarette consumption. *Am J Health Behav* 2021;45(5):464–485. [access]

consumer market. It is hard to imagine any adults would feel "well-served" by the measures advocated by Bloomberg-funded partners. These all involve unwanted barriers, restrictions, costs, and inconvenience applied to their chosen way to leave smoking behind and there is no visible support for Bloomberg's approach in the communities of users or people at risk. Without exception, consumer organizations oppose Bloomberg-funded campaigns.

**9.** A balanced approach to youth vaping and smoking will be more effective Intervention in tobacco and tobacco harm reduction necessarily involves trade-offs – between adults and adolescents, between smokers or would-be smokers and people who would never use nicotine, and between adolescents who would be likely to smoke and those who would never use nicotine. A combination of age restrictions, technology to enforce age restrictions, positioning new products as adult harm-reduction options for older smokers, credible educational information without sensationalizing new products, and controls on marketing – including on branding and packaging imagery targeted at young people would be appropriate in striking a sound balance.

A flavor can be viewed in three ways: (1) a recipe of chemical compounds; (2) a subjective sensory experience; or (3) as a descriptor – a name describing the product. There is a clear case to control the use of chemical compounds that are hazardous or potentially hazardous to health. There is also a good case to control marketing and branding, including flavor descriptors, that have a deliberate childish appeal. However, the elimination of almost all flavor sensations (for example, everything but tobacco or menthol flavors) would fatally degrade the essence of the product, of which flavors are significant element. That would be a blunt instrument, a quasi-prohibition that would make the product less appealing for *everyone* regardless of age, smoking status, and vulnerability to serious disease. It would constitute a protection of the incumbent cigarette trade and drive unintended perverse consequences.

# 10. Prohibition of vaping products

The Bloomberg Philanthropies response letter claims: "we are not calling for policies to prohibit the marketing of all e-cigarettes." However, when interviewed by the New York Times as part of his Presidential primary campaign, Mr. Bloomberg explicitly called for the prohibition of vaping:<sup>51</sup>

**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.

Whatever the stated aims of Bloomberg Philanthropies, the clear preference of the founder will not be lost on those seeking to gain or retain funding from the foundation. In reality, a comprehensive ban on flavors is a partial prohibition where full prohibition is not possible.

Notley C, Ward E, Dawkins L, Holland R. The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention. *Harm Reduct J 2018 151* 2018];15(1):1–12. [access] News release: How vaping helps even hardened smokers quit [access]

In fact, Bloomberg Philanthropies' promotion of prohibition of much safer alternatives to smoking covers most of the world's smokers. Key Bloomberg-funded partners such as The Union (International Union Against Tuberculosis and Lung Disease)<sup>52</sup> have been assertive in calling for the prohibition of e cigarettes and heated tobacco products in low- and middle-income countries (LMICs). The Union policy statement *Where bans are best: Why LMICs must prohibit e-cigarettes and heated tobacco product sales to truly tackle tobacco*,<sup>53</sup> uses just over 1,000 words under ten headings to set out its case for prohibition. It does not address any potential unintended consequences or trade-offs – it is a wholly inadequate basis for this policy, even though the overwhelming majority (approximately 800 million) of the world's <u>smokers</u> live in LMICs. On what basis does it make sense to deny any smoker access to products that have much lower risks when smoking products are pervasively available? What are the consequences for black markets, corruption, unsafe and unregulated products, and the maintenance of smoking within and between generations? Is there any analysis at all to support e-cigarette prohibitions despite the compelling counterarguments?<sup>54</sup>

# 11. Prohibition of vaping products: the case of India

In September 2019, the federal government of India banned e-cigarettes outright while leaving cigarettes, bidis, and other dangerous tobacco products widely available to India's young people and current 100 million smokers.<sup>55</sup> The Union, a major Bloomberg partner, strongly supported the ban and celebrated its own involvement in securing the prohibition:<sup>56</sup>

The Union and partners began collaborating with Indian Ministries of Health at the national and state levels in 2013 to support the formulation of an e-cigarette position, based on evidence of the products' impact on health. With Union support, fifteen states banned e-cigarettes at the state level, successfully resisting pressure from the tobacco industry and its front groups, leading central government to implement the national ban.

12

Such a prohibition protects India's partly state-owned cigarette producer and has the potential to reduce smokers switching to vaping and other noncombustible alternatives, increase vapers relapsing to smoking, add to India's burden of tobacco-related disease, and create the excessive or corrupt criminal justice responses that are associated with prohibitions. There is well-argued criticism of India's

<sup>&</sup>lt;sup>51</sup> Michael Bloomberg, Candidates Up Close: Should Vaping products Be Legal? New York Times (video interview), 25 January 2020. [access]

The Union is an implementing partner in the Bloomberg Initiative to Reduce Tobacco Use [access] [access via The Union] and the \$20 million STOP initiative [access] The Union co-manages a major tobacco control grants program funded by Bloomberg Philanthropies and has been active in India since 2005.

<sup>&</sup>lt;sup>53</sup> The Union, Where bans are best: Why LMICs must prohibit e-cigarettes and heated tobacco product sales to truly tackle tobacco'. 20 May 2020. [access].

<sup>&</sup>lt;sup>54</sup> INNCO, Why Bans of Low-Risk Nicotine Alternatives to Smoking in Low- and Middle-Income Countries (LMICs) Will Do More Harm Than Good. 16 March 2021 [access][PDF]

<sup>&</sup>lt;sup>55</sup> Chakma JK, Kumar H, Bhargava S, Khanna T. The e-cigarettes ban in India: an important public health decision. Lancet Public Heal. 2020;5(8):e426. [access]

<sup>&</sup>lt;sup>56</sup> The Union, Press release: The Union congratulates India for protecting non-smokers and youth by passing the Prohibition of of Electronic Cigarettes Act 2019, 11 December 2019 [access]

Bloomberg-backed policy, plausibly suggesting that it will do more harm than good. 57 58

# 12. Philanthropic governance and accountability

Bloomberg Philanthropies states that it has spent over \$1.1 billion on tobacco control in the past decade, working with a global network of partners and active in 110 countries, including China and India, which account for 40% of the world's smokers. By any standards, this is a very large intervention in public health advocacy. While much of this work may be beneficial, what happens if Bloomberg Philanthropies makes policy errors that work against the public interest? If it does make such errors, how does it correct them quickly? In short, what is the governance and accountability for the public interest behind this flow of philanthropic money? How does the foundation respond to informed critics with concerns that it may be doing more harm than good? What happens when Bloomberg-funded partners start using unscientific or unethical arguments in their advocacy? How does the foundation reassess its \$160m campaign to ban flavored e-liquids if evidence emerges that an e-liquid flavor ban has been harmful to public health, as discussed above in the case of San Francisco? What role did Bloomberg funds and partners play in India's prohibition decision, and what assessment has been made of the likely intended and unintended consequences of this prohibition? Is there any analysis that supports the prohibition?

These are not academic or theoretical questions: these policy decisions have real-world consequences manifest in deaths and disease. That means advocacy in this field demands robust governance.

# 13. Transparency

Bloomberg Philanthropies is a very large funder in tobacco policy, yet it provides limited transparency about who it is funding and by how much, both directly and indirectly through intermediaries. Though Bloomberg Philanthropies has a website for searching tobacco control grants, <sup>60</sup> this only details past grants that are now complete. It covers only a limited subset of the philanthropic funds spent on tobacco control and no longer discloses the dollar amounts of funding, even for past grants. It does not

13

detail *current* grants to its partners in LMICs. It does not disclose funding of major organizations listed as partners, including but not limited to the Campaign for Tobacco-Free Kids, the CDC Foundation, The Union, Johns Hopkins Bloomberg School of Public Health, the University of Illinois at Chicago, Vital Strategies, and the World Health Organization (and previously the World Bank). Bloomberg funds passed through to third parties via groups like the Campaign for Tobacco-Free Kids, The Union, Vital Strategies, or the University of Bath are not routinely disclosed.

Leaked documents suggest extensive lobbying activity in LMICs through Bloomberg-funded entities that

<sup>&</sup>lt;sup>57</sup> Anumpan Manur, Why e-cigarette ban in India will do more harm than good. Business Today India, 20 May 2021, updated 25 June 2021, accessed 30 June 2021 [access]

<sup>&</sup>lt;sup>58</sup> Alex Norcia, The unfolding tragedy of India's vape prohibition. *Filter*, 22 October 2020 [access]

<sup>&</sup>lt;sup>59</sup> Bloomberg Philanthropies, Reducing Tobacco Use, web page [access], accessed 30 June 2021.

<sup>&</sup>lt;sup>60</sup> Bloomberg Philanthropies, Tobacco Control Grants. [access] accessed 1 July 2021.

appear to be civil society organizations but ultimately represent Bloomberg interests.<sup>61</sup> There is also evidence of opaque interactions with government agencies, for example in the Philippines.<sup>62 63 64</sup> It has not been possible to locate any systematic disclosure of the organizations funded directly or indirectly by Bloomberg Philanthropies for advocacy or research in the United States, or by how much.

In short, Bloomberg Philanthropies does not enable interested stakeholders to "follow the money" and does not insist that those in ultimate receipt of Bloomberg funds (either directly or via an intermediary) disclose their status as beneficiaries. A substantial funder like Bloomberg Philanthropies working in a contested and controversial field should be highly transparent, but at present, it does not meet legitimate expectations.

#### 14. Conflicts of interest

The International Committee of Medical Journal Editors defines conflict of interest:65

The potential for conflict of interest and bias exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain).

Though aimed at academic publishing, this definition is more broadly applicable. Given that Bloomberg Philanthropies and its founder take strong policy positions – for example, hostility to tobacco harm reduction, bans on flavored e-cigarette products, and support for the prohibition of e-cigarettes – receipt or anticipation of funding from Bloomberg Philanthropies creates secondary financial interests, and a material conflict to the primary interest in public health and public interest. These conflicts are rarely disclosed or even recognized, yet they should be visible to politicians, officials, media, journals, and other organizations with whom Bloomberg grantees interact. Many Bloomberg-funded organizations are described as 'civil society', for example by the World Health Organization, but they do not have deep roots in their own civil society and could equally be characterized as proxies for their American funders. Legitimate stakeholders need to be able to determine which description is apposite.

# 15. The World Health Organization and the FCTC

Interest. Accessed July 1, 2021. [access]

The WHO Framework Convention on Tobacco Control includes harm reduction within its definition of tobacco control and focuses on improving population health.<sup>66</sup> Tobacco harm reduction is supported by many experienced experts in tobacco science and policy.<sup>67</sup> The MPOWER approach pioneered by Bloomberg and now adopted by the World Health Organization has attracted widespread support.<sup>68</sup> However, harm reduction should not be seen as an alternative to MPOWER or in competition with

Minton M, Exposed: Bloomberg's Anti-Tobacco Meddling in Developing Countries, Competitive Enterprise Institute, June 15, 2021. [access] <sup>62</sup> Minton M, Bloomberg's Philanthro-Colonialism: A Threat to Global Health and Science, Inside Sources, February 2, 2021 [access] <sup>63</sup> Manila Bulletin, FDA [Philippines] receiving foreign money 'shameful and scandalous' — vaping groups, October 27, 2020 [access] <sup>64</sup> Inquirer.net, FDA [Philippines] admits hiring people to draft regulations on vapes using anti-tobacco money, March 19, 2021 [access] <sup>65</sup> International Committee of Medical Journal Editors, Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of

traditional tobacco control measures. Tobacco harm reduction increases the range of pathways available to smokers in response to the MPOWER measures. However, both Bloomberg Philanthropies and the World Health Organization have adopted a hostile approach. Significant WHO reports funded and supported by Bloomberg partners have taken a confrontational approach to tobacco harm reduction, inaccurately positioning it as a Big Tobacco tactic.<sup>69</sup> There are concerns that Bloomberg and other private entities have had an excessive influence on WHO with poor accountability for its public interest impact.<sup>70</sup> WHO has now adopted a prohibitionist approach to tobacco harm reduction. For example, it gave a World No Tobacco Day special award to Dr. Harsh Vardhan, India's Minister for Health and Family Welfare, "for spearheading the Government of India's legislation to ban e-cigarettes and heated tobacco products in 2019" – a position promoted by Bloomberg Philanthropies' partner, The Union.

An alternative approach would enhance MPOWER to embrace the concept of tobacco harm reduction<sup>71</sup> and to use this synergy to pursue the public health objectives of the FCTC. This could underpin a strategy to meet the demanding SDG objectives on non-communicable diseases, which require an enhanced rate of adult smoking cessation to deliver results inn NCD mortality by 2030. It is an approach that Mr. Bloomberg is well-placed to champion and lead in his capacity WHO Global Ambassador for Noncommunicable Diseases and Injuries.

# 16. The WHO report on the global tobacco epidemic 2021

The recent WHO report on the global tobacco epidemic 2021, focusses on "addressing new and emerging products".<sup>72</sup> The report sees these new and emerging products as only a threat and never an opportunity. The report was not produced independently or at arm's length to the funder. The acknowledgments to the report (page 207) show extensive and selective involvement of a range of academics and activists that oppose tobacco harm reduction, including Bloomberg-funded Vital Strategies, the University of Bath, the Campaign for Tobacco-Free Kids, and the Bloomberg Initiative to

15

Reduce Tobacco Use. The extent of Bloomberg funding of others involved is not clear, nor are the criteria for selecting advisers and analysts to work on the report. There does not appear to have been an open process for engaging expertise or soliciting broader perspectives. Given Bloomberg Philanthropies funding and the extensive involvement of its partners in the production of the report, few dispassionate observers are likely to accept the disclaimer: "The contents of this document are the sole responsibility of

<sup>66</sup> FCTC 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 [access]

<sup>&</sup>lt;sup>67</sup> Comments on vaping and tobacco harm reduction from expert stakeholders, 31 May 2021 [access]

<sup>&</sup>lt;sup>68</sup> WHO Tobacco Free Initiative, MPOWER, [access] accessed 30 June 2021.

<sup>&</sup>lt;sup>69</sup> World Health Organisation, WHO report on the global tobacco epidemic 2019: offer help to quit tobacco use, July 2019. [access] <sup>70</sup> Mukaigawara M, Winters J, Fernandes G, Sridhar D. Balancing science and political economy: Tobacco control and global health. *Wellcome Open Res* 2018;3. [access].

<sup>&</sup>lt;sup>71</sup> See for example, proposals by Scott Ballin, Is it time for the WHO to Upgrade and Redefine its MPOWER Program? Nicotine Science & Policy, 27 October 2015. [access]

<sup>&</sup>lt;sup>72</sup> World Health Organisation, WHO report on the global tobacco epidemic 2021: addressing new and emerging products, July 2021. [access]

WHO and should not be regarded as reflecting the position of Bloomberg Philanthropies." It is unlikely Bloomberg-funded entities would accept a similar disclaimer in relation to industry funding and support.

Many of the issues raised in this briefing also apply to main themes of the 2021 report. These include: failures to recognize large differences in risk between combustible and non-combustible products; repeated suggestions that e-cigarettes may be as dangerous as cigarettes; misleading claims for gateway effects combined with confusion over correlation and causation; misleading references to EVALI, which is nothing to do with nicotine vaping; overlooking multiple strands of evidence suggesting vaping is effective for smoking cessation and displaces smoking and the population level; undue focus on relatively minor and distant risks to adolescents at the expense of immediate and substantial risks to adults; no consideration of young people with a propensity to smoke or engage in risk behaviors; positioning of tobacco harm reduction as "industry interference" when it is a legitimate public health strategy with a high level of expert support; support for prohibitions and other disproportionate measures against ENDS with no consideration of impact on smoking or other unintended consequences; and no sense of opportunities to use harm reduction to enhance MPOWER, only ways to use MPOWER to suppress harm reduction. The report is not a reliable guide for LMIC policymakers.

More detailed reviews of this publication are sure to follow, but one commentary by an experienced industry analyst suggested that the level of misinformation was now comparable or worse than the tactics of the tobacco industry in the past. In a post titled *Bloomberg Philanthropies - Taking Tobacco Tactics to the Next Level*, the Pieter Vorster of Idwala Research argues that the report:<sup>73</sup>

...lays bare the significant and inappropriate influence exercised by Bloomberg Philanthropies over WHO policy. The report is undeniably biased and reminiscent of tactics and pseudo-science employed by the US tobacco industry after the formation of the Tobacco Industry Research Committee in 1954, albeit worse because of the abuse of the public trust that the WHO is endowed with.

#### 17. Conclusion

Given the lives at stake, it is likely that today's advocacy will come under scrutiny in future and will be the subject of more empirical assessment. In this discussion document, it is argued that some aspects of Bloomberg Philanthropies' tobacco control program may now be doing more harm than good, and this should at least be a subject for further analysis and discussion. A philanthropic organization should be responsive to constructive expert criticism and be ready to change or moderate its approach in the light of new evidence or legitimate concern about the unintended consequences of its activities.

<sup>73</sup> Vorster P. Bloomberg Philanthropies - Taking Tobacco Tactics to the Next Level, Idwala Research August 9, 2021 [access]