Foundation for a smoke-free world

Derek Yach

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Correspondence to:
Derek Yach, Foundation for a Smoke-Free World, 205 Wakeman Lane, Southport, CT 06890, USA
derek.yach@smoke-freeworld.org

The current and future health effects of smoking are well described. More than 7 million deaths per year are attributable to smoking, and projections suggest 1 billion deaths this century.[1] Over a decade ago, in my role to facilitate the establishment of WHO's Framework Convention on Tobacco Control (FCTC), I warned about the potential for complacency in the years following the FCTC's adoption.[2] We knew that implementation of the FCTC would take decades, and that it would be challenged from the outset by constrained funding, shifting priorities and political will, weak human and institutional capacity, and continuing opposition from the tobacco industry.

Progress has certainly been made in implementing key provisions of the FCTC, as outlined in the 2017 WHO report on the global tobacco epidemic.[1] Bloomberg Philanthropies and the Bill & Melinda Gates Foundation have allocated critical funding to many operational aspects of the FCTC and, crucially, continue to do so. Nonetheless, the capacity of developing countries remains threatened by the growing health and financial burden associated with behavioural risk factors contributing to non-communicable diseases.[3] Furthermore, many of the most effective interventions, including increasing the price of tobacco products, are experiencing slow adoption.[1] Reasonably effective tax policies cover less than 10% of the global population.[4]

It takes decades before the full impact of smoking on death and disease becomes apparent. Supporting smokers in quitting or switching to reduced risk products is the most effective way to rapidly reduce the death rate in the next 20–30 years.[5] I believe that progress in this regard is lagging.[6] Available cessation interventions rarely exceed 10% success rates at 1 year, and the US Surgeon General's recent remarks about slow rates of progress in the USA apply globally.[7]

I believe this is the time to raise our ambition for what is possible and desirable in tobacco control, and specifically in harm reduction from smoking, for four reasons.

First, reduced risk products are more readily available, and there is a growing body of research on the extent to which they could cut future deaths and disease. Millions of people now use these products, including snus in Sweden and Norway; e-cigarettes in the UK, the European Union, and the USA; and heat-not-burn products in Japan.[8–10] For each of these products, there is emerging evidence of the health benefits relative to continued smoking. For e-cigarettes (vaping) in particular, there is emerging evidence from the UK and the USA that increases in use are helping some smokers to switch and to quit, and that these products are not directly associated with daily cigarette smoking among youth.[11,12] It will be crucial to conduct independent, unbiased, and replicable research to fully assess the risk profiles of these products and their potential role in harm reduction.

Second, the value of harm reduction as an integral part of global tobacco control is gaining acceptance. Harm reduction was included in the very definition of tobacco control in the preamble to the main FCTC text.[13] In 1998, we were impressed with the role that harm reduction was playing in reducing the burden of disease caused by HIV/AIDS, illicit drug use, and other complex areas of public health where a continuum of risk exists.[14] At that time, WHO remained cautious about its role in tobacco control, given the weakness of the underlying science. Presentations to us at WHO by tobacco industry researchers in 1999 were more heavily focused on public relations than on the verifiable evidence. Shortly after leaving WHO, I suggested that harm reduction could one day represent a new frontier for accelerated progress.[15] That day has come.

The Director of the US Food & Drug Administration (FDA), Scott Gottlieb, recently provided the most explicit statement by a major national health officer about the role that reduced risk products, combined with regulating nicotine, could have on reducing the effect of smoking on health. Gottlieb noted that: "Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year. The FDA's approach to reducing the devastating toll of

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Derek Yach

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tobacco use must be rooted in this foundational understanding: other chemical compounds in tobacco, and in the smoke created by combustion, are primarily to blame for such health harms."[16] This shift in FDA policy represents the most significant move since the basic tobacco control formula was developed in the 1970s. At last the focus is shifting to the product. FDA's call for better regulatory science and the need for verification of early progress demands investment and action in all countries.[16]

For more on the **Cochrane Tobacco Addiction Group** see http://tobacco.cochrane.org/

Third, leading multinational tobacco companies have increased investment in research and development to change the deadly century-old legacy cigarette. Even though the industry has known for decades that people "smoke for the nicotine, but die from the tar," it is only recently that tobacco companies have acted on this knowledge. New products are now being developed to lower exposures to known risks to health, which are in large part due to consumer and public health demand for new innovations that reduce risk. Long neglected areas of research are gaining traction, and internal industry investments are being made to reduce the health risks associated with cigarettes.[17]

The tobacco industry is just starting on the same path that other so-called dirty industries, such as energy and transport, have been on for many years. Many companies in these industries have been investing in research and development and corporate transformation to respond to investors' and consumers'—especially millennials—demands that they better align their products and services with social, health, and environmental goals. This is the concept of so-called shared value that Michael Porter and Mark Kramer have crystallised in their work at Harvard Business School (Boston, MA, USA).[18,19] The tobacco industry's future survival will depend on transforming itself in this way.

Fourth, smokers are responding positively to these marketplace changes. At WHO, we tried to avoid stigmatising smokers, though we rarely tried empathising with them and with their struggles to quit smoking. Our focus then—as it likely is now—was on implementing government-led, population-wide regulatory policies. That remains the cornerstone of sound policy, but we also need complementary actions that reach smokers with their preferred products and solutions. That is the niche filled by the variety of new reduced risk products.

These converging interests—corporate, consumer, and public health—create the potential to accelerate progress and challenge projections that there will be still 1 billion smokers a decade or two from now. The Foundation for a Smoke-Free World supports and endorses implementation of all elements of the FCTC, and aims to complement and add to the efforts led by WHO and supported by global philanthropies. The mission of the Foundation is to accelerate global efforts to reduce deaths and harm from smoking. Our ultimate vision is to eliminate cigarette smoking worldwide, and to mobilise support for people who are disproportionately burdened by the rapid transition away from smoking, starting with smallholder tobacco farmers in low-income and middle-income countries.

The FDA and the Cochrane Tobacco Addiction Group (CTAG) have outlined research priorities to accelerate the end of smoking. The CTAG spotlights the need for research that assesses the positive and potential downsides of reduced risk products, gives greater attention to interventions that will reduce inequalities in smoking, investigates new and innovative ways to promote cessation and switching to reduced risk products, and designs programmes to reach people with chronic diseases, including mental health problems.

As with many earlier research priority processes, the unanswered question is who will fund such work at sufficient levels and with the sense of urgency needed by regulators and smokers alike? The Foundation for a Smoke-Free World aims to partly fill that void. Its research priorities, focused on smoking harm reduction and smoking cessation, will be informed by the FDA, WHO, and the CTAG, and will be developed in consultation with the tobacco control community in an open and transparent manner.

The Foundation will also tackle an area of deep neglect: helping tobacco farmers in low-income and middle-income countries to create alternative livelihoods. Smoke-free tobacco products require less tobacco, and tobacco-free products of course require none. As the demand for tobacco decreases in the future, these

farmers will need help to transition to alternative crops and livelihoods.

The Foundation will also independently and objectively monitor and report on industry actions, including where these are obstructive to FCTC implementation efforts. The recent WHO report[1] provides some examples of tobacco industry interference, as does a recent investigation by Reuters.[20] The Foundation will consider how to develop a more rigorous and systematic way of doing this across all companies, and in doing so build on the work of the Access to Nutrition Index and the Access to Medicine Index.

The Foundation aims to work with those who are committed to a bolder science agenda and to strengthening the human and institutional capacity needed to drive future policy, especially in developing countries. Funding for tobacco control research in the USA has increased recently, but remains almost non-existent elsewhere. The Foundation hopes to develop a future cadre of tobacco control researchers able to straddle many fields such as systems biology and exposure assessment, behavioural economics, regulatory science, and epidemiology. My past work with the National Institutes of Health's (NIH) Fogarty Center and Canada's International Development Research Centre (IDRC) showed how modest funding can have disproportionately large impact.[21] Now is the time to take this to scale.[14,16,22]

The Foundation will initially be funded by Philip Morris International through an un-earmarked grant of US$80 million a year for at least 12 years. Many will ask how the Foundation's funding source will influence its operations, and whether it will undermine many policies that restrict researchers of being funded by and working with tobacco companies. In 2009, a group of tobacco control colleagues led by Johanna Cohen and Mitch Zeller published the outcome of a major consultation on this topic.[23] They set out eight criteria for researchers to consider before accepting research funding from the tobacco industry. They also laid out options for how this funding could be structured, with one being the development of a third-party entity such as an independent foundation.

The Foundation for a Smoke-Free World's Certificate of Incorporation and its Bylaws have taken Cohen and Zeller's criteria into account and build on them in many ways. Some include the following: The Board will have no tobacco industry representation; research topics will be developed transparently and with input from the broader research community; research institutions will be selected using a peer reviewed and competitive process; all results of research, including raw data, will be placed in the public domain and re-analysis will be encouraged; and after the Foundation is launched, Philip Morris International and other industry partners may not cite the existence of the Foundation or its work as part of their public relations or reputation programmes. Moreover, the Foundation will soon launch a transparent process to seek more input into how it can further ensure the independence of its governance, strategy, and activities.[24] The goals and objectives of the Foundation are squarely in line with the FCTC and Article 5.3, even though as a non-state actor we are not a signatory and do not fall into the categories mentioned in Article 5.3.[20] Our goal is not to "interfere in public policy," but rather to research, collaborate, build consensus and support a mix of initiatives that the evidence base demonstrates will most rapidly and effectively eliminate harm and deaths from smoking around the world.[20]

Our intent is to fund and support outstanding scientists and research, and then convene and support consensus-building on the policy implications of the science. The Foundation will not—and is not allowed to by law—engage in lobbying activities.

Many will also ask why Philip Morris International is allocating nearly US$1 billion over 12 years for a Foundation they do not seek to influence. Is this another giant ruse by the tobacco industry? For answers to these questions, I suggest readers study recent statements on Philip Morris International's website. In particular, Philip Morris International has committed to making cigarettes obsolete and is working to internally shift resource allocations and external engagements toward this goal. Independent, unbiased research on the harm reduction potential of alternatives to cigarettes can both inform their activities towards this goal and provide data relevant to regulators. Readers could also review the comments of hardnosed financial analysts who focus tightly on whether the promised business transformation can be done profitably. And, of course, readers will need to assess the sincerity of this corporate transformation by the actions Philip Morris International takes to reduce and eventually eliminate the sale of cigarettes, actions that the Foundation will assess and make public.

We know that trust is earned not announced, and that we will have to work hard to earn it. We know that we have to establish the Foundation's independence from commercial interests both in fact and in the eyes of all fair-minded observers. We know that we need to be ruthlessly objective about technologies, policy and regulation, and to show we have an unswerving focus on our mission to improve public health and human well-being. We do not expect everyone engaged in tobacco control to be convinced from the outset, but we do invite you to keep an open mind, observe and assess fairly what we do and how we do it, and—we hope—tolerate any early missteps as we find our feet!

What drives me to action and to accept this challenge is the massive, unprecedented potential to join a global effort to accelerate the decline in tobacco deaths and to prove wrong those who still project a billion smoking-related deaths this century. The Foundation will start this journey by seeking the best ideas about how to ensure that its work will be truly independent, and that

For more on the **Access to Nutrition Index** see https://www.accesstonutrition.org/

For more on the **Access to Medicine Index** see https://accesstomedicineindex.org/'

For the **Foundation for a Smoke-Free World** see www.smoke-freeworld.org

its proposed actions have the greatest chance of accelerating public health benefits. We actively seek all readers inputs to this process.

Declaration of Interests
DY was reimbursed by PMI for initial travel and time specifically related to the development of the Foundation. The relationship was terminated prior to the establishment of the Foundation and the Foundation's bylaws preclude DY or other Foundation staff or board members from accepting any remuneration from PMI.

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