The Foundation for a Smoke-Free World: Rationale for Creation, Progress, and Immediate Plans

Stakeholder Meeting Summary November 13, 2018 London, UK

Introduction

The following is a summary of the Stakeholder Meeting that was convened by the Foundation for a Smoke-Free World on November 13, 2018, in London. The moderator, Christopher Graves (President/Founder of the Ogilvy Center for Behavioral Science), began with an Irving Zola story of downstream factors (individual/micro issues) and upstream factors (macro issues) that show how human behavior is a reaction to short-term crises but neglects the causative issues. This analogy set the tone for the meeting as Dr. Derek Yach, Founder and President of the Foundation for a Smoke-Free World, gave a presentation to discuss the rationale for the creation of the Foundation; progress made by the Foundation in the health, science, and technology field and the need to invest in this field; transforming the tobacco sector; and supporting smallholder tobacco farmers as they transition to alternative livelihoods. He addressed a myriad of issues, obstacles, and opportunities in his presentation and the Q&A segment that followed.

The Foundation

Despite global progress in tobacco control, the world still has over 1 billion smokers. This is unacceptable, and sounds the alarm that more effective efforts are required to reduce this number quickly and significantly. The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) has set a global target of 30% relative reduction in the prevalence of current tobacco use by 2025. The Foundation will work tirelessly to contribute to reducing the prevalence of tobacco use globally.

The <u>Foundation</u> was created to help the world's billion smokers quit and reduce their risks from smoking, which is a leading cause of preventable morbidity and premature mortality. The purpose of the Foundation is to improve global health by ending smoking in this generation. Our mission is also to address the consequences of the globally reduced demand for tobacco on smallholder tobacco farmers, and to help them transition to alternative crops and livelihoods.

The Foundation has a <u>pledge agreement</u> with Philip Morris International (PMI), in which PMI has committed to provide the Foundation with funding for 12 years. When Mr. Graves asked Dr. Yach why he reversed the position he took 20 years ago against accepting tobacco industry money, Dr. Yach responded that the following reasons compelled him to do so: the opportunity that will arise from technological disruption, the fact that funding for smoking cessation and harm reduction is scarce, and the fact that the independence of the Foundation was secured when funding was accepted, precluding any influence from PMI on the governance and management of the Foundation.

My view changed because science changed, technology changed, and the evidence changed: We have seen over the past decade that nicotine can be separated from what causes harm. I think that all of us should be adapting when we see change.

Research and Development

The Foundation funds innovative research and supports collaborative partnerships to accelerate progress in smoking cessation and tobacco harm reduction in adults. Our efforts are aimed at

decreasing smoking-related deaths worldwide, particularly in developing countries. Dr. Yach spoke of recent <u>videos</u> commissioned by the Foundation, including a video that highlights the challenges faced by smokers as they try to quit. Another video announces the results of the poll that was commissioned by the Foundation in 13 countries around the world, whereby thousands of smokers were interviewed to determine what motivates them to quit smoking or switch to reduced-harm alternatives.

Dr. Yach showed that approximately 90% of publicly funded research in the areas of smoking cessation science and harm reduction are funded and executed by institutions in the United States and Europe, whereas 80% of the world's smokers live in low- and middle-income countries. "That's a big need for more research focus where the actual smokers are," Dr. Yach stated. Indeed, most smokers are not in the United States and Europe. WHO data indicate that the prevalence of smokers in China is 26%. A study estimated that, in 2015, approximately 61 million Indian adult men aged 15–69 years smoked cigarettes (40 million exclusively) and 69 million smoked bidis (48 million exclusively). As per more recent 2016-2017 data from WHO, 99.5 million of all Indian adults currently smoke tobacco; 199.4 million currently use smokeless tobacco; and 266.8 million currently use tobacco (smoked and/or smokeless tobacco), of whom, 71.6 million smoke bidis. These numbers underscore the dire need for smoking cessation and harm-reduction efforts in underserved populations.

Developing effective and affordable smoking cessation tools requires innovative research. The most optimistic quit rate figure attributed to current pharmaceutical cessation treatments after one year is <25%. As a matter of fact, WHO indicated that pharmacological nicotine replacement therapy, either alone or in combination with other prescription cessation medications, increases quit rates by only about 7%. The pipeline for new therapies is virtually empty, and the earliest we could expect any of the new products to be available is in 5-10 years. Dr. Yach deemed that such market failure for effective cessation in the face of consumer demand must be rapidly understood and addressed. He also noted that consideration must be given not only to smokers who are seeking full abstinence, but also to those who gain pleasure from smoking and who are looking for harm-reduction alternatives:

We want to encourage cessation and address the underlying science. But we also know that a large number of cigarette smokers tell you that they get some form of pleasure [from smoking], some kind of reward from the nicotine, and they don't want to lose that. For them, we believe that harm-reduction products are a good solution. In the long term, I would hope that we have substantially better cessation products and that we'll have harm-reduction products that cut the risks below the 99% reduction mark when compared to combustibles.

Dr. Yach also spoke about indigenous populations, noting that the Foundation recently funded a Centre of Research Excellence that will focus on ending smoking among the Maori population, indigenous people in New Zealand. The Centre, Indigenous Sovereignty and Smoking, is based in Auckland, New Zealand, and directed by Dr. Marewa Glover, who is a Foundation grantee. Why start with indigenous health? The reason is both symbolic and material. We know that smoking prevalence among indigenous peoples is considerably higher than corresponding nonindigenous peoples across countries worldwide. Exploring solutions to lower the smoking rates among indigenous populations will require us to understand the socioeconomic and anthropological determinants of smoking. Among New Zealand women who reported smoking when they became pregnant, most (67.2%) continued to smoke beyond the first trimester.

Transformation

Technology disruption creates unprecedented opportunities for rapid progress in smoking cessation and much needed change in the current state of affairs. Dr. Yach showed how previous legacy industries (e.g., coal mines and waste management companies) undertook significant business transformations. As consumers of combustible tobacco are increasingly rejecting the deadly product, a transformation of the tobacco industry could be a crucial catalyst of that process. He stated that technology, consumer demand, and regulations contribute to creating a necessary change. An important question to answer is, how do we transform the largest manufacturers of cigarettes? One of these manufacturers is based in China, where approximately 40% of worldwide cigarettes are made.

Michael Russell, a psychiatrist at the Addiction Research Unit at Maudsley Hospital in London, England, said in 1976: "People smoke for nicotine but they die from the tar," that is, from the tar that is created by burning tobacco. Dr. Yach stated, "The problem is burning stuff. Combustion causes the cancer [and] kills you." Mr. Graves then asked how many premature deaths from smoking could be prevented if smokers switched to e-cigarettes. Dr. Yach referred to a Georgetown Lombardi Comprehensive Cancer Center study, led by Dr. David Levy, which showed that more than 6 million cigarette smokers in the United States would live substantially longer lives if they switched to e-cigarettes. Dr. Yach estimated that that may translate to "between 10 and 40 million lives saved in China over a decade." He also mentioned that different forms of smokeless tobacco are associated with various levels of health risks inflicted on their users, on a harm continuum. For example, the relative risk of oral cancer associated with Pan (paan) and gutkha tobacco use is about seven and nine, respectively, versus one with snus use. As data point to the utility of tobacco reduced-harm alternatives, what is holding back progress in transforming the industry? Dr. Yach answered, "Misinterpretation of risk by policy makers, physicians, and smokers."

Obstacles to Transformation

The meeting addressed the concepts of smoking cessation and harm reduction. There seem to be two conflicting views of cessation and harm reduction: a "prohibitionist" view and a "pragmatic" one. The prohibitionist viewpoint is one that advocates total abstinence as the only method available to avoid the hazards of tobacco use. The pragmatic viewpoint, on the other hand, considers that harm reduction associated with vapor products (i.e., vaping devices, heated tobacco products, and snus) is a less detrimental option. The pragmatic approach may also serve as a bridge to eventual cessation. In this case, vapor products could disrupt the tobacco market and move the industry in a new, less harmful direction. Adherents to a prohibitionist mindset appear to have a mistrust of any product coming from the tobacco industry and a fear that activities such as vaping will lead young people to initiate smoking. Dr. Yach addressed those apprehensions as follows: (1) the Foundation is committed to working with evidence-based research and "believes you have to engage the very best scientists," no matter their associations, in the name of public health and saving lives; and (2) he stated, "Obviously, kids should not smoke, they should not vape, full stop. We should be doing anything we can for both of those [activities] to stop." His concern is ensuring that debate and action are based in reality not theory. As he explained,

Over the years, [the] ethics of tobacco harm reduction have not been seriously looked at. We are trying to balance the long-term needs of kids – and the theoretical concerns of what may happen to them with these products – versus the reality of bringing the deaths down earlier among adult smokers. From an ethical perspective, we must balance preventing premature deaths over the next decade or so, versus a fear of untoward consequences in kids that would become visible 40-50 years from now.

Educating various stakeholders, including regulators, on the relative risks of harm-reduction products versus combustibles, and allowing them to make informed evidence-based decisions, is fundamental in the process of transformation. The United Kingdom has made great strides in the regulation of reduced-harm products. The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom declared in 2016 that nicotine-containing products – including e-cigarettes, are to be regulated as medicines. This directive would allow people to access such safe products (compared to combustibles) that may also be effective smoking cessation tools. Public Health England (PHE) supports the regulation by the MHRA. According to PHE, vaping "poses only a small fraction of the risks of smoking, and switching completely from smoking to vaping conveys substantial health benefits." Furthermore, e-cigarettes could contribute to at least 20,000 successful new quits per year [in the UK]. There is a dire need to address misperceptions and misunderstandings about nicotine. PHE added that "less than 10% of adults understand that most of the harms to health from smoking are not caused by nicotine." Dr. Yach emphasized that we must take action to correct these misperceptions.

Where the world should go indeed [is] towards more reasonable, actionable policies, but we have to help them do that by educating regulators. Regulators need to follow the science.

Economics of Tobacco Control

When one considers implementation of harm reduction, one also must also take into account the economic impact of the global decline in tobacco demand. Dr. Yach shed light on the depth of work that is required to create a framework for governments to respond appropriately to both harm-reduction solutions and the impact that billions of dollars in lost revenue would have on them. Addressing these questions, and the Foundation's intent on involving governments in these issues, he said:

I would hope we will be thinking of that deeply when we're moving to Year 2. [I] agree that they [financial people in governments] need to be on board. The closer you get involved to the people in technical aspects of tax, revenue, losses, and gains, the more likely you are going to have a great discussion, and the more countries' tax offices have to talk to the industry. Eventually this would lead to [a] regulative framework which is proportionate, risk-based, and where the categories are labelled, taxed, and communicated in a way which is in line with scientifically proven risk. If you have sudden, high-fee taxes, you kill the product. We've seen that in tobacco control. The most effective method to sway consumer adoption off a product is by excise taxes. So, it's an extremely important point – we need to make sure categories are well-defined and taxed according to risk.

Dr. Yach pointed to the success North Carolina had in transforming much of its economy and farms from a dependence on tobacco to vegetation and other farming resources. According to a report by the lowa State University, North Carolina saw a considerable decrease in the number of farmers from 1950 to 2012; the total number of farmers decreased from 288,508 in 1950 to 50,218 in 2012, and the number of tobacco farmers decreased from 150,764 to 1,682. In recent decades, North Carolina's tobacco farmers have been forced to diversify their crops or transition their farm operations. However, most tobacco farmers who have chosen to continue farming opted for less profitable grain and livestock industries. The Foundation could help tobacco farmers transition to profitable crops and other sustainable livelihoods.

Dr. Yach referred to the Foundation's work in the agricultural sector being conducted in Malawi. The mission of the Foundation's Agricultural Transformation Initiative (ATI) is to prepare

smallholder tobacco farmers for an era of significantly reduced demand for tobacco, focusing first on populations with the greatest need. Dr. Yach acknowledged that continued progress in tobacco control will mean job losses, a problem that will need to be addressed by exploring viable and sustainable solutions. To this end, the Foundation will partner with a diverse set of stakeholders to facilitate the establishment of more secure income strategies for tobacco farmers and to ensure the success and sustainability of our strategy. He also emphasized the large impact job loss will have on India (45.7 million people in India rely on the tobacco industry for their livelihood), including the women who work in the tobacco sector. The Foundation's work on industry transformation is driven by the need to find market-led solutions to complement the regulatory processes that are supported by the FCTC. We have issued an RFP whereby the awarded grantee(s) will provide evidence on how companies are addressing tobacco industry transformation. We will develop and implement means to critically evaluate industry progress, and assess actions taken to undermine progress toward a smoke-free world.

Closing Thoughts

Dr. Yach reiterated that, despite sometimes heavy criticism, the work of the Foundation is necessary if we are to end smoking in a generation. We stand ready to work openly and rigorously with all who share our goal. Drawing attention to smokers with diseases who are not receiving the health care they need, he stressed that prevention and health promotion considerations must see smokers as individuals and understand the impact that public health decisions and initiatives will have on them, creating synergy moving forward. Dr. Yach closed the meeting on a warm, welcoming note, inviting the attendees to join him and the Foundation "to help to stop the tide eventually."