

**Fight
Against
Smoking
.org**



Commission Report:

Reignite the Fight Against Smoking

Prepared by

The International Commission to
Reignite the Fight Against Smoking

SEPTEMBER 2021

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About the Commission

Commission Background and Objectives

Worldwide, an estimated 1.14 billion people use tobacco. Nearly 8 million die each year of tobacco-related causes, and 200 million years of life are lost. Since the creation of the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC) treaty 18 years ago, tobacco demand has declined, but far too slowly and, in some low- and middle-income countries (LMICs), not at all. At current rates, 6.5 million people will die in 2060, only a small decline in total mortality over 40 years.

The International Commission to Reignite the Fight Against Smoking was established with the belief that efforts to prevent premature deaths from tobacco require much greater imagination and ambition. It is simply unacceptable that more people smoke cigarettes today than 30 years ago.

The possibility for dramatic change, however, has emerged with new technologies that deliver nicotine without combustion. These technologies significantly reduce harm so that smokers who cannot quit can turn to alternatives that have far less chance of sickening or killing them. This approach, based on scientific research and supported by intelligent public policy, holds the best hope for finally ending the scourge – especially for those in LMICs, who have been largely neglected by international organizations and their own governments.

This report offers facts, analysis, and recommendations aimed at reinvigorating a noble effort that has stalled, mired in an outdated paradigm that has been superseded by new technology, new ideas, and new concerns for neglected countries and communities.

Commissioners' Profile

This diverse collection of experts from around the globe reflects the breadth and depth of knowledge needed to address the global nature of the task at hand.¹

Ambassador (ret.) James K. Glassman, United States of America

Former U.S. Under Secretary of State for Public Diplomacy and Public Affairs

Dr. Rosemary Leonard, United Kingdom

General Practitioner

Dr. Kgosi Letlape, South Africa

Ophthalmologist, President of Africa Medical Association and President of Medical Councils of Africa

Mr. Vivan Sharan, India

Partner, Koan Advisory

Dr. Tikki Pangestu, Indonesia

Former Director of Research Policy and Cooperation at WHO

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To request additional information, please go to fightagainstmoking.org.

¹ The contributions and views expressed by the Commissioners represent their own personal independent expert opinions and do not in any way represent the positions of the organizations with which they are affiliated.

Comments on the Report

Donald Kenkel

PhD, Andrew Dickson White Professor in the Cornell Jeb E. Brooks School of Public Policy and the Department of Economics, Cornell University

"This report thoroughly documents the global health toll of smoking, now and in a likely future. But the report also shows that through continuing technological innovation, tobacco harm reduction is an immediate, achievable goal. Evidence-based economic policies and regulations that support tobacco harm reduction offer real hope to help people quit smoking and improve their health."

Gerry Stimson

Emeritus Professor at Imperial College London and Director of Knowledge-Action-Change

"This is a hugely authoritative call to reshape global efforts to help smokers switch from smoking. Tobacco-control measures to discourage smoking have not been matched by appropriate, affordable, and effective methods for helping smokers quit. Helping smokers remains the weakest link in global tobacco-control efforts, characterized by the report as 'frozen in time.' As the report indicates, technological innovations, consumer interest in safer nicotine products, industry transformation, and policies that promote tobacco harm reduction herald an historic opportunity in the switch from smoking."

Jed E. Rose

PhD, President and CEO of the Rose Research Center

"This report does a superb job of describing the global impact of tobacco use on public health and detailing the new approaches available to promote cessation and tobacco harm reduction that every clinician should be informed about. A vital message that the report conveys effectively is the importance of correcting misinformation on the health effects of nicotine when separated from toxins of tobacco and smoke, as these approaches have the promise to save millions of lives from tobacco-related disease."

Sally Satel

MD, Resident Scholar at the American Enterprise Institute and lecturer at the Yale University School of Medicine

"This highly readable volume is an excellent guide to tobacco harm reduction. Vaping and other ways of consuming non-combustible tobacco are the future of public health for smokers. The chapters present the latest data on the benefits of new products, correct rampant misinformation, offer a level-headed approach to the issue of teen vaping, and portray the extremely promising experiences of countries where non-combustible products are improving the health of consumers through policy approaches."

Sukriti Chauhan

PhD, LLM, INLAKS Scholar
and Chief Executive
Officer of ETI

"This is an extremely comprehensive report that highlights tobacco use in India to provide a holistic image. There is no doubt that tobacco severely contributes to the burden of NCDs that have a profound negative impact on women. To tackle these challenges, it is crucial that we develop affordable solutions. This is possible only after comprehending the gaps in the current scenario. This report provides us with such knowledge and gives us an understanding of potential tobacco harm-reduction benefits to the social and economic development of the country. It is critical that we develop an intersectional and multi-sectoral framework to tackle the challenges faced due to tobacco use in the country."

Sharifa Ezat

MD, MPH, PhD,
Professor in the
Department of
Community Health at
the National University
of Malaysia

"This is a wonderfully written report, accentuating major points and highlighting relevant details in policy around tobacco consumption. Current issues, especially in low- and middle-income countries, are discussed from multiple points of view, providing a concise analysis of tobacco use and its socioeconomic effects."

**Hafiz
Choudhury**

Principal with The M
Group, Inc.

"The Commission Report is an excellent compilation and analysis of the underlying factors that explain the persistence of smoking worldwide. It delivers important insights that will aid in improving regulatory and economic policies to help reduce smoking. The work on regulatory issues breaks new ground; it shows the need to ensure that economic, tax, and regulatory policies are aligned to support positive change. The detailed analysis of ten countries provides key insights for work in the tax area. Accurate measurement of the tax incidence of various nicotine products and calculation of the relative levels of harm caused by each can help establish risk-adjusted regulation of nicotine products to incentivize less harmful behaviors."

**Abhishek
Kumar**

Partner at
Indicc Associates and
Convenor of New
Indian Consumer
Initiative

"This exhaustive report provides all crucial dimensions to put together a holistic strategy towards tobacco harm reduction. An extremely rich report, it also makes for a highly readable volume and reaches out effectively to all concerned stakeholders, including consumers and citizens. It has all the ingredients to catalyze a wider discussion on tobacco harm and contains thoughtful and implementable recommendations. The number of tobacco users in India is considerable. For a country with the majority of the population in a low-income group, the health and economic burden from tobacco use is an important issue. Harm reduction from tobacco is therefore an imperative."

**Solomon
Rataemane**

Professor and HOD at
Sefako Makgatho
Health Sciences
University, South
Africa

"The report is comprehensive and well researched. It is very informative for everyone interested in understanding the tobacco landscape. It will enlighten policymakers, and everyone interested in the use of tobacco and its health consequences. The report is balanced and reassuring in its scientific approach and will be helpful in the continuous evaluation of policies regulating tobacco use worldwide, including proposals from WHO and stakeholders with different views on the use and sale of tobacco products."

**Joseph
Magero**

Chair of Campaign for
Safer Alternatives

"This well-written report lays emphasis on an evidence-based approach in the fight against smoking, based on the best science and supported by intelligent public policy. Indeed, the regulatory environment around tobacco control and harm reduction in low- and middle-income countries needs to change. A timely report for the more than 800 million smokers in such countries, who have been largely neglected by international organizations and their own governments."

**Abrie
du Plessis**

Associate at Trade
Law Centre, Cape
Town

"This report is a timely reminder of the negative consequences of opting for a stagnant instead of a dynamic approach in the fight against smoking. As an expert in the field of public international law, I was moved by the report to reflect on the ideal that the vision of world institutions should not remain frozen in time and should be capable of evolution and adaptation, an ideal that is often undermined by the rigid nature of international treaties. In this respect it should be noted that the text of the FCTC, as a relatively new treaty, does contain sufficient references and mechanisms to support the dynamic approach."

**Riccardo
Polosa**

MD, PhD, Professor of
Internal Medicine in
the Department of
Clinical and
Experimental
Medicine of the
University of Catania,
Italy

"A tobacco-control strategy that blanket bans e-cigarettes will lead nowhere. This report emphasizes the great opportunities offered by low-risk products. In Italy, where tobacco use kills about 1 million people every year and cigarettes are easily available, the adoption of safer alternatives to conventional cigarettes could help to save millions of lives."

**Didik J.
Rachbini**

PhD, Senior
Economist at INDEF
and Chancellor of
Paramadina
University, Jakarta

"This report gives a clear understanding of tobacco production and consumption in large economies such as that of Indonesia. With analyses of health, economic, and socio-cultural factors, this report provides solutions to reduce, and even end, smoking for the young generation."

Executive Summary

With an estimated 1.14 billion people still using tobacco, the fight to create a world without smoking has stalled. Tobacco kills nearly 8 million people and eliminates nearly 200 million disability-adjusted life years annually. The cost to the world is nearly \$2 trillion dollars a year – roughly 2% of gross domestic product. The need to reignite the fight against smoking is clear and urgent.

This report examines: trends in tobacco use; challenges to cessation efforts, including misguided attempts to minimize the potential of harm reduction and thwart it outright; the emergence of technological innovations; the role of physicians; the proper function of industry; economic and regulatory policy; smoking and youth; and lessons from the COVID-19 pandemic. Based on this information and analysis, the report makes specific recommendations to achieve the goal of ending smoking worldwide.



Trends in Tobacco Use

Discerning trends in tobacco use is complicated by a nearly two-decade lag between when a person starts smoking and when harms are manifested. This lag creates an opportunity to intervene. The harms of tobacco use can be largely avoided if a person quits before entering middle age. Tobacco use varies by region, sex, income, socioeconomic status, and ethnicity, among other sociodemographic characteristics. Understanding those differences can guide efforts to promote quitting. Key trends and insights include:

- Tobacco use is concentrated in China, India, and Indonesia. These three are home to nearly half of all global tobacco users.
- Tobacco use is substantially more common in men than women but, in a number of countries, use has levelled off, or even risen, among women while declining among men.
- Tobacco use is higher among those with lower household income, lower socioeconomic status, and lower levels of educational attainment.
- The prevalence of tobacco use has declined across all country-level income categories.
- Tobacco use is often disproportionately higher among certain racial and ethnic groups.
- The burden of disease is exceptional among such populations as those with mental health disorders, as well as those who are homeless, identify as indigenous peoples, or identify as lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

RECOMMENDATION #1

Research institutions should quantify the size of the financial gap and the funding mechanisms to implement effective tobacco cessation and harm reduction in LMICs.

Cessation Efforts Stall

The persistence of smoking in many LMICs and by vulnerable groups in higher-income countries is evidence that previous efforts at tobacco cessation have been ineffective or stalled, or both. The continuing toll of tobacco use is unacceptable, and, if current trends continue, the number of deaths from cigarette and other harmful forms of tobacco will grow from 100 million in the 20th Century to 1 billion in the 21st Century. Averting such devastation requires recognizing that:

- Many tobacco users want to quit but are thwarted by lack of proven cessation tools – especially tobacco harm-reduction (THR) products. These non-combustible THR products, far less dangerous to health than smoking, require support from public policy and education.
- Misinformation about the true risk of THR is rampant. There is a widespread and erroneous belief that THR products are as risky as cigarettes and that nicotine is a substance that causes illness and death. Correcting these misperceptions appears to be an essential first step in reigniting the fight against smoking.
- If the world can take full advantage of new cessation and THR solutions, about 3.5 million people will die from tobacco in 2060 – a reduction of 3 to 4 million annual deaths from tobacco within four decades.

RECOMMENDATION #2

Undertake multi-national, multi-disciplinary and participatory foresight studies, especially in LMICs to identify optimal policy responses needed to end smoking and its health impacts, the impact of technological innovations and how these innovations may reshape the landscape over the next 20 years.

Emergence of Technological Innovations

Evidence clearly shows that tobacco harm reduction products are substantially safer than combustible cigarettes, and the products have been proven to be effective aids to help persistent adult smokers quit. There is an urgent need to scale up tobacco harm reduction. THR technologies, which were barely a glimmer when the FCTC was being signed in 2003, now herald a new chapter in reigniting the fight against smoking. Key insights and takeaways include that:

- Major tobacco companies are at the forefront of technological innovation in tobacco harm reduction.
- There has been an explosion of innovation with nearly 74,000 patents filed in the past decade led by major tobacco companies. As of 2018, vaping devices were the fastest-growing category among all new patents, ahead of 3-D printing and machine learning. The innovation explosion suggests that certain tobacco companies are shifting towards “pharmaceuticalization” through technologies that are therapeutic instead of recreational.
- Making these new technologies easily accessible to companies producing combustible products, especially in LMICs, where most smokers live, can save between 3 million and 4 million lives a year. There is also an immediate and urgent need to reach marginalized communities with higher-than-average combustible smoking rates, such as the mentally ill, Aboriginal and First Nations, the working poor, and LGBTQ populations.

RECOMMENDATION #3

Develop private-public partnerships in selected LMICs to improve access, affordability, and local acceptability for cessation and THR products, drawing inspiration from two decades of experience for infectious diseases.

RECOMMENDATION #4

Expand access to tobacco harm reduction products in LMICs. Because these products can be expensive, THR patents must be shared by their owners with companies that have weaker R&D capacity but can manufacture products locally.

RECOMMENDATION #5

Support development of more effective biomarkers of exposure to the wide range of tobacco products available, as well as biomarkers of early health outcomes that can predict long-term morbidity and mortality outcomes.

Mobilizing Physicians

In the 20th Century, physicians played a crucial role in getting people to stop smoking. It is time for physicians to take the lead once again with new THR technologies added to their repertoire. Barriers to doing so, however, persist and overcoming them requires recognizing that:

- Physicians report lacking knowledge about THR and, in some parts of the world, believing the false idea that quitting cold turkey may be best.
- Physicians in LMICs such as China and Indonesia have other pressing diseases to deal with – and continue to smoke themselves. Worldwide, physicians devote inadequate time to discussing smoking alternatives with their patients even though smoking kills more people than almost any other condition.
- The need to share evidence-based best practices and address misperceptions about harm reduction among physicians is paramount.

RECOMMENDATION #6

Encourage medical bodies such as the Royal College of Physicians and the World Medical Association to re-establish the leadership role of doctors in ending smoking in LMICs.

RECOMMENDATION #7

Determine doctors' knowledge, practices, personal views, and behaviors (for example, do they personally smoke) vis-à-vis nicotine on a periodic basis using digital technologies. Based on those insights, develop and promote evidence-based programs tailored to their knowledge base, practices, and regions to discover what works to end smoking in adults.

RECOMMENDATION #8

Support research to design more effective ways of ending smoking in high-risk patients who smoke, including patients with mental health conditions, tuberculosis, heart disease and early-stage chronic lung disease.

RECOMMENDATION #9

Support development of easy-to-access, up-to-date information for physicians on three aspects of nicotine: emerging science and knowledge about the health effects, consumer perceptions and how they affect product use, and trends in the creation of future products to end smoking.

The Proper Role for the Industry

It is easy to understand why the tobacco industry is mistrusted, given its long history of lies and intimidation. Parts of the industry, however, are changing dramatically, with technology and THR playing an ever-greater role in the battle to eradicate smoking. Key insights and takeaways include that:

- Research shows that leading tobacco companies understand that alternative THR products will replace combustibles for good.
- These efforts need to be paired with reasonable and respectful dialogue and multi-stakeholder engagement to displace boycotts and ostracism as the best way to build solutions to end death and disease.
- Smoking opponents should consider the validity of the research itself, not where it comes from or who funds it. The FCTC itself contains a fundamental flaw by allowing signatory nations to own tobacco companies in whole or part and thus profit from a habit that they are meant to fight. These signatories have put themselves in the untenable position of agreeing to curtail a practice from which they continue to profit.

RECOMMENDATION #10

Encourage tobacco companies (multi-national and local) and state tobacco monopolies to have a clear plan to phase out high-risk combustible products. The plan should include performance metrics for CEOs and senior management to achieve this goal.

RECOMMENDATION #11

Find the best ways for tobacco manufacturers and public health agencies to work with social media companies to develop and implement guidelines to detect, reduce and counter disinformation on THR and the role of nicotine.

Improving Regulatory Policies

THR products can effectively facilitate smoking cessation, but engagement with these products is deeply influenced by the economic, tax, and regulatory policies a country adopts. The analysis of countries finds that policy responses to THR products vary greatly. Key insights and takeaways include that:

- Several countries, such as the United Kingdom, Japan, South Korea and Sweden, recognize the potential of THR products with a raft of measures to encourage persistent smokers to switch to alternatives.
- Under such regulatory frameworks, alternatives appear to reduce the harms of tobacco use while simultaneously allowing public health agencies to externalize the cost of smoking cessation, suggesting that such policies make both clinical and economic sense.
- As countries have wrestled with how best to regulate alternatives to cigarettes, the evidence increasingly supports reducing harm for smokers through correcting misperceptions, communicating risk appropriately, replacing bans with risk-proportionate regulation, and considering evidence on flavors and nicotine caps.

RECOMMENDATION #12

Advocate for risk-proportionate regulations as a means of making it easier for smokers to switch from combustibles and quit.

RECOMMENDATION #13

Fund research aimed at documenting the early and medium-term health effects (five years) of smokers switching completely or partly to THR products or cessation in large populations of adult users matched to smoking controls.

RECOMMENDATION #14

Support research to adapt profitable business model designs used by leading multi-national companies with large THR portfolios to state-owned tobacco monopolies.

RECOMMENDATION #15

Develop mechanisms to assess the impact of recently introduced risk-proportionate policies on switching from combustibles to THR and on cessation. Those policies include changes involving the treatment of pricing and taxation, flavors and nicotine levels, and health messages.

RECOMMENDATION #16

Leverage multi-national, multi-disciplinary and participatory foresight studies to identify health gains from optimal policy responses needed to end smoking.

Smoking and Children/Youth

Young people smoke at a far lower rate than adults, and youth smoking prevalence is declining in high-income countries. Still, too many teenagers continue to smoke cigarettes, especially in LMICs, where both national governments and international organizations have not effectively addressed smoking among youth. The increased use of alternative nicotine-delivery systems raises concerns as well. Addressing these concerns requires recognizing that:

- Banning or restricting sales of both combustibles and THR products to minors is a necessary step, taken by many countries, but current prohibitions are ineffective, particularly in LMICs. In these countries, enforcement is lax, and children themselves are often sellers as well as users of cigarettes, bringing home essential cash to hard-pressed families.
- Data on youth cigarette smoking are spotty and inconsistent. The WHO has reported that 6.5% of adolescents overall are smokers (with the highest rates in Europe and upper-middle-income countries globally) because access to cigarettes requires access to money.
- For both children and adults, there is a clear correlation between declining rates of smoking and rising rates of using e-cigarettes and other alternatives. The consensus view is that young people, like current non-smokers, should not initiate the use of any form of tobacco. Demonizing e-cigarettes for youth, however, can have spillover effects for adults, discouraging them from switching and giving them an excuse to keep smoking.
- Smoking by children is an emotional issue that can obscure the more clear and present danger, which is the imminent disease and mortality faced within the next 20 years by current cigarette smokers in their 30s, 40s, and 50s. Conflating the dangers of tobacco and alternatives makes sense for adolescents, but for adults, the spillover effects could lead to millions of needless deaths.

RECOMMENDATION #17

Support development of a global multi-company alliance that endorses and commits to enforce a common set of the highest voluntary standards, which include responsible marketing practices to restrict combustible tobacco and THR product access to those under the age of 21. Require a third party to evaluate and monitor compliance.

RECOMMENDATION #18

Advocate for governments to mandate the use of technologies to verify the age of prospective purchasers of cigarettes and THR products at the point of sale and online. These technologies already exist in nascent form in high-income countries, but government and industry support and additional research are needed for faster development, especially with an eye to adapting the tools to the needs and realities of LMICs.

Considerations from COVID-19

The COVID-19 pandemic has brought new attention to public health, including its role in tobacco control. Key insights and takeaways include that:

- The success of U.S. vaccine development demonstrates the power of multi-sectoral engagement and public-private partnerships (PPPs). Despite its past, the tobacco industry is well positioned to contribute to tobacco control through innovation in THR products, and strong PPPs can help make those products accessible and affordable to LMICs and marginalized communities.
- Correcting misinformation is crucial. Tobacco communicators contend with misinformation campaigns and sensational media portrayals – particularly with respect to e-cigarettes. In conveying messages about tobacco control, it is necessary not just to provide information, but to make the evidence resonate.
- The precautionary principle can be perilous, as we have seen in cases of vaccine hesitancy. There are enormous costs to blocking new interventions (with sufficient current research to back them up) until their long-term effects are conclusively known. The precautionary principle keeps millions from being vaccinated and inspires governments to deter THR products – even though in both cases the known benefits far outweigh the known risks.

RECOMMENDATION #19

Adopt best practices to combat misinformation and build a healthier information environment for tobacco harm reduction. Identify leading sources of misinformation, harnessing technology to slow the spread of falsities and to share accurate information. Encourage trusted messengers such as doctors to disseminate clear information. Also fund research to understand sources of misinformation, identifying evidenced-based interventions, and work closely with consumer and media advocates to reach communities disproportionately affected by misinformation.

Glossary

WHO-FCTC

World Health Organization Framework Convention on Tobacco Control

LMICs

Low- and middle-income countries

DALYs

Disability-adjusted life-years

COPD

Chronic obstructive pulmonary disease

IHME

Institute of Health Metrics and Evaluation

CDC

Centers for Disease Control and Prevention

THR

Tobacco harm reduction

NRT

Nicotine-replacement therapy

COM

Commitment fulfillment progress

PMI

Philip Morris International

BAT

British American Tobacco

HNB

Heat-not-burn

MHRA

Medicines and Healthcare Products Regulatory Agency

MRTPs

Modified risk tobacco products

SLT

Smokeless tobacco

PPPs

Public-Private Partnerships

The Problem

Chapter 1 Global Tobacco Use Trends

Summary

This chapter provides an overview of the key trends in the epidemiology of tobacco use.² In doing so, it seeks to establish a clear and consistent fund of knowledge that can serve as context for the subsequent chapters. Chapter 1 opens by highlighting the scale and scope of tobacco use around the world. It notes the way in which the lag between tobacco initiation and the manifestation of its harms can complicate a full appreciation of emerging trends and efforts at cessation, and then examines how tobacco use varies by region, sex, income, socioeconomic status, and ethnicity, among other sociodemographic characteristics. The chapter closes by describing the burden of tobacco use among people with mental health disorder and among other vulnerable groups. It finds that:

- There are an estimated 1.14 billion tobacco users globally.
- Tobacco-related disease kills an estimated 8 million people and costs 200 million disability-adjusted life-years (DALYs) annually.
- The economic toll of tobacco-related disease is nearly \$2 trillion a year, or 1.8% of the world's gross domestic product.
- There is often a two-decade lag between initiating tobacco use and its harms, which creates an important opportunity to intervene.
- Tobacco use is concentrated in China, India, and Indonesia, with these three Asian countries being home to nearly half of all tobacco users globally.
- The prevalence of tobacco use has declined across all country-level income categories.

² While the principal aim of the report is to place an emphasis on ending the use of combustible tobacco products such as cigarettes, the report also focuses on the need to reduce the use of other forms of toxic tobacco, such as varieties of smokeless tobacco popular in many parts of Asia.

- Tobacco use is substantially more common in men than women but, in a number of countries, it has remained steady or even risen among women while declining among men.
- Tobacco use is higher among those with lower household income, lower socioeconomic status, and lower levels of educational attainment.
- Tobacco use is often disproportionately higher among certain racial and ethnic groups.
- The burden of disease is similarly disproportionate among other populations, such as those with mental health disorders, who are homeless, and those who identify as indigenous peoples and as lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

Global Tobacco Use Trends

With an estimated 1.14 billion users, tobacco is among the leading causes of preventable death in the world. Tobacco-related diseases cause nearly 8 million deaths each year and approximately 200 million disability-adjusted life years, or DALYs (Reitsma 2021). Much of this loss is through cancer, chronic obstructive pulmonary disease (COPD), heart disease, and tuberculosis (WHO 2020; WHO 2009). The costs associated with these diseases are substantial, roughly \$467 billion in terms of purchasing power parity – about 6% of all global health expenditures – each year. Coupled with productivity losses, tobacco use costs the world nearly \$2 trillion, or 1.8% of total global gross domestic product each year (Goodchild 2018). As detailed below, tobacco use varies substantially by region, with LMICs bearing a disproportionate burden of tobacco-related disease. More than 80% of all tobacco users live in LMICs and nearly 40% of the resulting economic burden falls on these countries (WHO 2020; Goodchild 2018). Within all countries, tobacco use also varies based on sociodemographic characteristics.

The Lag Between Tobacco Initiation and Its Harms

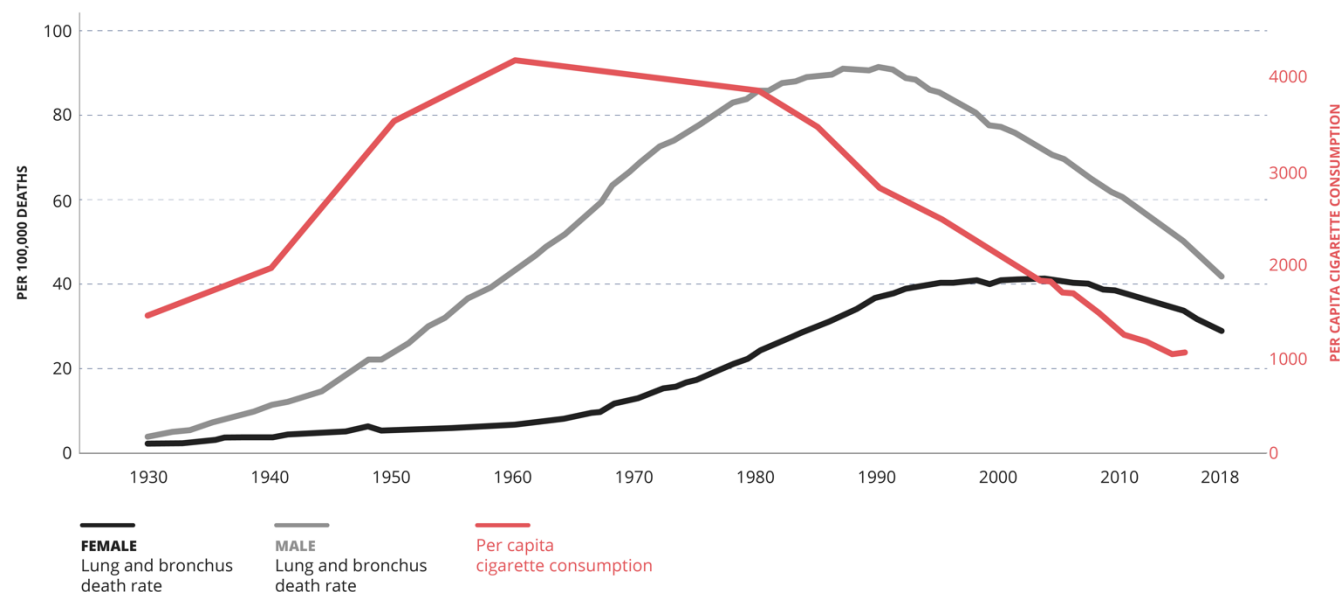
To be clear: adult tobacco use is the principal focus of this report, but youth tobacco use – through combustibles and THR products – must be unequivocally banned by law and discouraged by policy. For individuals who do start smoking habitually – regardless of age – a substantial time lag exists between initiation and consequent harms. Data from the American Cancer Society reveal at least a two-decade gap between the rise in smoking and a rise in lung cancer deaths (see Figure 1-1). A similar lag period can be observed between smoking and other common tobacco-related diseases such as cerebrovascular disease, COPD, and heart disease (Jha 2020).

Additional studies have revealed that this lag represents an important opportunity to promote smoking cessation and prevent subsequent harms. Over the course of two decades, Sir Richard Peto and colleagues conducted a prospective study of about 120,000 individuals. They found that those who started smoking before the age of 15 were twice as likely to die before those who never smoked but, critically, that those who quit smoking before age 40 largely avoided much of the excess risks of smoking (Thomson 2020). The findings

underscore the importance of how critical smoking cessation can be for all individuals, even those who began smoking at a young age and whose attempts to quit have been refractory to traditional treatment.

Figure 1-1:

Trends in Per-Capita Cigarette Consumption and Age-Standardized Lung Cancer Deaths in the United States



Source: American Cancer Society 2019.

Tobacco Use by Region and Key Sociodemographic Characteristics

REGION

Tobacco use varies substantially by region. Examining tobacco use and prevalence in countries around the world (see Table 1-1) brings three findings into sharp relief. First, a substantial number of tobacco users are concentrated in Asia. China and India combined are home to more than 500 million tobacco users between the ages of 16 and 64. Indonesia is home to another nearly 70 million. Collectively, these three Asian countries account for nearly half of all tobacco users between the ages of 16 and 64 globally. Among the top ten countries with the greatest numbers of tobacco users in this age range, only three – Brazil, Russia and the United States – are outside Asia. Second, the concentration of tobacco users in Asia does not simply reflect how populous these countries are. Tobacco prevalence (the percentage of adults in each country who smoke) is also highest in South and Southeast Asian countries, with Bangladesh, Indonesia, and Myanmar having prevalence rates near or above 40%. Third, the vast majority of tobacco users in these countries are men. In China, tobacco prevalence is 25 times higher among men than women. In Indonesia and India, that figure is closer to 13 and 3 times higher, respectively, among men than women.

Table 1-1:

Top 20 Countries with the Highest Number of Tobacco Users by Country, 2018

Source: World Bank 2018.

| Country | TOBACCO USERS (16-64) | TOBACCO PREVALENCE (15+ YEARS) | | |
|--------------------|-----------------------|--------------------------------|----------|------------|
| | Number of smokers | Total | Male (%) | Female (%) |
| China | 251, 959,234 | 24.7 | 48 | 1.8 |
| India | 250,002,133 | 27.0 | 42 | 12.1 |
| Indonesia | 69,100,353 | 37.9 | 71 | 5.3 |
| United States | 53,739,876 | 25.1 | 31 | 19.3 |
| Bangladesh | 42,608,838 | 39.1 | 61 | 17.7 |
| Russian Federation | 27,061,501 | 28.3 | 41 | 15.7 |
| Pakistan | 26,076,132 | 20.0 | 34 | 6.4 |
| Brazil | 24,012,440 | 16.5 | 22 | 11.5 |
| Philippines | 16,662,039 | 24.3 | 42 | 7 |
| Japan | 16,643,904 | 21.9 | 33 | 10.5 |
| Myanmar | 16,222,767 | 45.5 | 70 | 20.8 |
| Turkey | 16,035,550 | 29.3 | 42 | 17 |
| Germany | 15,057,793 | 28.0 | 30 | 26 |
| France | 14,360,288 | 34.6 | 36 | 33.2 |
| Egypt, Arab Rep. | 12,936,097 | 21.4 | 42 | 0.4 |
| South Africa | 11,850,184 | 31.4 | 47 | 16 |
| Mexico | 11,384,538 | 13.9 | 21 | 6.5 |
| Italy | 9,015,005 | 23.4 | 27 | 19.6 |
| Spain | 8,613,145 | 27.9 | 29 | 26.7 |
| United Kingdom | 8,155,473 | 19.2 | 21 | 17.3 |

Diversity of Tobacco Use

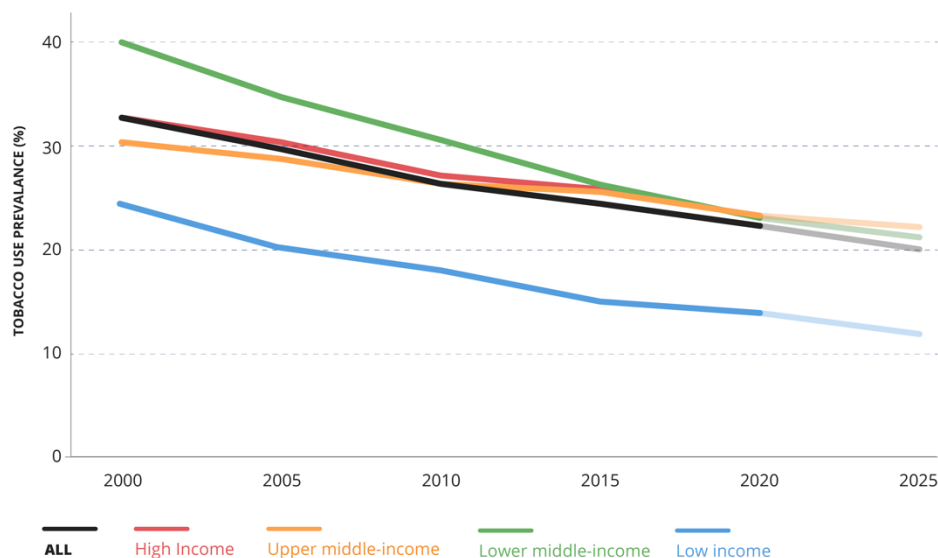
Tobacco cessation efforts largely focus on the health damage caused by conventional combustible cigarettes, which make up about 89% of tobacco products by sales value. However, a diversity of harmful tobacco products exists throughout the world, some considerably more dangerous. For instance, smokeless tobacco (SLT) products or chewing tobacco are used by 274 million adults worldwide with 228 million users living in South Asia region alone with little change in prevalence of chewing tobacco use in the past two decades. (Kendrick, 2021). India has some of the highest rates of smokeless tobacco use and oral cancer in the world (FSFW, 2021).

COUNTRY-LEVEL INCOME

Tobacco use has declined across all country-level income categories (see Figure 1-2). Most of the world's smokers now reside in LMICs, and, as the burden of tobacco-related disease mounts in these countries, results will be devastating. The WHO and the World Bank project that, by 2030, some 80% of all tobacco-related deaths will occur in LMICs and nearly 40% of the global economic cost of tobacco will be shouldered by these countries (WHO 2008; Goodchild 2018). Tobacco use dovetails with certain sociodemographic characteristics more common in LMICs than in their higher-income counterparts. In addition, traditional tobacco control policies have lacked full implementation in LMICs, and research focused on them has been insufficient. After all, many of the policies promoted by the FCTC were designed with high-income countries in mind, and the differences between those nations and LMICs – in terms of the different types of favored tobacco products, in the risk landscape, heterogeneous behaviors, and in divergent agricultural and market influences – may render traditional policies less than effective in geographic regions where tobacco use is now greatest (Dobbie 2019).

Figure 1-2:
**Global Trends in Tobacco
Use Prevalence by Income
Group**

Source: WHO 2019.



SEX

Tobacco use is lower – often substantially so – among women than men in virtually every region and country-level income group. The differences in tobacco use prevalence between men and women are often greatest in LMICs (WHO 2019). Overall, however, declines in tobacco use have progressed more swiftly among men and, in a few countries, tobacco use by women has remained steady or even risen (GBD 2017). This trend is true even among youth, suggesting that, unless a new and effective approach to promote cessation is implemented, the gap between men and women regarding tobacco use and its harms may close (see Table 1-2) (Solomon 2020).

Recent evidence from the Institute of Health Metrics and Evaluation (IHME 2017) indicates that lung cancer rates among women are already beginning to exceed breast cancer rates, especially in countries where smoking among women is projected to increase. These observations underscore the importance of more gender-specific analysis (Solomon 2020).

Table 1-2:

**Male to Female
Smoking Prevalence
Ratios**

Source: Solomon 2020.

| Country | AGES 10 TO 14 | | AGES 15+ | |
|----------------|---------------|------|----------|------|
| | 2000 | 2015 | 2000 | 2015 |
| Sweden | 0.65 | 0.49 | 0.88 | 0.94 |
| Bulgaria | 0.72 | 0.52 | 1.70 | 1.48 |
| UK | 0.70 | 0.58 | 1.07 | 1.13 |
| Slovenia | 1.36 | 0.61 | 1.57 | 1.35 |
| Australia | 0.68 | 0.62 | 1.22 | 1.21 |
| Croatia | 1.24 | 0.63 | 1.57 | 1.29 |
| Ireland | 0.75 | 0.65 | 1.18 | 0.95 |
| Canada | 0.79 | 0.66 | 1.24 | 1.20 |
| Czech Republic | 1.45 | 0.74 | 1.60 | 1.62 |
| France | 0.88 | 0.76 | 1.41 | 1.27 |
| Germany | 1.08 | 0.81 | 1.51 | 1.37 |
| Chile | 0.90 | 0.81 | 1.36 | 1.28 |
| Argentina | 0.91 | 0.87 | 1.45 | 1.52 |
| Poland | 1.83 | 0.94 | 1.65 | 1.48 |

HOUSEHOLD-LEVEL INCOME AND SOCIOECONOMIC STATUS

Tobacco use correlates with household-level income and socioeconomic status in predictable ways. Smoking tends to gain popularity in households with rising levels of disposable income. Within those households, smoking often gains traction among men first and then women. As the harms of tobacco use become manifest, policymakers respond with efforts to promote cessation, which gain traction among populations with higher levels of household income. As a result, tobacco use becomes concentrated among the lowest rungs of the socioeconomic ladder as multiple studies have shown (Nargis 2019; CDC 2020; Hiscock 2012a; Barbeau 2004). For example, in the United Kingdom and the United States, tobacco use is greatest among populations making less than £10,000 and \$35,000 USD annually, respectively (see Figures 1-3 and 1-4). Similar trends have been observed in India and Indonesia (Hiscock 2012a; Hiscock 2012b; FSFW 2019a; FSFW 2019b; FSFW 2019c). Studies suggest for those with lower socioeconomic status, quitting is hampered by reduced social support among peers, low motivation, and a greater likelihood of being unable to complete treatment. The persistence of smoking underscores the importance of targeted tobacco cessation efforts for such communities.

Figure 1-3:
Cigarette Smoking in Great Britain by Income Group

Source: Office for National Statistics 2020.

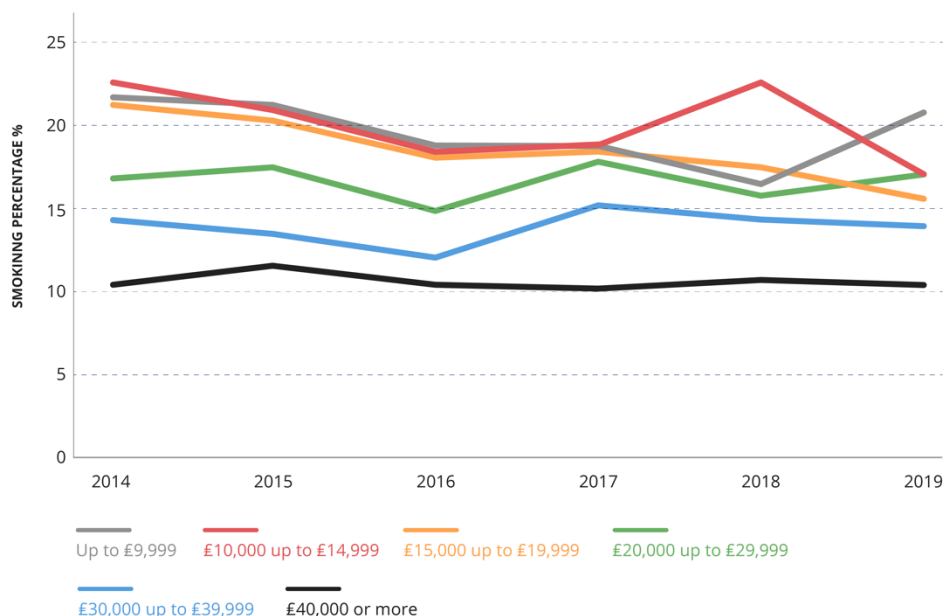
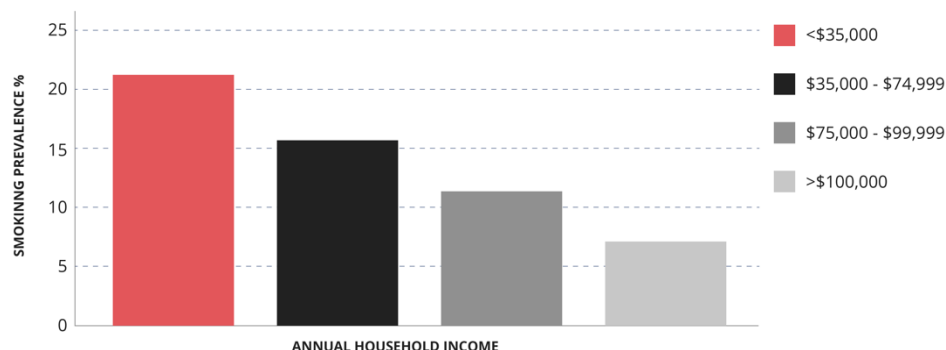


Figure 1-4:
Smoking Prevalence in the United States by Income Group, 2019*

*For individuals aged 18 and over.
Source: CDC 2020.

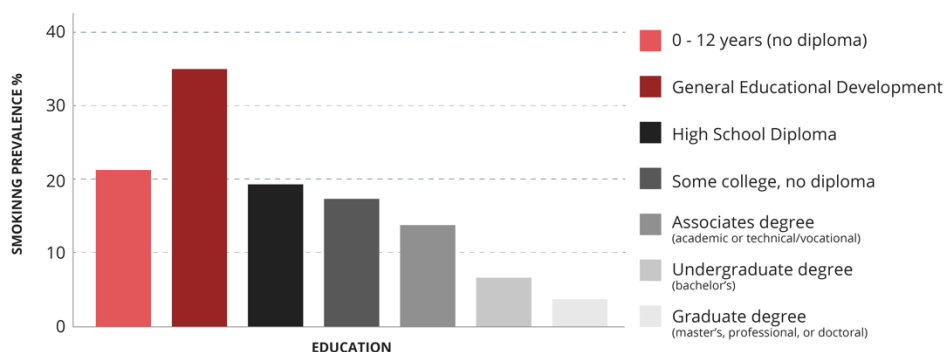


EDUCATIONAL LEVEL

Given the close relationship between socioeconomic status and educational attainment, tobacco use is also associated with educational level in predictable ways. The US Centers for Disease Control and Prevention (CDC) found that tobacco use is highest among those with lower levels of educational attainment, with the notable exception with those with less than 12 years of education, who may be less able to afford cigarettes. Smoking is reported by more than 35% for those whose top attainment is high school diploma, and then steadily declining for those with successively higher levels of educational attainment (see Figure 1-5). That percentage is well above the average prevalence of tobacco use in the United States (14%) (CDC 2020). Similar patterns have been observed in most countries.

Figure 1-5:
**Smoking (Cigarette)
Prevalence in the United
States by Education, 2019**

Source: CDC 2020.

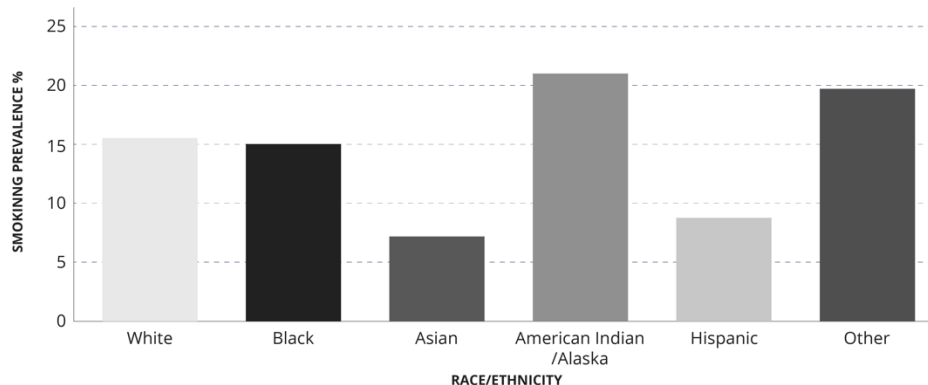


ETHNICITY

Tobacco use also varies by race and ethnicity. As shown in Figure 1-6, smoking prevalence is highest among non-Hispanic American Indian/Alaskan adults (20.9%) and lowest among non-Hispanic Asian adults (7.2%). Such variations are common among most countries.

Figure 1-6:
**Smoking (Cigarette)
Prevalence in the United
States by Ethnicity, 2019**

Source: CDC 2020.



RISKS OF DEATHS AND DISEASES COMMONLY ASSOCIATED WITH TOBACCO

According to the IHME, tobacco use substantially increases the relative and attributable risk for major causes of death such as cancer, COPD, cardiovascular disease, and tuberculosis, among others. Specifically (see Table 1-3), nearly 67% of tracheal, bronchus, and lung cancer deaths, more than 63% of laryngeal cancer deaths, more than 53% of COPD deaths, 47% of lip and oral cavity cancer deaths, nearly 22% of heart disease and more than 15% of tuberculosis deaths are attributed to tobacco use (IHME 2019).

Tobacco use results in more than 8 million deaths each year and more than 200 million DALYs lost annually. Its contribution to common diseases like the ones mentioned above is particularly striking (see Table 1-4). In 2019,

tobacco accounted for nearly 2.6 million deaths and more than 59 million DALYs from cancer generally (including nearly 93,000 deaths and 2.5 million DALYs from lip and oral cancer specifically), 1.7 million deaths and 38 million DALYs from COPD, 3.2 million deaths and 83 million DALYs from cardiovascular disease, and 198,000 deaths and 6.3 million DALYs from tuberculosis (IHME 2019).

Table 1-3:

**Percentage of Deaths
Attributable to Tobacco
Use, 2019**

Source: IHME 2019.

| Rank | Cause | Percentage |
|------|---------------------------------------|------------|
| 1 | Tracheal, bronchus, and lung cancer | 66.5 |
| 2 | Larynx cancer | 63.4 |
| 3 | Chronic obstructive pulmonary disease | 53.2 |
| 4 | Other pharynx cancer | 47.0 |
| 5 | Lip and oral cavity cancer | 46.5 |
| 6 | Esophageal cancer | 43.4 |
| 7 | Aortic aneurysm | 34.6 |
| 8 | Bladder cancer | 33.9 |
| 9 | Peripheral artery disease | 26.1 |
| 10 | Nasopharynx cancer | 25.0 |
| 11 | Ischemic heart disease | 21.9 |
| 12 | Pancreatic cancer | 21.4 |
| 13 | Leukemia | 19.3 |
| 14 | Kidney cancer | 18.1 |
| 15 | Stomach cancer | 18.0 |
| 16 | Liver cancer | 17.7 |
| 17 | Lower respiratory infections | 17.2 |
| 18 | Stroke | 16.8 |
| 19 | Upper digestive system diseases | 16.3 |
| 20 | Tuberculosis | 15.5 |

Table 1-4:

**Global Deaths and DALYs
Lost Due to Tobacco Use,
2019**

Source: IHME 2019.

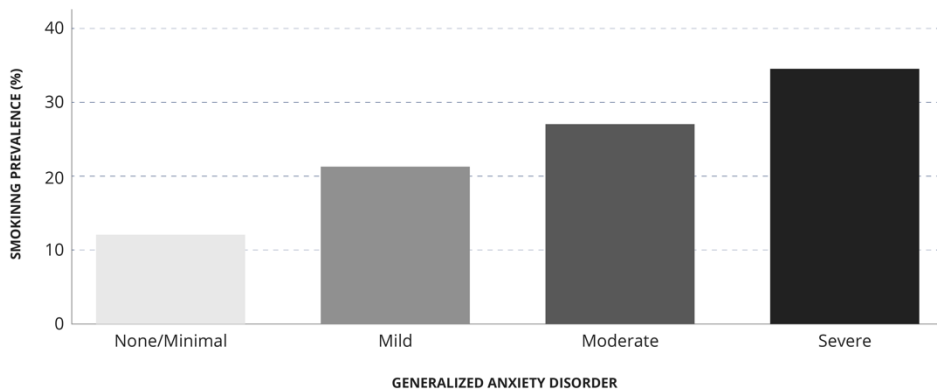
| Disease | Deaths | DALYs |
|------------------------|-----------|------------|
| All cancers | 2,598,825 | 59,323,572 |
| Lip and oral cancers | 92,660 | 2,472,250 |
| COPD | 1,744,688 | 37,938,429 |
| Cardiovascular disease | 3,192,804 | 82,876,355 |
| Tuberculosis | 197,515 | 6,267,583 |

MENTAL HEALTH DISORDERS AND TOBACCO USE

People with mental health disorders often bear a disproportionate share of the smoking burden (Lipari 2017; Prochaska 2017). About one-third of individuals with mental illness are smokers, and they smoke more cigarettes each month than smokers without a mental illness (Lipari 2017). In the United States, lifetime smoking rates are higher among people with major depressive disorder (59%), bipolar disorder (83%), or schizophrenia and other psychotic disorders (90%) (American Lung Association 2020). Moreover, in the U.S., individuals diagnosed with generalized anxiety disorder had higher smoking rates than those with no or minimal anxiety (12%), with smoking rates of 21.5%, 27%, and 34.5% for mild, moderate, and severe anxiety, respectively (see Figure 1-7) (CDC 2020). The result is predictable and devastating, with individuals with mental illness accounting for more than 200,000 of the 520,000 tobacco-attributable deaths in the United States annually (Prochaska 2017). Similar trends have been observed in Australia, the United Kingdom, and other countries (Public Health England 2021).

Figure 1-7:
Smoking Prevalence in the United States by Individuals with Generalized Anxiety Disorder, 2019*

**For individuals aged 18 and over.
Source: CDC 2020.*



Smoking Among Vulnerable Groups

It is important to highlight smoking or tobacco use among vulnerable groups. These include:

Homeless people. Smoking is endemic among the homeless, who are disproportionately affected by tobacco-related diseases (Scheibein 2020).

Indigenous people. Indigenous peoples constitute 5% of the world's population and 19% of the poorest peoples of the world. Smoking cigarettes has become the largest preventable cause of premature death among indigenous peoples in many countries. However, because smoking is all too often overlooked in this population, not much reliable data are available (Glover 2020). Smoking prevalence among indigenous people ranges from very low (generally in countries naive to tobacco) to extremely high. In general, in countries that were colonized by European empires, smoking prevalence in indigenous people is disproportionately high compared with that of the dominant ruling ethnic group (Glover 2020). As examples: 83% of Yolngu men in remote Arnhem Land communities in Australia smoke; 41% of male and 36% of female Aboriginal and Torres Strait Islanders in Australia smoke; 51% of male and 53% of female Inuits in Canada smoke; 51% of males in the indigenous Koraga population in India smoke and 42% of male and female Northern Plain American Indians smoke. The drivers of tobacco use by indigenous people are complex and multifactorial. An understanding of those drivers is critical to develop policies that are equitable and address harms.

LGBTQ/Rainbow communities. People with varied sexual and gender identities and orientations have disproportionately high rates of smoking compared with the heterosexual population. Individuals in these communities typically begin smoking much earlier in life as well (Glover 2020). Smoking prevalence among individuals in rainbow communities in Australia and the United States is reportedly 1.5 to 2 times that of the national population. One US study showed that gender-diverse youth were three times more likely to have tried smoking tobacco than students who identified as female. Although data are limited on smoking among transgender individuals, another study found disproportionately higher rates of smoking among transgender adults than cisgender adults (Glover 2020).

Chapter 2

Cessation Efforts Stall

Summary

The fastest way to reduce the number of deaths from tobacco is to get people to stop smoking, a view that is backed by copious research. Efforts at cessation, however, have stalled. In the 20th Century, 100 million people died from diseases related to cigarette smoking or other dangerous uses of tobacco. If current trends continue, in the 21st century that figure will rise to 1 billion people.

- The WHO-FCTC is the cornerstone of policy aimed at reducing the burden of tobacco-related disease globally. While the FCTC has made modest progress in some areas of tobacco control, little progress has been made in implementing taxes and price increases, banning advertising and promotion, instituting plain packaging and warning labels, and establishing smoke-free places. The data calls into question the idea that, 16 years after the treaty entered into force, serious progress has been made in implementing tobacco control.
- Cessation solutions currently on the market have been successful in helping only a small proportion of smokers quit, and such solutions have limited availability in LMICs. Many countries have not introduced cessation efforts in primary health care settings.
- Millions of tobacco users want to quit but are thwarted by lack of proven cessation tools and tobacco harm reduction (THR) products. Misinformation about THR risk is rampant.
- If current cessation policies continue, by 2060 about 6.5 million people will die from tobacco-related causes. If, on the other hand, we take full advantage of new cessation and harm reduction solutions, about 3.5 million people will die from tobacco in 2060 – annual deaths will be cut nearly in half over four decades.

Cessation Efforts and Approaches

Decades of action have made little difference in the number of tobacco users worldwide and have led to only marginally improved outcomes. More people smoke today than 30 years ago. According to the WHO report on the global tobacco epidemic, many countries have not introduced cessation programs in primary health care settings and have inadequately implemented the WHO-FCTC MPOWER measures (see textbox, FCTC and MPOWER Measures) (WHO 2021c). Adult cessation interventions have had a modest impact on quitting rates, and only slow progress has been made in reducing smoking prevalence in people over 50 years of age.

Solutions currently on the market have been successful in helping just a small percentage of smokers quit, as the 2018 EY-Parthenon report shows. Smoking cessation products – including pharmaceuticals, nicotine-

replacement therapy (NRT) nasal sprays, oral inhalators, patches, and gum – were effective for fewer than 25% of smokers after 12 months (EY-Parthenon 2018). A different study looked at cessation rates in smokers with COPD, an at-risk population that would greatly benefit from quitting. One study group underwent standard smoking cessation intervention and the other received long-term NRT. Rates of abstinence at 12 months were almost the same: 11.7% and 12.2%, respectively (Ellerbeck 2018).

Cessation tools of any kind are not widely used in LMICs. The failure to make effective cessation tools universally available impedes global progress toward ending the harms of tobacco.

Effective cessation tools are also poorly used within clinical settings with high-risk patients in all countries. Populations with behavioral health disorders, many types of cancer, COPD, and tuberculosis have high rates of smoking, which worsens disease outcomes. Unfortunately, physicians and nurses are not trained to recognize the value of effective tools for cessation and THR (see Chapter 4 for more detail).

Long-Term Trends in Tobacco Use

In the 20th century, 100 million people died from diseases related to cigarette smoking or other dangerous uses of tobacco. If current trends continue, in the 21st century that figure will rise to nearly 1 billion people – the equivalent of the entire populations of Indonesia, Brazil, Nigeria, Bangladesh, and the Philippines combined. WHO has not revised this estimate downward since 2008 (WHO 2008). Although daily adult smoking prevalence has decreased globally, there are wide disparities among countries. If current cessation policies are extended, maintaining the status quo, we can predict that in 2060 about 6.5 million people will die from tobacco. If, on the other hand, we take full advantage of new cessation and harm reduction technologies, about 3.5 million people will die from tobacco in 2060 – a reduction of 3 to 4 million annual deaths from tobacco within four decades. In no other area of public health do the potential gains approach that order of magnitude (see Figure 2-1).

FCTC and MPOWER Measures

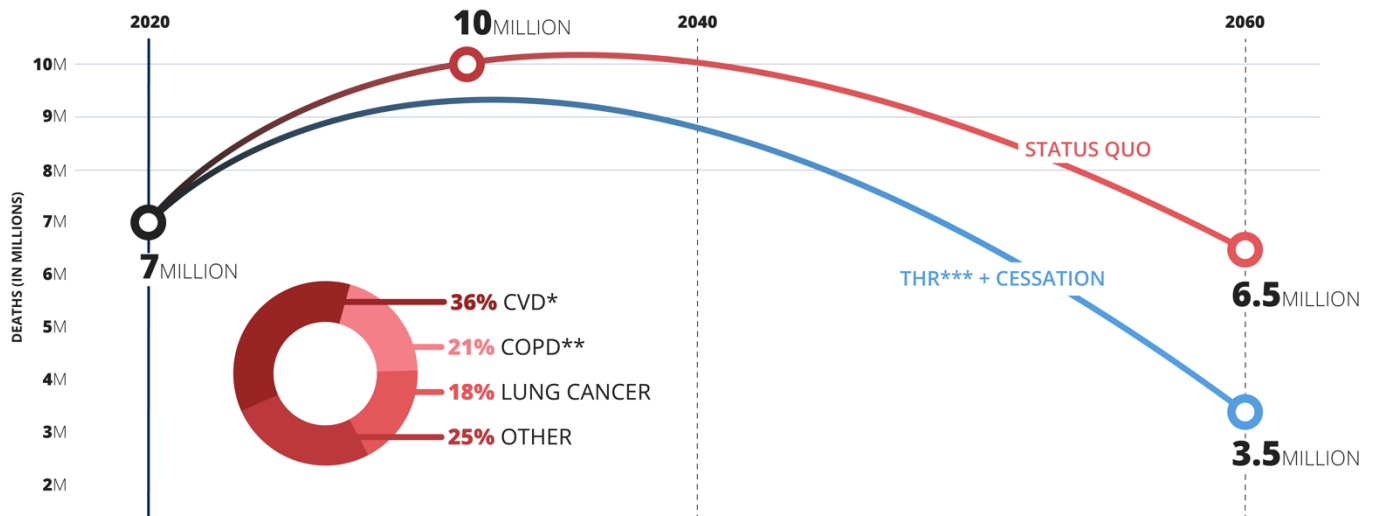
The WHO-FCTC, adopted by WHO member states in 2003, is the cornerstone of policy aimed at reducing the burden of tobacco-related disease globally. Created in response to the globalization of the tobacco epidemic and the efforts of the tobacco industry to thwart anti-smoking measures, the treaty specifies a mix of price and tax measures together with education, regulation of tobacco product contents and labelling, and demand reduction steps (WHO 2003). A total of 181 countries have now ratified the treaty (WHO 2018a).

Introduced in 2008, MPOWER presents six evidence-based strategies for tobacco control. If fully implemented, the effects of MPOWER could be considerable. The MPOWER strategies are as follows (WHO 2008):

- Monitoring tobacco use
- Protecting people from tobacco smoke by promoting adoption of smoke-free policies
- Offering the public help to quit tobacco use
- Warning about the dangers of tobacco
- Enforcing bans on tobacco advertising, promotion, and sponsorship
- Raising taxes on tobacco

Figure 2-1:

Estimated Trends in Tobacco-Related Deaths, 2020–2060



Source: Yach 2020a.

The Cornerstone of Tobacco Control Efforts

In the years since it came into force, the FCTC has made modest progress in certain areas, but little or no progress in others (see textboxes, FCTC and MPOWER Measures, and Need for Cessation Programs). Only 32 WHO member states out of 193 are on track to achieve the target of a 30% reduction in tobacco use prevalence between 2010 and 2025 (WHO 2021a). A 2019 analysis found no significant change in the rate at which global cigarette consumption had been decreasing since adoption of the FCTC in 2003 (Hoffman 2019).

Despite the lack of sophisticated technology at the time, THR was part of WHO's own definition of tobacco control in the original FCTC document (Article 1): "[T]obacco 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" (WHO 2003).

Over time, however, instead of embracing harm reduction, WHO has actively thwarted efforts to expand access to technologies such as e-cigarettes and heated tobacco products. For instance, the WHO has worked in concert with The Union, a group that manages grants from the Bloomberg Initiative to Reduce Tobacco Use and whose

Need for Cessation Programs

"Offering help to quit ... is an essential component of any tobacco control strategy Unfortunately, only 13 new countries have started providing comprehensive cessation programs since 2007. There are now 23 countries protected by this measure, up from 10 countries in 2007."

—WHO Report on the Global Tobacco Epidemic, 2019a, 2019b

2020 position paper “Where Bans Are Best” called for complete prohibition of e-cigarettes and heated tobacco products in LMICs (The Union 2020). There is little evidence that these strategies have helped tobacco users (WHO 2019a; Yach 2020a).

Implementation of the FCTC and MPOWER

A little more than a decade after the introduction of MPOWER, tobacco demand reduction policies have had limited success. An analysis of 155 countries did find that, if tobacco control had remained at the 2008 level, smoking prevalence would have been slightly higher than the observed 2017 rates, with 31 million, or about 3%, more smokers (ages 15 years and up) worldwide (Flor 2021). However, progress was disappointingly low for the global implementation of taxes and price increases, advertising and promotion bans, plain packaging and warning labels, tobacco mass media, and smoke-free places (see textbox, Potential of MPOWER to Curb Tobacco Use). The effects were most pronounced on youth, but only marginal on helping adult smokers to quit (Puska 2019; Yach 2020a). Moreover, the impact of tobacco control policies has been uneven. Countries with higher initial tobacco control preparedness and a higher smoking burden – for the most part, developed or high-income countries – have considerably reduced adult daily smoking prevalence. In LMICs, implementation of the provisions of the FCTC has been slow (Husain 2020). Specifically,

Potential of MPOWER to Curb Tobacco Use

According to economists Ngo et al (2017), who assessed the impact of MPOWER measures policies in a global context for the years 2007–2014 on cigarette smoking prevalence and consumption, if the MPOWER package had been implemented globally to the highest levels from 2007 to 2014, there would have been a reduction in smoking prevalence of 7.3% among adults and a reduction of 13.8% in cigarette consumption (Ngo, 2017).

- **Taxes and price increases:** Tax and price increases are among the most effective tobacco control strategies (Flor 2021). However, global progress in tobacco price and tax increases has lagged, and effective tax policy is underutilized. In the 2019, the percentage of countries in which WHO’s commitment fulfillment progress (COM) indicators for tobacco taxes had been fully achieved were 19.3% (WHO 2021b). Cigarettes remain highly affordable in many countries, particularly high-income nations. Average total tax as a proportion of price amounts to 67% in high-income countries, compared to 51% in low-income countries (WHO 2021d). In LMICs, inefficient tiered-excise tax systems enable a wide range of price differences among a variety of tobacco products (e.g., cigarettes, bidis, kreteks, cigars, hand-rolled), allowing consumers to find cheaper alternatives.
- The Royal College of Physicians in its 2021 report on tobacco control noted that the close link between smoking and poverty makes tobacco tax increases regressive (Royal College of Physicians 2021). Still, reluctance to let the tax burden fall on lower-income smokers only perpetuates health harms and economic inequities. Eradicating or greatly reducing smoking could inject billions of dollars back into low-income communities. For the best results, tax increases

should be used in concert with strategies and tools that make smoking cessation as easy as possible, such as making taxes proportionate to the varying risks associated with different types of products (see Chapter 6 for more details).

- **Advertising and promotion bans:** Full advertising and promotion bans can be effective in decreasing tobacco consumption and smoking initiation rates, particularly among youth. Yet the WHO 2020 mid-point evaluation reports that in 2019, tobacco advertising bans had been fully achieved in only 25% of countries (WHO 2020).
- **Plain packaging and warning labels:** In 2019, graphic warnings were fully achieved in only 47% of countries (WHO 2020). Large pictorial graphic warnings are the most effective in grabbing smokers' attention but are lacking in countries with high numbers of smokers, including China and the United States (Flor 2021). Plain packaging can have unintended consequences as well. In Australia, for instance, plain packaging legislation caused some smokers to switch to cheaper brands and increase their tobacco intake (Underwood 2020).
- **Tobacco mass media:** Anti-tobacco mass media campaigns³ are an effective and relatively inexpensive way to educate the public about the dangers of smoking and to encourage cessation but remain underutilized. More than half of the world's countries did not run a sustained anti-tobacco mass media campaign from 2019 to 2021, leaving 17% of the world's population unreached. Of the 45 countries that did mount a best-practice mass media campaign, 15 were high-income countries, 27 were middle-income, and just three were low-income. (WHO 2021d). In the United Kingdom, £23 million (\$43 million USD) was spent on mass media campaigns in 2008, the year that immediately preceded the highest uptake of National Health Service smoking cessation services by smokers. U.K. mass media spending plummeted in 2010 and has remained low since (Royal College of Physicians 2021).
- **Smoke-free places:** Secondhand smoke substantially increases the burden of smoking-related diseases and death in nonsmokers. In 2017, 2.2% of all deaths globally were attributable to secondhand smoke, with women and children bearing most of the burden (Flor 2021). Few countries prohibit smoking in all private workplaces, pubs, and bars (Chung-Hall 2019). According to WHO 2021, about one third of countries in each income group (low, middle, and high) are covered by comprehensive smoke-free bans. More than half of these countries are middle-income countries. Among high-income countries, 30% have no or minimal smoking bans (WHO 2021d).



³ Tobacco mass media control uses major channels of communication, such as television, radio, newspapers, billboards, internet, leaflets, or booklets, to deliver tobacco control messages to a large population.

Lack of Progress in Cessation

Rates of smoking cessation, which are important indicators of the impact of tobacco control, tend to be low globally. Quit rates for smoking are lowest in three of the four most populous countries: China, India, and Indonesia. In seven countries (Bangladesh, China, Egypt, India, Indonesia, Malaysia, and Russia), the quit rates for men are less than 20% (quit rates tend to be higher for women than for men in most countries).

A study of almost 120,000 Cuban adults over nearly 20 years found that smoking accounted for a quarter of all premature deaths among the study subjects. Quitting before about age 40, however, prevented almost all the excess mortality due to smoking (Thomson 2020) (see textbox, Value of Quitting by 40). In fact, substantial benefits can be achieved when cessation occurs as late as the 60s. No population is a lost cause (Yach 2020b).

However, the original FCTC did not make clinical, personalized, or medical solutions high priorities (Yach 2020a). Implementation of cessation assistance (Article 14, Demand-Reduction Measures Concerning Tobacco Dependence and Cessation) is weak, with only 23 countries providing services at the best-practice level, and Article 1 does not expand on the potential of harm reduction. (WHO 2019a).

It is critical to note that the omission of both NRTs and THR as cessation tools by the WHO is telling as the two are intimately linked to cessation. Both are predicated upon the idea that cessation can be achieved by providing smokers with a safer, less harmful experience that can satiate their physiological dependence on nicotine without exposing them to the dangerous toxins found in a cigarette. The lack of attention paid to both NRTs and THR by the WHO thus represents a blind spot in its approach to cessation.

Many Desire to Quit but Are Thwarted

In most countries, large proportions of tobacco users want to quit (WHO 2021d). In Norway, 72% of respondents answered yes to the question, “Are you planning to quit smoking?” compared to 23% of respondents in Japan (see Figure 2-2). A total of 83% of respondents in Norway said they had made a serious attempt to quit smoking in the past, compared to 37% in Greece (Global State 2020). In 2015 in the United States, 68% of adult smokers reported wanting to stop, and 55% had made a past-year attempt to do so (CDC 2020). Yet fewer than one-third

Value of Quitting by 40

“[E]ven among smokers who started very young, the sooner they quit, the lower their risk of premature death; and those who quit successfully before age 40 years ... avoided most of the excess risk of premature death that would otherwise be caused by prolonged smoking.”—Thomson et al, 2020

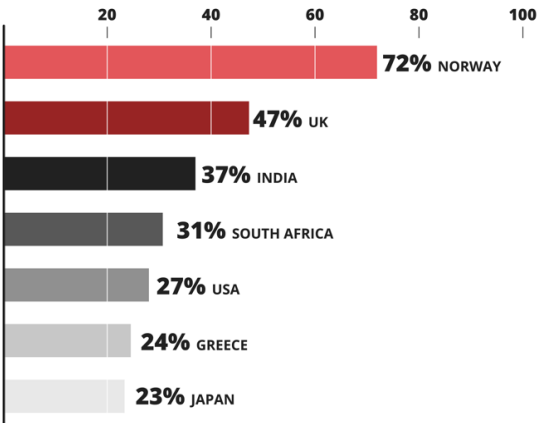
“Cessation, particularly before age 40 years, yields large reductions in mortality risk. Up to two thirds of deaths among smokers are avoidable at non-smoking death rates, and former smokers have about only a quarter of the excess risk of death compared to current smokers.”—Jha 2020

“Smoking cessation or adopting harm-reduction strategies before age 50 can completely eliminate excess risk of mortality due to smoking.”—Hajat et al 2018

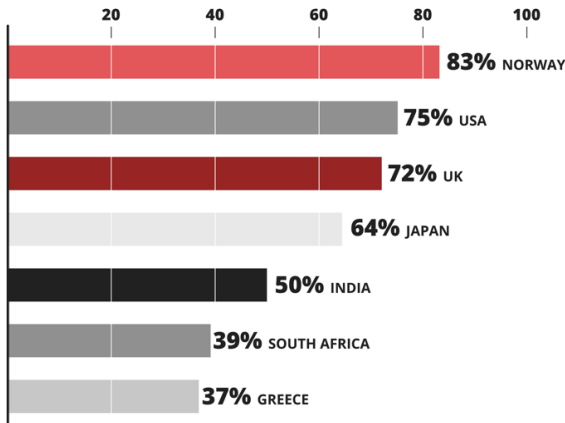
of people trying to quit in 2000–2015 used evidence-based cessation techniques, such as combined counseling and medication (Babb 2017). NRTs and medications including varenicline and bupropion, have been shown to be effective aids to quitting across broad range of populations. Varenicline and bupropion may be underused due to prescriber concerns over possible adverse effects (Aubin 2014; Burke 2016; Roddy 2004).

Figure 2-2:
Desire to Change Behavior, by Country

Percentage of respondents who answered YES when asked **are you planning to quit smoking?**



Percentage of respondents who answered YES when asked **in the past, have you ever made a serious attempt to quit smoking?**



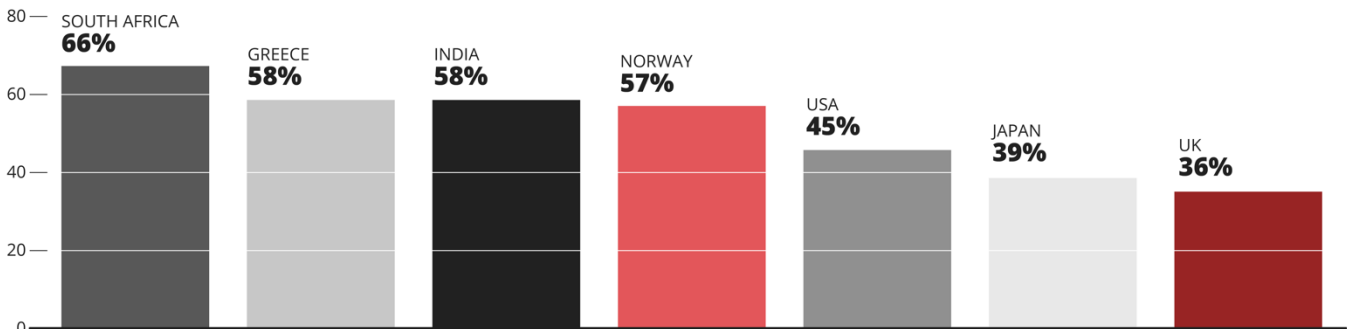
Source: Global State 2020.

Misinformation and Misunderstanding About THR

There is widespread misinformation and misunderstanding about THR and its role in cessation (see Figure 2-3). Two-thirds of those questioned in South Africa thought e-cigarettes were equally or more harmful than combustible cigarettes. In the United Kingdom, despite its relatively progressive views on THR, one-third of respondents held this view.

Figure 2-3:
Perceptions of E-Cigarette Risk

Percentage of respondents who answered they believe **e-cigarettes are equally or more harmful than combustible tobacco**:



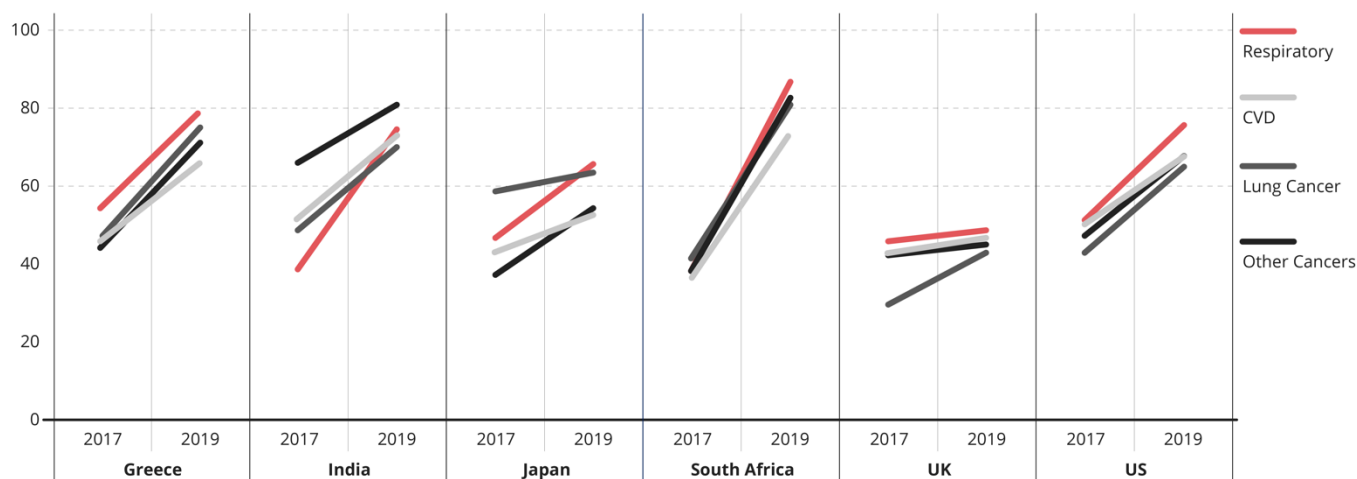
Source: Global State 2020.

Inaccurate perception of specific health risks associated with THR products is also widespread (see Figure 2-4). In South Africa, the proportion of respondents who thought nicotine/e-cigarettes/vaping cause lung cancer doubled to more than 80% (Global State 2020). See Chapter 6 for more detail.

Figure 2-4:

Perceptions of Specific Health Risks, 2017 vs 2019

Based on what you know or believe, do you think nicotine/EC/vaping devices cause...

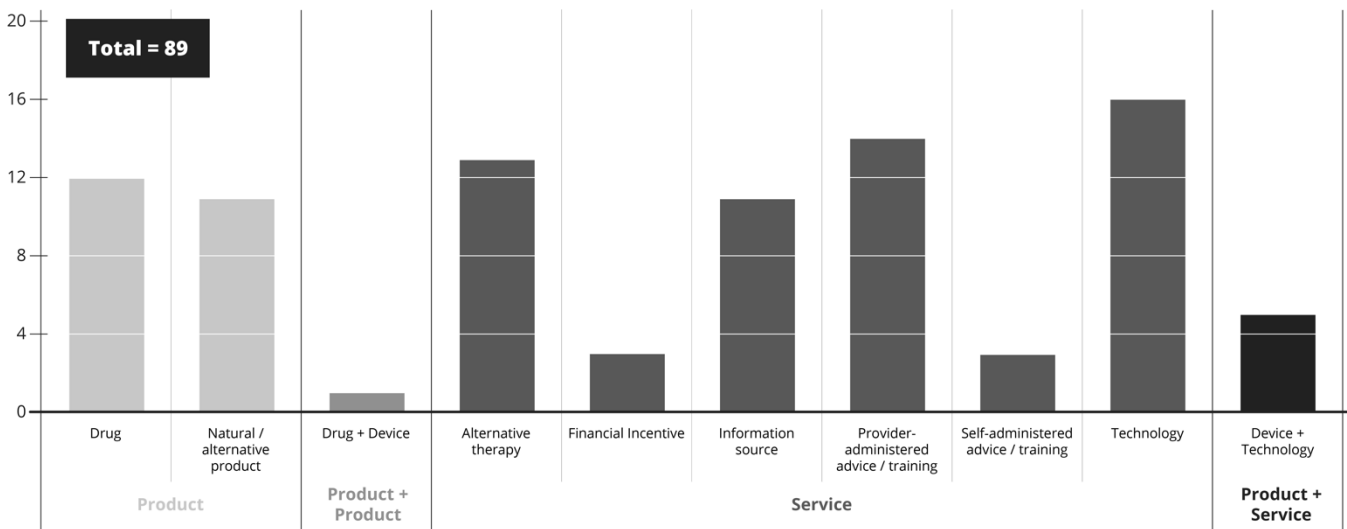


Source: Global State 2020.

The Challenge of Quitting Smoking

Although most smokers want to quit, success is elusive and nearly always requires repeated attempts. With no help whatsoever, only about 3% of smokers manage to stop, while a survey by the CDC found that, with or without assistance, only 7% of smokers were able to refrain from smoking combustible cigarettes for 6 to 12 months (Babb 2017). There are 89 products on the market specifically to help people quit smoking and 12 smoking alternatives that may help but are not designated as such (see Figure 2-5) (EY-Parthenon 2018). Assistance includes drugs, natural substances, mindfulness training, financial incentives from life insurance companies, and new technologies. Physicians for decades have prescribed a combination of prescription drugs, such as varenicline or bupropion, with NRT products such as gum, patches, spray, and lozenges. Withdrawal from tobacco produces symptoms that include irritability, insomnia, an inability to concentrate, headaches, weight gain, and even flu-like responses (What to Expect 2019). Relapse is common. A combination of NRT with prescription medication increases the quit rate to 6% to 15% (Cox 2018), still a low proportion. Clearly, willpower, NRT, and drugs are not enough.

Figure 2-5:
Marketed Available Products and Services by Type



Source: EY-Parthenon 2018.

Cessation and Marginalized Persons

Especially for those who are marginalized in society, in both LMICs and wealthier nations, smoking cigarettes may help relieve a sense of hopelessness, dispel anger and frustration, encourage participation in a traditional ritual, or may simply provide a pleasant way to pass time. People in these groups may lack access to proper medical care, health insurance, smoking cessation aids, and support. In addition, many mental health professionals are reluctant to encourage their patients to quit because of the presumed negative effect on emotional status (Glover 2020).

Cessation Support in LMICs

A 2020 study found that NRTs were not available in 62 of the 195 countries surveyed, and only 25% of nations with availability partially or wholly covered costs of cessation treatments and services (Patwardhan 2020). The WHO Model List of Essential Medicines, which is used to guide drug access, does include NRT products for tobacco addiction, but only 13 countries place such products on their own national essential medicines lists. In addition, among the 10 countries with the highest numbers of tobacco users and substantial burdens of disease from tobacco use, only two (Brazil and Pakistan) include NRT products as essential medicines (Shah, in review for publication). Other factors also may make smoking cessation more difficult in LMICs. For example, South Africa – deemed the world's second most stressful country in which to live, with high rates of depression and anxiety – has an estimated 7 million smokers. These comorbidities complicate cessation, as services may need to include psychological and behavioral support (Tadzimirwa 2019).

Searching for Solutions

Chapter 3

Emergence of Technological Innovation

Summary

As the battle to eradicate combustible smoking continues, THR products offer a way to switch to safer alternatives on the road eventually to quitting completely. Harm reduction technologies herald a new chapter in the fight against combustible tobacco, and major tobacco companies are at the forefront of this technological innovation. Making new technologies easily accessible to people worldwide, including LMICs, where the vast majority of smokers live, can help stem the death toll linked to combustible tobacco. The tobacco industry is taking a lead role in THR product research, development, and patents. Partly as a result, traditional anti-tobacco forces are resisting the notion of a continuum of harm when it comes to tobacco – even though many of the same people and organizations embrace harm reduction in other realms, such as methadone clinics for those addicted to opioids.

What Is Tobacco Harm Reduction?

Combustible tobacco, no matter its form, is a dangerous product. But tobacco exacts its health cost slowly over decades, and, by the time a smoker is diagnosed with lung cancer, cardiovascular disease, or COPD, it may be too late.

This is where THR comes in. The WHO does not define THR but alludes to it as part of its definition of tobacco control. According to Article 1 of the FCTC, 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” (WHO 2005). Although the ideal is for smokers is to quit completely, a large proportion does not want to quit or has been unable to do so despite repeated attempts, so tobacco harm reduction strategies are likely to reduce the risks to their health (McNeill 2004).

The pragmatic principle of THR is the urgent need to save millions of lives. THR replaces combustible tobacco with noncombustible products that contain nicotine, the addictive chemical compound that keeps smokers coming back for more but has not itself been linked to tobacco-related cancers and other diseases such as COPD (FDA Nicotine 2020).

THR devices such as e-cigarettes, heat-not-burn (HNB) products, snus, and nicotine pouches are now disrupting the market in a world where most health authorities still concentrate on what has been called the “unrealized and unrealizable perfection of nicotine prohibition” (Abrams 2018).

Along with NRTs, counseling, and support groups, these THR products are becoming a key part of a realistic effort to reduce the serious health risks of smoking. In its infancy when the FCTC was approved, THR now plays a vital role.

Emergence of New Technological Innovations

In 2003, as the landmark WHO-FCTC was being signed, Chinese pharmacist Hon Lik introduced what would become the world’s first commercially successful e-cigarette. Called “Ruyan,” which in Mandarin means “like smoke,” the device was Lik’s response to the death of his father from tobacco-related causes and to his own futile attempts to quit smoking (Boseley 2015).

Looking much like e-cigarettes (only larger), with a battery, a plastic cartridge that contained a nicotine solution, and an atomizer that caused the solution to vaporize, Ruyan was a harbinger of this century’s “disruptive technologies” that have shaped THR. An influential article in the *Harvard Business Review* defines a disruptive technology as one that “unexpectedly displaces an established technology” (Christensen 2015). E-cigarettes, with their ability to deliver nicotine in a less harmful way than combustible cigarettes containing more than 7,000 chemical compounds, including more than 60 carcinogens, certainly seem to fit that description (Glynn 2014).

This role for new THR technologies plays out along a continuum of harm reduction (see Figure 3-1), with dangerous combustible smoking on one end and not smoking at all on the other. THR fits what economist Klaus Schwab calls the “Fourth Industrial Revolution,” or 4IR – one in which governments, organizations and individuals need to innovate and cooperate in ways they have never done before. This industrial revolution fuses the digital, biological, and physical worlds, thus influencing all disciplines, economies, and industries (Schwab 2017). For the tobacco industry, 4IR means a shift to create products and services that meet current consumer needs and anticipate future ones. And what most consumers who are smokers want is a way to quit combustibles (Wall Street Journal custom content, undated).

To that end, the technological disruption in the tobacco industry has been enormous, with more patents and scientific publications than ever before. The new generation of reduced-risk, noncombustible products include:

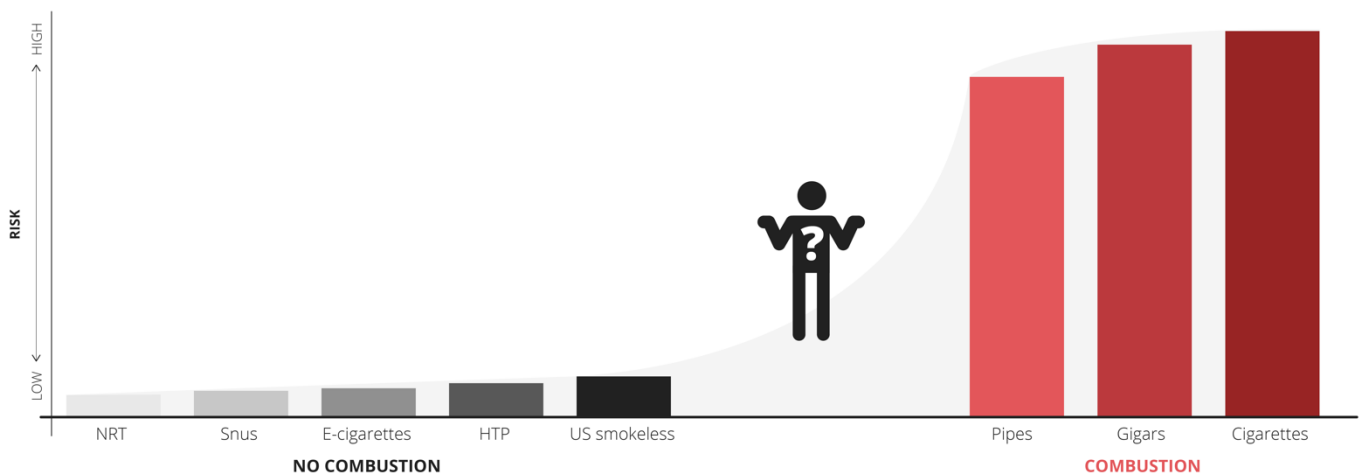
- **Various iterations of e-cigarettes, also known as vapes** – battery-operated devices that people use to inhale an aerosol that typically contains nicotine. Products now on the market include Enovap, a smart e-cigarette and application meant to help users wean themselves off combustible cigarettes and an addiction to nicotine, and the

Voke 0.45 mg inhaler, approved by the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) in 2014 and sold as an over-the-counter nicotine reduction therapy (EY-Parthenon 2018; Enovap; PR Newswire 2019).

- **HNB products** – also known as noncombustible cigarettes. These are devices that heat tobacco, creating an aerosol, as opposed to burning tobacco and chemical additives, releasing toxic smoke. HNB products warm the tobacco enough to create an aerosol the user then inhales. Examples include IQOS from PMI, Ploom TECH from Japan Tobacco International, Glo from BAT, and PAX from PAX Labs (WHO HNB Fact Sheet).
- **Oral smokeless tobacco** – primarily products such as snus, available in both in loose form and portioned packets, placed behind the upper lip for as long as it takes for the user to feel the need for another dose of nicotine. Popular mostly in Sweden and Norway, snus is a variant of dry snuff from the 18th Century. Snus differs from snuff and other oral tobacco products, however, because its production process decreases both the amount of microbial activity and the level of toxic, tobacco-specific nitrosamines that are linked to cancer.
- **Nicotine pouches** – white, pre-portioned pouches that contain either a tobacco-derived or synthetic form of nicotine, but no tobacco leaf, dust, or stems. The pouches are a tobacco-free form of snus, so new to the market that they have not yet been subject to independent testing. A recent report says they have the potential to be “credible, viable, and safer” alternatives to cigarettes (Patwardhan 2021).

Figure 3-1:

Relative Risks of New THR Technologies Compared to Combustible Products



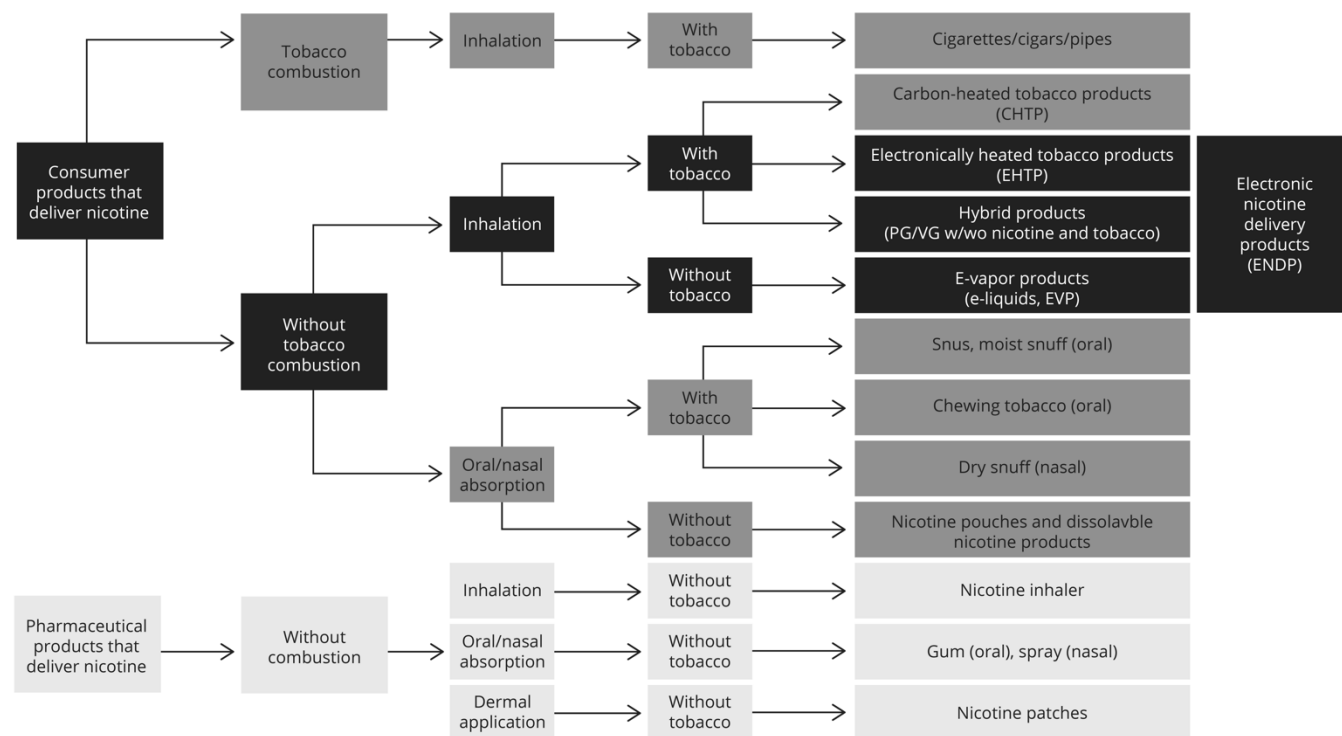
Source: Shapiro 2020.

In addition, in the spirit of “4IR,” smart phone, smart watch, and smart lighter technologies are available, and a smart nicotine patch is in development. Some of these products have software through which users can log progress and access counsel and support (EY-Parthenon 2018, Ortis 2020).

In a perfect world, all these products would be tested, and re-tested, and measured over decades before they are deemed safe. But millions of people are dying from smoking, and decades of epidemiological research have demonstrated how smoking kills (Peitsch 2021). Remove or drastically reduce the elements of tobacco use that cause disease and death and you reduce risk, as Figure 3-2 illustrates.

Figure 3-2:

Toxicological Evaluation of Lower Risk and Higher Risk Electronic Nicotine Delivery Products

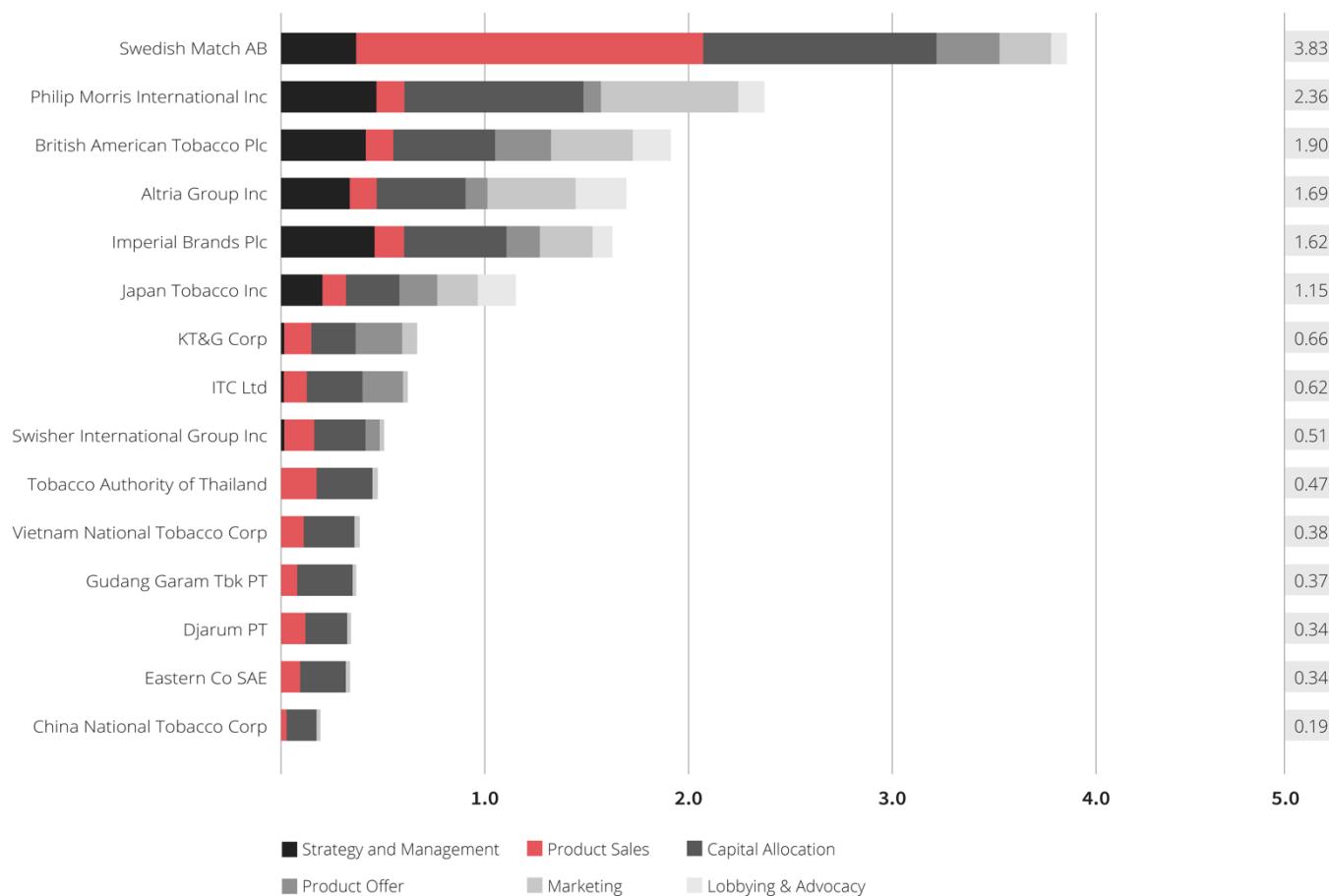


Source: Peitsch 2021.

Progress is also measured by the Foundation for a Smoke-Free World's Tobacco Transformation Index, which is meant to cultivate and dramatic industry change while holding companies accountable for their actions regarding THR. In its first-ever report, the index found that the highest-ranked companies tend to be publicly traded multi-nationals, with private and state-owned companies lagging far behind (Figure 3-3).

Figure 3-3:

Tobacco Transformation Index Ranking



Source: Tobacco Transformation Index 2020.

The 2020 edition of the Global State of Tobacco Harm Reduction report cautions there is no such thing as “absolute safety.” What is clear is that even newer products have been in circulation for more than 10 years, providing evidence that there may not be immediate harms. At the same time, the WHO maintains its estimate that 1 billion lives will be lost to smoking-related causes by the end of this century, thus underscoring the urgency of the research and the need to accept a reduced risk approach (Shapiro 2020).

Learning From the Past Informs a Healthier Future

Harm reduction itself is already widely practiced. For example, we use seatbelts when in a car or an airplane to temper risk. We don’t stop driving or flying altogether to prevent risk entirely. Vaccination comes with its own harms, but it reduces the risk of contracting COVID-19, measles or influenza.

In 1991, The *Lancet* published an editorial with the headline, “Nicotine use after the year 2000,” which outlined a strategy of encouraging “purified nicotine products as substitutes for smoking” to reduce risk. “There is no good

reason why a switch from tobacco products to less harmful delivery systems should not be encouraged,” the editorial read. “Smoking-related deaths after the year 2000 would fall steadily and substantially if this can be achieved” (Lancet 1991).

Yet little was done. Tobacco companies began research into less harmful products as early as the 1950s, but their “reduced-tar” cigarettes proved to be a smokescreen. Efforts by the WHO and other public health agencies have remained focused on stopping youth from taking up the habit and getting adults who do smoke to quit outright.

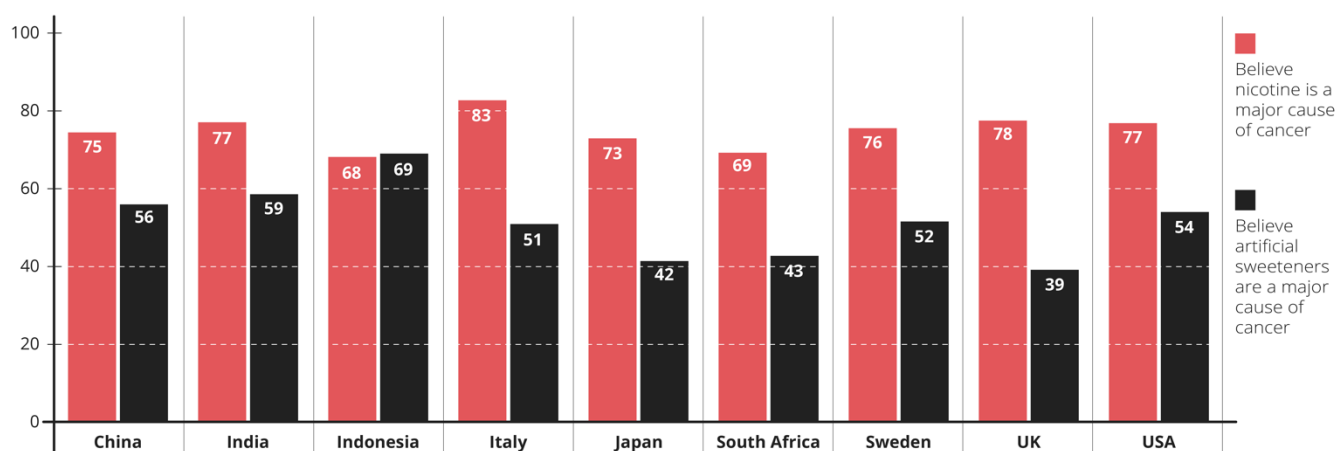
There is nothing in the FCTC that recognizes the current technological disruption (WHO 2005). The treaty did not acknowledge the possibility of patents or intellectual property advances that could help to reduce risk – even though the agreement was formulated at a time when effective HIV/AIDS drugs were becoming widespread. The WHO simply did not consider the tobacco industry capable of transformation.

But studies, including one based on US population surveys that was published in a 2017 issue of the *British Medical Journal*, have found that a substantial increase in e-cigarette use is associated with a statistically significant increase in the rate of cessation of combustible smoking (Zhu 2017). While warning of the possibility that young people who use e-cigarettes could transition to combustibles, a 2018 report by the US National Academies of Sciences, Engineering and Medicine stated that e-cigarettes may help adults quit the habit (Eaton 2018).

Michael Russell, a psychiatrist known as the father of THR, wrote that people smoke for the nicotine but die from the tar (Russell, 1976). But in the public and political discourse, nicotine, the addictive element in tobacco products, is erroneously linked to diseases caused by burning tobacco. A survey conducted last year in China, India, Indonesia, Italy, Japan, South Africa, Sweden, the United Kingdom, and the United States, found that three-quarters of respondents believe nicotine causes cancer -- while significantly fewer respondents believe that artificial sweeteners do the same. Findings are shown in Figure 3-4 (FSFW Insights Survey 2020). Misinformation persists. According to the National Cancer Institute, despite past fears, there is no clear evidence that artificial sweeteners cause cancer in humans [National Cancer Institute 2016].

Figure 3-4:

Believe Nicotine/Sweetener Causes Cancer



Source: FSFW Insights Survey 2020

It is in large part because of misperception about nicotine that many countries conflate combustibles with THR products. Australian adults, for example, now need a doctor's prescription to buy e-cigarettes that contain nicotine even though they can still buy packs of cigarettes in corner stores (see Chapter 6 for more detail). India, which ranks second behind China in deaths from tobacco, bans vaping and HNB products altogether (see Appendix that details on regulations in select countries). South Korea's government decrees that vaping could be just as dangerous as combustible cigarettes, perhaps even more so (Shapiro 2020, Australian Government: Department of Health, Aziani 2020).

Signs of Progress: Rapid Explosion of Patents and Research Papers

With a few of the companies introducing new technologies to encourage smokers of combustible products to switch to products that are less risky to their health, now is an opportune time to revisit the notion that all tobacco companies are the enemy and instead differentiate between the leaders and the laggards within the industry. A successful harm reduction strategy could in the long-term help drive combustible consumption down significantly; in the shorter-term, such a strategy can improve health outcomes and prolong millions of lives. The stakeholders – the WHO, interest groups, scientists, health care workers, consumers, and tobacco companies – each have a role to play, but it is the companies that are producing some of the best tools to end smoking. In nearly all cases, they are left out of the discussion. A recent study of patents and research papers on harm-reduction innovation brings several key insights into sharp relief:

- **Volume of Patents:** 73,758 patents on tobacco harm reduction technology have been published between 2010 and 2020, illustrating enormous activity by companies towards transformation (see Table 3-5).

- **Ownership Distribution of Patent Portfolios:** Figure 3-6 shows that government-owned China National Tobacco Corp (CNTC) has the largest number of patents across the three technology spaces, followed by PMI and BAT, with a Chinese e-cigarette company, Kimree Technology, in fourth place. CNTC published the vast majority of its patents in heated tobacco technologies with a focus on processing and preparation methods for tobacco.
- **Geography:** Besides China, which accounts for nearly 27% of all patent publications, the remaining activity was filed by the U.S. (24%), World Intellectual Property Organization (14%), Japan (10%), Australia (6%), Republic of Korea (6%), European Patent Office (5%), Canada (5%), Russia (1%) and Taiwan (1%) (Ghafele 2021). Much of the patent activity is taking place in wealthier countries, leaving developing countries, for now, out of the progress in harm reduction. Sharing intellectual property of less harmful technology and know-how with LMICs for the greater good, as some pharmaceutical companies have done, may be a way to increase access to and affordability of THR products. Tobacco companies must not forget that modern corporate social responsibility carries new weight and expectations.
- **Pharmaceuticalization of Tobacco:** Many of these nicotine technologies are patented under therapeutic classifications – for the treatment of health issues as opposed to recreational use (Ghafele 2021) -- although some critics have questioned the ethics of tobacco companies profiting from sales of therapeutics (Hendlin 2017).

Table 3-5:

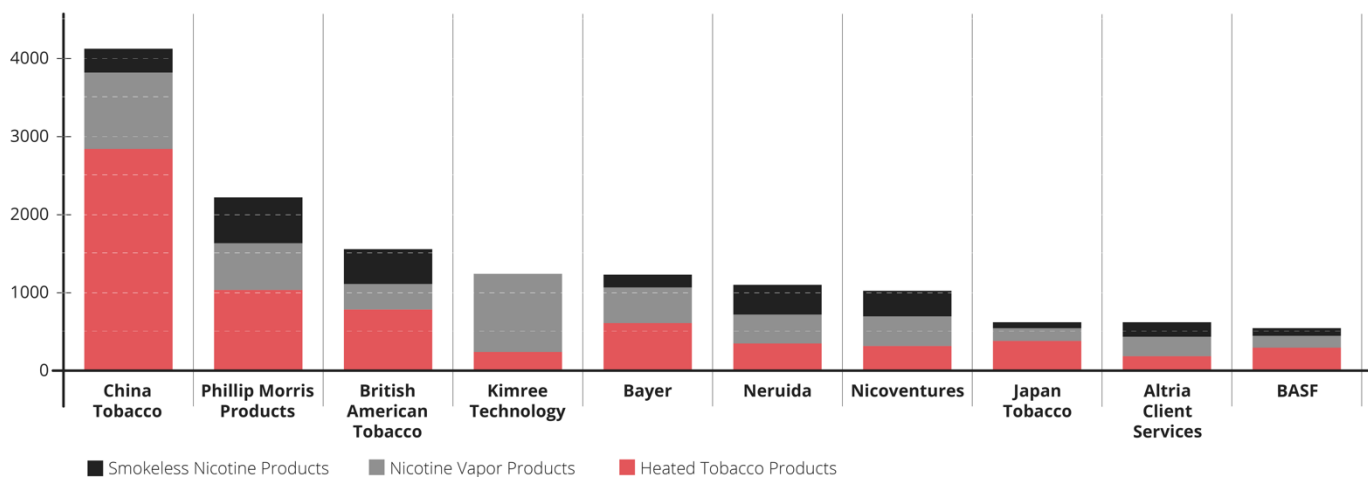
Estimates of tobacco-harm reduction technology patent volumes, 2010–20

| Technology Area | Patent Number | % of Total | CAGR % |
|------------------------------|---------------|------------|--------|
| Nicotine Vapor Technology | 26,540 | 36% | 9.1 |
| Heated Tobacco Technology | 30,432 | 41% | 4.1 |
| Smokeless Tobacco Technology | 16,786 | 23% | 1.1 |

Source: Ghafele, 2021

Figure 3-6:

Patents in each technology space by top 10 companies by number of patents



Source: Ghafele, 2021

Access to Technology Signals Way Forward

With access to harm reduction technologies, developing countries may be able to lower the death toll of combustible smoking. In 2015, for example, Public Health England released an independent report that found e-cigarettes were 95% less harmful than combustibles (McNeill 2015), and the U.K. government has promoted alternatives as an effective way to quit smoking. In the U.S., on the other hand, authorities have been more cautious in their characterization of THR products, in part because of a fear that e-cigarettes could be a gateway for younger smokers into combustible smoking and because of an outbreak in 2019 of heart attacks and dire lung injuries that were tied to black market e-cigarettes that contained THC and vitamin E acetate, an incident termed EVALI (e-cigarette or vaping use-associated lung injury). Reports, including a widely cited article published in June 2019 (Bhatta 2019), were definitively refuted by a retraction in February 2020 in the *Journal of the American Heart Association* (JAHA 2020).

Public Health England's latest update shows that among longer-term former smokers, fewer are using NRT while many more are using vaping products. The most common reasons for vaping were found to be quitting combustible smoking, staying off combustible smoking, and reducing the amount of combustible tobacco smoked. It is critical to understand consumer perspectives and lived experiences. Meanwhile, European Union data from 2017 show that Sweden has the lowest rate of daily cigarette use in the EU, at a mere 5%, while the use of oral tobacco, or snus, is 20%. The country also has the lowest rate of tobacco-related mortality in the EU and the lowest incidence of male lung cancer (Clarke 2019). These data show a correlation between the use of snus and better health – a classic example of productive harm reduction. Nevertheless, snus is banned in most European countries and can be difficult and expensive to buy elsewhere in the world (Clarke 2019).

In the United States, the FDA has not cleared any e-cigarette brand for marketing as a modified risk or modified exposure product, but it did clear the way, in October 2019, for Swedish Match USA to market eight of its

smokeless tobacco/snus products as “modified risk tobacco products” (MRTPs). A message on the packaging reads, “using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” (FDA news release 2019).

And in July 2020, the FDA issued four orders for Philip Morris S.A. to market as MRTPs its heated tobacco product (systems and chargers), called IQOS (for I Quit Original Smoking), and three types of heat sticks. The order contained a provision that the company must conduct post-market surveillance and studies to “determine the impact of the [MRTP marketing] order on consumer perception, behavior, and health, and to enable the [FDA] to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the [FDA], including constantly tracking the potential for increased use among youth.” The decision came more than three years after the company submitted more than 1 million pages of documentation to the FDA for review (FDA news release 2020; Philip Morris International 2020).

Regulatory Framework for Reducing Harm from Tobacco Must Include Nicotine as a Centerpiece

Four years ago, Scott Gottlieb, at the time the commissioner of the US Food and Drug Administration (FDA), and Mitch Zeller, who still serves as director of the FDA's Center for Tobacco Products, co-authored a paper arguing that the regulatory framework for reducing harm from tobacco must include nicotine as a centerpiece. “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,” they wrote. “The FDA’s approach to reducing the devastating toll of 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.” The two officials noted that while experts on both sides of the debate have expressed uncompromising views about the benefits and risks of e-cigarettes, the FDA would continue to build its understanding of the product’s potential benefits for addicted smokers based on careful regulatory science. “Rendering cigarettes minimally addictive or nonaddictive, within a landscape including other, noncombustible products such as e-cigarettes, represents a promising foundation for a comprehensive approach to tobacco harm reduction,” they continued. “Ultimately, we may be able to transform the tobacco marketplace and the delivery of nicotine to protect future generations of young people and save millions of lives” (Gottlieb 2017).

In the often-emotional debate over tobacco harm reduction products, the FDA does not begin with a position for or against. Instead, it considers the scientific data and considers public welfare *and* harm (Sharfstein 2015) (see textbox, Regulatory Framework for Reducing Harm from Tobacco Must Include Nicotine as a Centerpiece). To that end, a recent article in the journal *Mayo Clinic Proceedings* proposed a roadmap for responsible e-

cigarette development and distribution (Glynn 2021) – guidelines that could be applied to all new disruptive nicotine technologies.

The first step is to refocus tobacco control efforts on combustible cigarettes, continuing current tobacco policies that have proven effective, such as smoke-free workplaces and age limits on purchase. Responsible development requires a dialogue among all parties and the ability to conduct research with transparency and without fear of reprisal or condemnation.

Roadblocks to Acceptance

The demonization of both the tobacco industry and nicotine by the WHO, public health groups, and organizations such as Bloomberg Philanthropies can sometimes seem an insurmountable barrier to recognizing the value of THR as a tool to lessen health risks and get smokers to switch and quit.

The Bill and Melinda Gates Foundation and Bloomberg Philanthropies have donated about \$1 billion to support efforts of the FCTC, with little regard for the effectiveness of disruptive technologies (McInerney 2019). In particular, Michael Bloomberg, the former mayor of New York City, and his philanthropic organization have shown hostility to the concept of e-cigarettes and THR. In 2018, the organization committed \$20 million over three years to fund a partnership called “Stopping Tobacco Organizations and Products” (STOP) among the Tobacco Control Research Group at the University of Bath (U.K.), the Global Center for Good Governance in Tobacco Control, the International Union against Tuberculosis and Lung Disease, and Vital Strategies. The partnership is meant to “rigorously expose the tobacco industry’s efforts to derail tobacco control and hook a new generation of users,” a veiled reference to THR strategies (Bloomberg Philanthropies, 2018). In 2019, Bloomberg announced a \$160 million campaign in concert with Campaign for Tobacco-Free Kids to ban flavored e-cigarettes, linking the effort to the EVALI incident (Wang 2019). In a New York Times op-ed, Bloomberg and Matthew Myers of Tobacco-Free Kids noted there is no enticement like candy to get a child’s attention (Bloomberg 2019).

This overheated atmosphere was decried in an opinion piece by Dana Mowls Carroll of the University of Minnesota and several PhD students. The “continued promotion of select, polarized stances on e-cigarettes will threaten the integrity of research and the objective consideration of complicated public health issues,” they wrote. Especially worrying, they continued, is that scientists at the start of their careers may feel they have to take sides, thus affecting their perspectives, compromising research, and hindering progress in the elimination of tobacco-related disease and death (Carroll 2021). The same issue has also been raised by researchers who work in tobacco control for the industry. In a letter to the journal *Addiction*, Hughes and colleagues wrote that the industry is in a classic Catch-22 position because if industry researchers do their own studies, many journals refuse to publish them, no matter the scientific merit, while if they sponsor scientists to conduct independent research, those who agree to do so are stigmatized, including being barred from presenting at meetings or serving on tobacco control boards (Hughes 2018).

Still, new technology tends to overcome obstacles. It is more efficient, or more economical, or it fills a need in a way that is healthier than before. New nicotine-delivery systems can potentially save millions of lives in the long-term. Several tobacco companies that are dedicating human and financial resources to research, development, toxicology testing, and ease of use, are in a good position to explain what makes their products less harmful than the combustible cigarettes that still dominate the market today. Unfortunately, they are almost universally barred from doing so in advertising and other promotional pieces.

Impact on Tobacco Farmers and Tobacco-dependant economies

As the market transforms and shifts towards tobacco harm reduction, there are likely to be impacts on global dynamics of tobacco production, supply chains and those involved in the tobacco value chain particularly smallholder tobacco farmers in tobacco-dependant economies. Barclays, for instance, estimates that if 100% of PMI's cigarette volumes were to transition to IQOS, its tobacco leaf consumption would decline by 60% even with no decline in volumes (Barclays 2021). Further research is required to understand the analogous transitions to other THR products (snus, nicotine pouches and e-cigarettes) and its impact on the tobacco ecosystem. Some countries may be able to adapt to the transformation either through diversifying to alternative crops and livelihoods or through finding alternative uses of the tobacco plant such as extracting nicotine for tobacco cessation and harm reduction products to help growers move up the value chain into profitable and sustainable livelihoods.

Chapter 4

Mobilizing Physicians

Summary

In the last century, physicians played a crucial role in getting people to stop smoking, by both providing counsel and setting an example. In the wake of a 1962 Royal College of Physicians report that definitively linked cancer to combustible tobacco, medical doctors were among the first cohorts to quit (Berridge 2007). With more than 1 billion smokers worldwide today, physicians can take the lead once again, this time with new THR technologies added to their repertoire. But many are not doing so – for several reasons, including a lack of knowledge about THR, the false idea that quitting cold turkey is the only way to go, and the fact that many physicians, especially those in LMICs, believe they have other pressing diseases to deal with, while they also continue to smoke themselves. No matter where they practice, physicians may need more targeted support in providing tobacco harm reduction solutions for people who are trying to quit, for marginalized groups with high smoking rates – and for themselves.

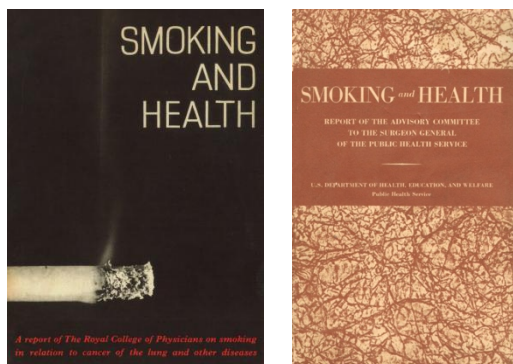
Overview

In an address to a Royal College of Physicians conference in 1964, Sir Robert Platt urged doctors to advise and push their patients to make changes that benefit their health, including stopping smoking (Platt 1964). “To talk of health education still smacks a little of vitamins, diets, and cold baths valetudinarianism in general,” he said. “However, this is an old-fashioned view to take,” he added, “for science has given us new powers and we are all concerned nowadays in giving advice about preventive inoculations against diphtheria, tetanus, tuberculosis and poliomyelitis, so why should we not give advice about the only common and preventable form of cancer yet known to medical science?” Platt chaired the College’s Commission on Smoking and Health, which produced the landmark 1962 report.

In the wake of both the 1962 report and the US Surgeon General’s report on the same subject (Image 4-1), which had been released just 12 days before Platt’s address, his message was that doctors should face facts and give up smoking cigarettes as an example for others to follow (Platt 1964).

Image 4-1:

Covers of 1962 and 1964 Reports



Sources: Royal College of Physicians 1962, NLM Profiles in Sciences 1964.

And they did, in great numbers. In 1951, for example, 68% of U.K. doctors smoked. By 1966, that proportion had fallen to 50%, and by 1991, to 18%. In the United States, Luther Terry, the surgeon general who initiated the commission, switched from cigarettes to a pipe, while commission member Leonard M. Schuman, an epidemiologist, quit smoking outright (Time 1964).

Physicians quitting smoking was a remarkable change, what has been called the harbinger of a new era of “coercive permissiveness” in health, with physicians giving patients unsolicited advice about lifestyle choices – advice they had previously avoided (Berridge 2007). Physicians have influence. Before the taciturn, hyper-masculine Marlboro Man or super-cool Joe Camel were ever conceived, before models for Virginia Slims declared, “You’ve come a long way, baby,” tobacco manufacturers used physicians to sell their brands as trusted role models and trend setters (Elliot 2008).

A new Royal College of Physicians (RCP) report on smoking and health emphasizes the leading role physicians can play in both getting patients to quit smoking and, with the help of current THR technologies, to reduce the risk to their health (Royal College of Physicians 2021). As a group, physicians are the second-most trusted professionals in the world, after scientists, according to an international survey (Ipsos 2019). The new RCP report underscores the powerful role physicians still play: “Quit attempts prompted by health professional advice appear to be more likely to involve gradual reduction and use of treatments” (Royal College of Physicians 2021).

Developing Countries

Although the WHO highlights the importance of *all* health care workers – physicians, nurses, dentists, and pharmacists, among others – in the battle against combustible tobacco (WHO 2005), physicians are the most important group, and their role is enshrined in the “Five A’s Approach,” first developed by specialists at the National Cancer Institute: Ask about tobacco use, Advise quitting, Assess a willingness to quit, Assist in the attempt to do so, and Arrange follow-up meetings. A 2019 review, however, found that many doctors stop after

the first two A's, while other physicians never even ask if their patients smoke (Nilan 2019, Agency for Healthcare Research and Quality 2012).

One big reason some physicians do not ask about smoking is that some may themselves be smokers, especially in LMICs, where 80% of the world's smokers live and where the health, economic, and environmental burdens of tobacco are increasing (Action on Smoking and Health 2019). China, Bosnia/Herzegovina, Turkey, and India all have physician smoking rates that hover around 50% (Cattaruzza 2013).

Some 35% of male physicians in upper-middle-income countries still smoke, as do 45% of male physicians in LMICs. Some 37% of doctors in Central and Eastern Europe smoke, 29% in Africa, 25% in Central and South America, and 18% in Asia. Some 27% of doctors in Ukraine continue to smoke, 59% in Latvia, 50% in Mongolia, and 40% in both Egypt and Algeria (Nilan 2019). Many physicians even smoke in their offices, in front of their patients: 70% of physicians who smoke in Senegal, for example, admitted they did so, and 66% in Costa Rica. In China, a 2004 survey of 3,500 physicians found that 23% were regular smokers, with a significant gender difference that was mirrored in the general populace: 41% of male physicians smoked but only 1% of female physicians. More than one-third of the smoking doctors admitted to having done so in front of their patients (Jiang 2007).

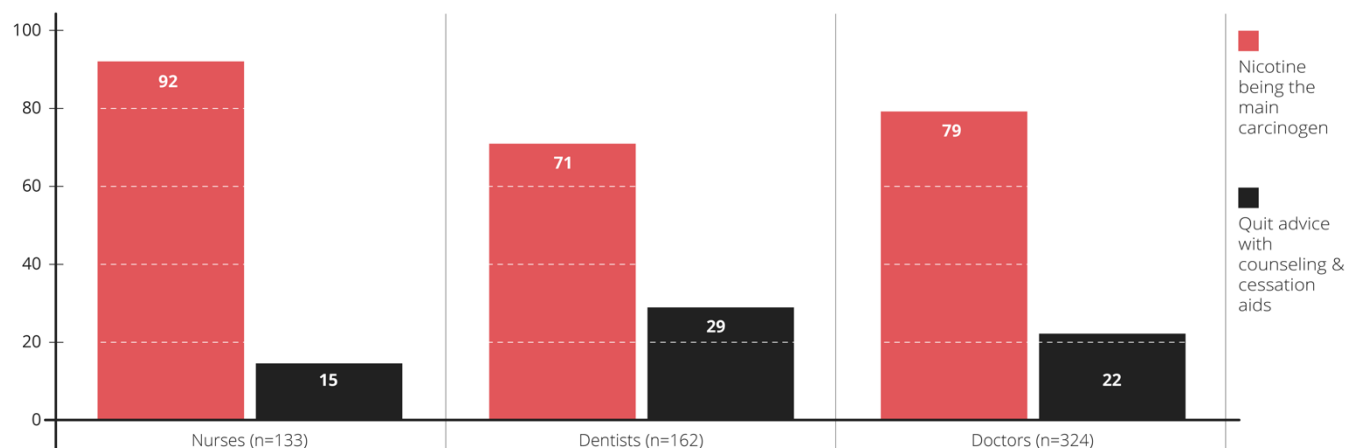
Leadership Role of Physicians

In 2020, medical researchers published the results of a pilot study that evaluated the knowledge of 619 health care workers in India about tobacco use and cessation. A key finding was that 92% of nurses, 71% of dentists, and 79% of physicians believe it is the nicotine in tobacco products that causes cancer or is at least as dangerous as other extremely toxic ingredients (see Figure 4-1) (Patwardhan 2020). At the same time, the respondents had only a vague, rudimentary understanding of the carcinogenic contents of tobacco products in general, and most had never received specific training in tobacco cessation services. Another study found that 91.7% of pharmacists surveyed in Nigeria agreed smoking cessation services should be an important part of their job, but only 12.5% actually provided such services (Akanke-Sholabi 2021). In the same study, more than half the respondents admitted to knowing little about smoking cessation and THR, and 100% said that this lack of knowledge was a barrier to providing such services in the first place.

Such findings are not confined to India and Nigeria. A Rutgers University survey of attitudes among US physicians found that 83.2% "strongly agree" that nicotine directly contributes to the development of cardiovascular disease, 80.9% "strongly agree" that nicotine contributes to the development of COPD, and 80.5% "strongly agree" it contributes to the development of cancer (Steinberg 2020).

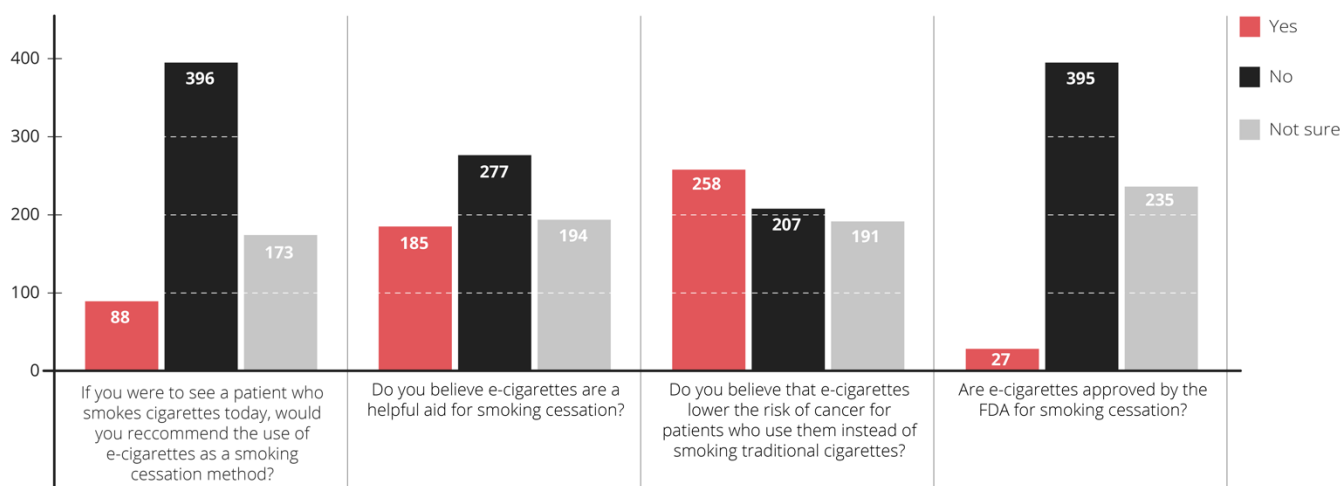
A survey of 654 medical students at the University of Minnesota in 2018 found that 84.7% had never received any education about e-cigarettes (see Figure 4-2). Of those students who said they did receive education, it came either through one required lecture in first or second year, an optional lunchtime lecture, or a student interest group (Hinderaker 2018).

Figure 4-1:
Survey of Health Care Providers



Source: Patwardhan 2020.

Figure 4-2:
E-Cigarette Knowledge and Attitudes of Year 1–4 Medical Students

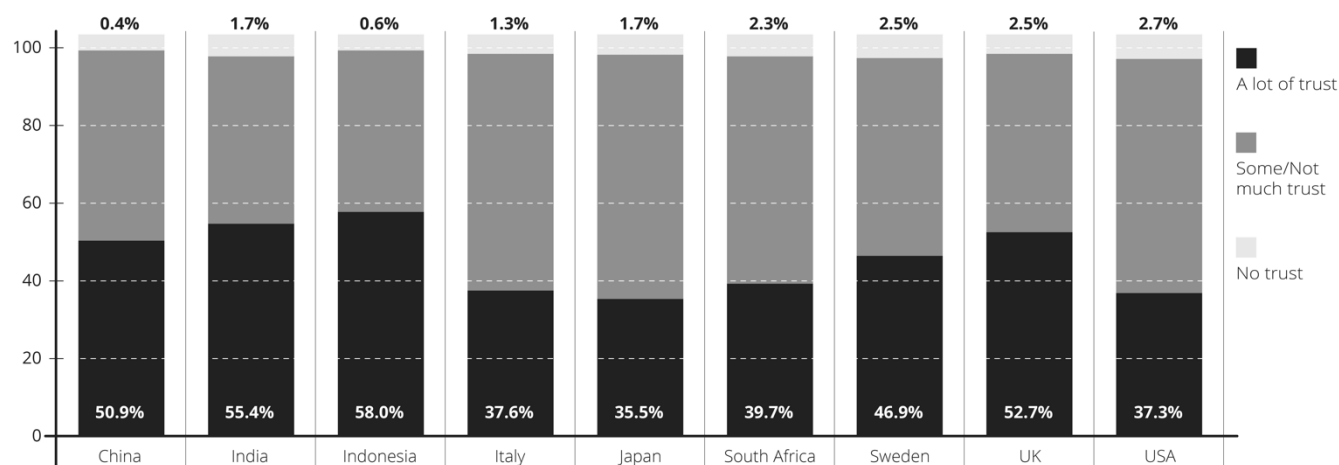


Source: Hinderaker 2018.

This lack of knowledge underscores the need for the world's 11.5 million physicians (WHO 2021) to step up, inform themselves, and update their knowledge so they can give proper guidance to patients who are trying to quit combustible smoking. As in the 1960s, when many physicians educated themselves about the lethal nature of combustible tobacco and were among the first wave to quit, they should be assuming a lead role once again. The public trusts the medical profession consistently across countries (see Figure 4-3) – more than national governments, charitable organizations, or NGOs (FSFW Insights Survey 2020).

Figure 4-3:

Trust in the Medical Profession



Source: FSW Insights Survey, 2020.

Challenges Facing Physicians

Because of their years of education and experience, physicians are held in high regard by patients, and in some countries – South Korea and the United Kingdom especially – they play a central role in educating the public about smoking risks and guiding consumers to resources, including pharmaceuticals and harm reduction products, to aid cessation (Hampsher 2020). But in most countries, including higher-income nations, physicians are overworked, with clinical responsibilities overwhelming their daily schedules. Experts such as Steve Schroeder, the former CEO of the Robert Wood Johnson Foundation who now heads the Smoking Cessation Leadership Center at the University of California-San Francisco, note that quitting smoking is a longer-term proposition, with patients repeatedly trying, failing, then trying again. Schroeder suggests that providing them with smoking cessation advice requires an investment of time that physicians simply do not have (Yach “Role of Physicians in Tobacco Harm Education” tba).

Of course, there is no guarantee of success. Also, many physicians who do want to help their patients stop smoking are caught in a heated debate over how to interpret the same scientific evidence. The result is that many doctors tell patients to use only approved, longstanding medications such as NRT, which have a limited record of success, while ignoring harm reduction products that have a much better, although shorter, track record (Glynn 2021).

The science so far indicates that e-cigarettes are substantially less harmful than combustible cigarettes. Still, the fact that e-cigarettes may do *some* harm can deter physicians who live by the Hippocratic Oath of first doing *no* harm (Kozlowski 2021) – a stricture which, taken literally, makes little sense in a world of sophisticated medicines and vaccines that can have side effects but whose potential benefits far outweigh possible harms.

Rejecting the notion of harm reduction becomes even more poignant when applied to those with mental health conditions, whose smoking rate is two to four times higher than that of the general population (see Chapter 1 for more details; CDC 2020). While THR may be highly valuable in helping these patients reduce their health risk or quit smoking altogether, mental health professionals often tolerate smoking among their patients, regarding the habit as only a minor vice for someone with mental illness and ignoring the opportunity to encourage THR (Smith 2019).

A Prescription for Action

The evidence indicates that the best way for physicians to improve the chances of better health outcomes for their patients who smoke is to quit smoking themselves. Many physicians, in addition, appear to need education on harm reduction and on new technologies, updating their instruction every few years. The “quit-or-die” ethos of the 1980s and 1990s has a powerful grip on physicians, in part because of outdated curricula in medical, dental, and nursing schools. Improving the health of smokers means reaching people who would otherwise be isolated and allowing them to record their progress and to access support, and it means devoting time to such an undertaking. For many physicians, getting a patient to stop smoking or to switch to less harmful nicotine-delivery systems is one of the best ways to improve health dramatically. By their counsel and with their steadfast support, physicians and, by extension, other health care professionals, can continue to save lives in the 21st century, just as so many of them did more than 60 years ago.

Shortage of Health Care Providers

Eleven years ago, the WHO warned that 57 countries had an “absolute shortage” of about 2.3 million physicians, nurses, and midwives altogether, thus an insufficient number of trained health care professionals to provide essential services (WHO 2010). Countries with the lowest doctor-to-patient ratios include Tanzania, with a mere two physicians for every 100,000 people; Sierra Leone, three physicians; and Uganda, eight physicians (United Nations Human Rights Development Report 2007/8). In India, the second most populous country in the world, there is one doctor for every 1,445 people, lower than the WHO-prescribed norm of one for every 1,000 people, many of them concentrated in urban areas (PTI 2019). In what the WHO has termed the Year of the Health and Care Worker, the slack is filled by workers such as India’s Accredited Social Health Activists (ASHAs) – people trained in their local areas due to a shortage of trained professionals (Sushmita 2020).

The Proper Role for Industry

Summary

It is easy to understand why the tobacco industry, with its long history of lies and intimidation, is distrusted. Undoubtedly, however, the industry is changing, with technology and THR playing a greater role. A concerted strategy of developing new harm reduction products to satisfy the strong preference of current smokers to quit could eventually drive combustible tobacco consumption down significantly. Yet, as in the electric car industry, change happens slowly (see textbox, Learning from the Transition of the Car Industry).

Private tobacco companies such as Swedish Match, PMI and BAT are ahead of the game. Their research has more pragmatic applications than does the research being conducted in academic institutions and other public health networks, which tend to revolve around public policies and punishment.

At the same time, the FCTC itself contains a fundamental flaw. It allows signatories to the agreement to own tobacco businesses within their borders, thus profiting from a habit that they are meant to fight. Seventeen countries that are signatories to the WHO-FCTC own all or part of a national tobacco company, putting themselves in the untenable position of agreeing to curtail a practice that benefits them.

In addition, rather than simply fund initiatives against tobacco companies, the WHO-FCTC should recognize the merit of tobacco research findings themselves, not where the research originates or who funds it. All stakeholders, no matter where they are situated, must listen to each other in civil fashion.

Origins of Distrust

Tobacco companies have lied in the past. They have prevaricated and pushed, intimidated, and spied upon people they saw as their adversaries. Thwarted by government regulations, they have engaged in the illicit trade of their product, from Africa to Canada and beyond, avoiding excise taxes while selling large quantities of their products, and they have mounted aggressive campaigns aimed at developing countries, where the number of smokers is growing (Malarak 2003, Irvine 2020).

In the past, products that the companies claimed reduced harm – for example, filtered cigarettes introduced in the 1950s and low-tar or low-nicotine cigarettes in the 1960s and 1970s – proved a sham. In 1998, a RICO case settlement in the United States required companies to release online for a period of ten years no fewer than 35 million previously hidden documents, complete with internal indexes that provided a road map to perfidy (Tobacco Litigation Documents, “State of Minnesota, et al. v. Philip Morris, et al”).

This malfeasance goes back at least to 1954, when major U.S. tobacco companies, responding to studies that linked combustible tobacco and cancer, produced what they called “A Frank Statement to Cigarette Smokers.” Published in more than 400 newspapers, it sounded sincere, concerned, and reassuring, but its thrust was to contend that there was no hard proof that cigarette smoking caused lung cancer and that statistics that seemingly linking the two had been questioned by “numerous scientists” (Frank Statement 1954). “We accept an interest in people’s health as a basic responsibility, paramount to every other consideration in our business,” the statement read. “We believe the products we make are not injurious to health. We always have and always will cooperate closely with those whose task it is to safeguard the public health” (Frank Statement 1954). Yet they did not safeguard public health.

In 1978, South African academic Mike Muller published research that found the industry was marketing cigarettes in developing countries that contained twice the amount of tar as cigarettes sold in the United Kingdom. “Smokers with the least amount of information about smoking’s hazards are put most at risk,” Muller wrote in *Tobacco and the Third World: Tomorrow’s Epidemic*. “It is unethical, if not criminally dangerous” (Muller 1978).

As such sinister practices within the industry continued, skepticism gave way to mistrust and danger. The FCTC, which was conceived in the early 2000s, enshrined these attitudes for posterity in Article 5.3, which shields tobacco control policy from *any* industry influence, including the work of researchers who may be even remotely affiliated with it. As Dr. Margaret Chan, the director-general of WHO when its Report on the Global Tobacco Epidemic was released in 2008, remarked at the time: “I want to remind governments in every country of the range and force of counter-tactics used by the tobacco industry – an industry that has much money and no qualms about using it in the most devious ways imaginable.” (WHO 2008)

So, why believe the industry now? Why believe PMI, which on the home page of its [website](#) promises to deliver a smoke-free future, or [BAT](#) which says that “combustible cigarettes pose serious health risks, and the only way to avoid these risks is not to start or to quit”? Or [Altria](#), which promises on its website home page to move

“beyond smoking”? Why believe them? Because the results of their own transparently conducted scientific research tell an important story.

Harm Reduction Progress is Extremely Slow

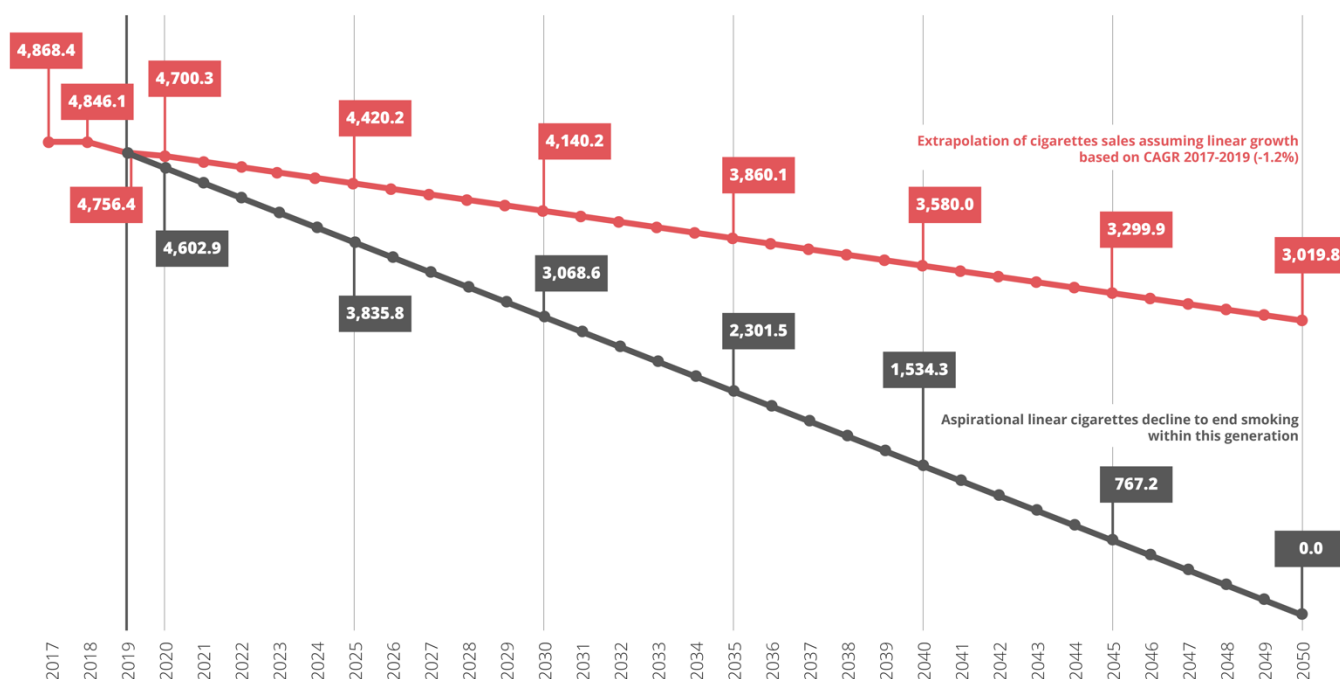
The Tobacco Transformation Index evaluates the progress of 15 companies around the world in their pursuit and implementation of THR strategies. So far, the progress has been slow. Between 2017 and 2019, the total number of individual cigarettes sold globally fell only from 4.9 trillion to 4.8 trillion. At that rate, eliminating combustible smoking altogether will take at least 40 years (Tobacco Transformation Index 2020). Meanwhile, the number of smokers dying will increase, and societies will continue to bear the health and economic costs of the habit, including lost workdays, hospitalizations, and the fallout from second-hand smoke exposure (Tobacco Transformation Index 2020).

Six of the 15 companies evaluated in the Tobacco Transformation Index *have* acknowledged their role in THR and have made commitments to tackle the challenges of tobacco-related death and disease. Although most of these companies have so far failed to shift a significant share of their sales toward THR, a case study from PMI shows that smoke-free products now represent about 25% of the company's net sales from 2.7% in 2016 (PMI Integrated Report 2020). In the same period, the company's shipment volume of smoke-free products increased nearly 10-fold, from 7.7 billion units to 76 billion, while shipment of combustible products decreased, from 845 billion to 654 billion (PMI Integrated Report 2020).

The top-ranked tobacco companies do appear to be moving more financial resources toward THR products, putting billions of dollars into research and development, mergers and acquisitions, and capital expenditures to enhance sales of e-cigarettes and HNB devices. But among the six companies claiming commitments to harm reduction, between 30% and 55% of their marketing budgets are still devoted to high-risk products (Tobacco Transformation Index 2020). Figures like these, the Index continues, demonstrate that no matter a company's commitment to reducing risk, there is much more to be done to translate strategies into meaningful results (See Figure 5-1).

Figure 5-1:

Cigarette Volume Sales Globally (Bn Sticks) and Extrapolation of Future Data Based on Linear Growth, 2017–2050



Source: Tobacco Transformation Index 2020.

The six companies at the top of the Index's ranking are all publicly traded, and so are subject to more reporting requirements and scrutiny from investors, public health authorities, governments, and other stakeholders. Most operate in multiple markets with different regulations and other dynamics that affect both industry competition and consumer preferences. Taken together, these factors lead to a higher level of transparency and may encourage the companies' greater responsiveness to THR. The nine other companies fail to acknowledge any role in tackling the challenges of tobacco-related death and disease and have made no explicit commitment to THR. Collectively, these companies account for almost 60% of global cigarette volume sales and dominate in LMICs, where most smokers live.

CNTC alone sells 48.6% of the cigarettes associated with companies in the Index; it also continues to set targets to increase sales of high risk products. Two other companies, Egypt-based Eastern and Vinataba, from Vietnam, are following the same path. KT&G, in South Korea, and Swisher International, a cigar manufacturer based in the United

China National Tobacco Company

CNTC is the world's largest tobacco manufacturer and focuses on its home market of China. The company claims to be reaching the target of reducing smoking rate for people over 15 years old to 20% by 2030 but the increase of its annual cigarette sales targets year on year implies an opposite position. In addition to cigarettes, the company is active in cigars and has engaged in heated tobacco products for export. The company continues to make significant capital investments in high-risk products (Tobacco Transformation Index 2020)

States, have made some investment in harm reduction products but are still planning to grow their high risk tobacco sales, thus demonstrating that they have not yet fully embraced encouraging adult consumers to switch to less risky products (Tobacco Transformation Index 2020).

Government Action?

A snapshot of the tobacco industry right now shows a global market valued in 2020 at more than \$932 billion USD, with revenue growth expected at an annual rate of 1.8% through 2028 (Kolmar 2021). Table 5-2 and Figure 5-3 show the market share for combustible cigarettes and just how fragmented the e-cigarette market is.

Table 5-2:

Top Transnational Tobacco Companies and Ownership

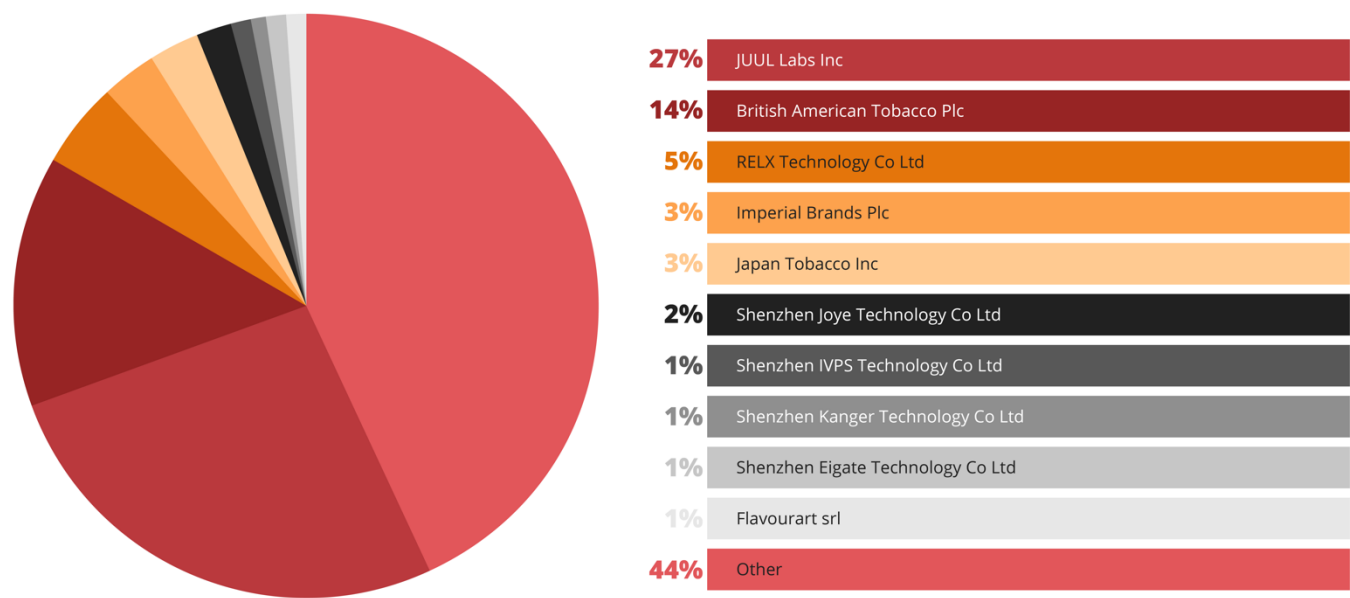
| Company Name | Unit | 2018 (Euromonitor) | Parent |
|----------------------------------|----------------|--------------------|---|
| China National Tobacco Corp | Million Sticks | 2,321,765.20 | Government of China |
| Philip Morris International Inc. | Million Sticks | 681,768.50 | |
| British American Tobacco Plc | Million Sticks | 473,475.70 | |
| Japan Tobacco Inc. | Million Sticks | 374,990.10 | Government of Japan |
| Imperial Brands Plc | Million Sticks | 176,026.00 | |
| Altria Group Inc. | Million Sticks | 113,527.90 | |
| Reynolds American Inc. | Million Sticks | 85085.20 | |
| Gudang Garam Tbk PT | Million Sticks | 77455.50 | |
| Eastern Co. SAE | Million Sticks | 75659.80 | |
| ITC Ltd.* | Million Sticks | 63554.50 | State-owned companies and Government of India |
| Vietnam National Tobacco Corp. | Million Sticks | 49357.10 | Ministry of Industry - Vietnam |
| KT&G Corp.* | Million Sticks | 42953.00 | State owned companies - Korea |
| Darjuna PT | Million Sticks | 39053.70 | |

*Note: State-owned tobacco company

Source: Yach 2020

Figure 5-3:

Global Company Retail Value Share of Open and Closed Vaping Systems, 2020

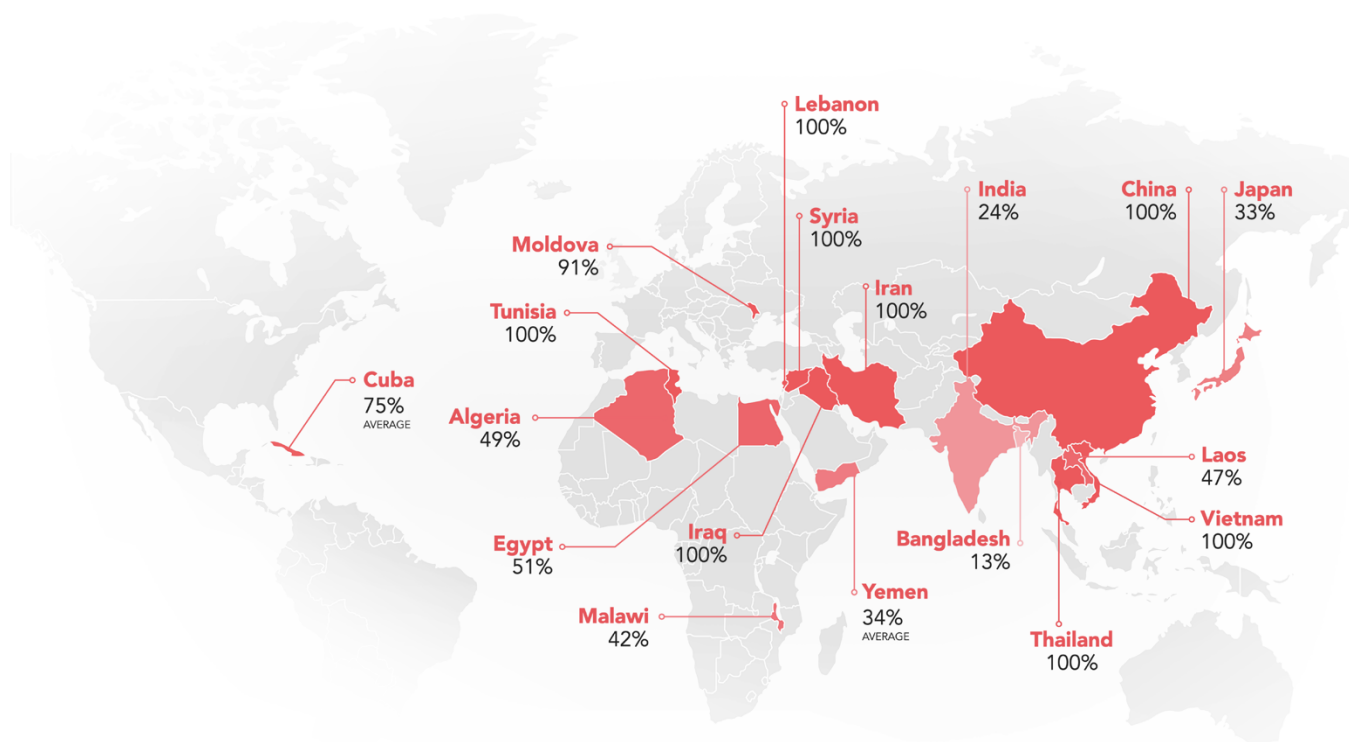


Source: Euromonitor 2020.

No fewer than 17 of the 18 countries whose governments own tobacco companies in whole or in part are in a sticky ethical position because they are signatories to the FCTC, according to a recent study by business ethicist Daniel Malan (see Figure 5-4) (Malan 2020). Besides China, India, and Japan, the signatories are Algeria, Bangladesh, Cuba, Egypt, Iran, Iraq, Laos, Moldova, Thailand, Tunisia, Yemen, Lebanon, Syria and Vietnam (Malawi is not a signatory of the FCTC).

Figure 5-4:

Companies with State Ownership



Source: Malan 2020.

China National Tobacco Corporation, which caters to smokers who consume 2.3 times as many cigarettes as the world average, has annual revenues of \$108 billion (see textbox on CNTC above for more details). Among the other companies with significant government ownership are Japan Tobacco Inc, with the state owning 33%, and India's ITC Ltd, a multi-tentacled conglomerate, 24% of which is owned by government. Along with combustible cigarettes, ITC includes in its portfolio consumer goods such as cookies, soap, paperboard products, and hotels (Xu 2019; Malan 2020; ITC Portal).

The top private tobacco companies are PMI, with annual revenues of \$80 billion, and the UK-based BAT Plc, with annual revenues of \$36 billion (Kolmar, 2021). These and other multi-nationals are subject to strict regulation in the 180-odd countries in which they operate and are under frequent criticism, especially from the WHO, which accuses them of continuing to target younger generations of smokers and racing to develop new products that are not as strictly controlled (WHO Newsroom 2020). The state-owned tobacco firms are treated differently.

The WHO faces a contradiction and a conundrum. By signing the FCTC, nations have agreed to develop national guidelines and measures to prevent the use of tobacco, yet many of these same countries – including the largest, China – continue to produce and market combustible tobacco products and to plan for more growth. This is a clear violation of the FCTC's objective of protecting “present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.” (Part II, Article 3, FCTC; WHO 2005).

Preventing a new generation from taking up smoking in any form has been the preponderant aim of the WHO and governments around the world – a priority born of larger tobacco companies' history of marketing to youth to renew their client base (TobaccoFreeCA 2020). Today, in response to official government bans on such marketing tactics in most countries, most companies have clear, written policies that proscribe youth-oriented campaigns in favor of those geared to adult consumers. Conversely, some new e-cigarette companies have aggressively marketed their products to young people. The response by policy makers, the media, and interest groups, from condemnation to legal challenges and legislative action such as bans on certain flavors, risks being too broad, deterring adult smokers from switching to less harmful alternatives as choices narrow (see Chapter 7).

At the same time, government efforts against nefarious practices have been frustratingly slow. Not one country has fully implemented measures to protect public health policy from tobacco industry interference at the best-practice level (Chung-Hall 2019). This inaction may be attributed to a lack of government commitment and legislative ability, and, in many LMICs, the lack of capacity for science, research, and innovation (Puska 2019; Bialous 2019).

Each FCTC signatory, Malan noted, is sent a questionnaire every 2 years to detail what that nation has accomplished to satisfy Article 5 of the convention, which requires establishing an essential infrastructure for tobacco control and developing and implementing comprehensive tobacco control strategies, plans, and legislation to prevent and reduce tobacco use, nicotine addiction, and exposure to tobacco smoke – all while ensuring the process is not affected by the interests of the tobacco industry itself (Malan 2020). China's response to the question in the 2018 questionnaire was a terse "Not applicable." And in its 2019 report on the global tobacco epidemic, the WHO did not once mention China Tobacco, while it referred to PMI and BAT more than 20 times in critical fashion (WHO 2019).

To make real progress, Malan suggested that if governments with state-owned tobacco interests (partial and full) shift over time from the production and marketing of combustible products to those that promote harm reduction, they could simultaneously alleviate the conflict as signatories to the FCTC and save lives (Malan 2020). The same advice, and same challenge, can be issued to other tobacco companies, too. Improve the science, research biomarkers, and other long-term phenomena, continue to introduce innovations that reduce the risks to people's health, and share the results – and do so at the expense of the combustible cigarette market.

At the same time, less attention has been paid to bidi and smokeless tobacco manufacturers. Smokeless tobacco use is more popular in India, South and Southeast Asia than smoking tobacco in any form (GATS2 2017). Interference by the smokeless tobacco industry in India in development, implementation and enforcement through lobbying, tax evasion tactics, and litigation has hindered the introduction of policies to regulate and control it (Yadav 2020).

There is also wide variation between companies. Despite leading patent publications, China Tobacco has made only limited attempts to diversify into harm reduction, scoring a mere 0.19 on the index rankings out of a possible 5.00 (OxFirst, Tobacco Transformation Index 2020). By contrast, Swedish Match, which, as the maker of snus, has helped lower smoking levels dramatically in Sweden, has a Tobacco Transformation Index score of

3.83. Also ranking relatively high on the Index is PMI, which has set of goal of having smoke-free products account for more than 50% of its revenues by 2025 (PMI 2020).

New technologies are already here, and they demonstrate the direction some leading tobacco companies will be taking over the next five to 10 years. A review of the papers and patents filed shows clearly that the work of the industry itself is more practical and innovative than the work of institutions that focus on policies and legislation (Ghafele 2021).

A Need to Come Together

Right now, there are few opportunities for a free exchange of ideas and findings to speed the progress of harm reduction. But some exist. The Morven Dialogues, for example, started by the Institute for Environmental Negotiation at the University of Virginia, is one such important venue, with its ongoing theme, “The Changing Environment of Tobacco, Nicotine and Alternative Product Regulation: Developing a More Coherent and Rational Approach.” Its core principles are a model of measured response, including calls for science-based regulatory oversight, recognition of the differences between combustible and noncombustible products, transparent and collaborative research, a clear public message about the role and relative risks of nicotine, and a civil dialogue among all stakeholders (Institute for Engagement and Negotiation, University of Virginia).

Another important venue that bucks anti-industry sentiment is the Global Tobacco & Nicotine Forum (GTNF), an annual conference. Here, public health experts, government representatives, investors, and representatives of the tobacco and nicotine industries meet for a civil exchange of often divergent views about everything from the need for science-based regulations to the disparity among countries in terms of THR policies.

The Society for Research on Nicotine and Tobacco, an international nonprofit that focuses on nicotine research and tobacco use from a public health and scientific perspective, also manages to bridge the gap, at least partially, between organizations such as the WHO and industry through its journal, *Nicotine & Tobacco Research*. Although the society does not accept funding from the tobacco industry, it does participate in civil debate over THR, e-cigarettes, and other noncombustible products.

These opportunities for discussion are important because in the end, the WHO will find it difficult to reach its own FCTC goals unless it cooperates with private tobacco companies and state-owned firms. The treaty itself has been described as “frozen in time” (Yach 2020), and its main priority has been to concentrate on preventing children from taking up smoking while neglecting adult consumers who are trying to quit. “If you only focus on children not taking up smoking, you will see health benefits fifty years from now, but we want that impact in fifteen to twenty years,” Yach recently told the journal *Tobacco Reporter* (Rossel 2021).

Reaching out does not mean selling out. Rather, it means listening to another side; being open to research rather than considering it tainted from the start. These days, as the by OxFirst report show, some tobacco companies are operating more like pharmaceutical firms, committed to publishing and peer review in a medical context. “Pharmaceuticalization” means transforming human conditions, capabilities, and capacities into

opportunities for intervention by medicines (Williams 2011). Examples of the tobacco industry's transformation, or pharmaceuticalization, of itself through the manufacture and sale of noncombustible products were detailed, successful submissions by Swedish Match and PMI to the FDA for permission to market snus and IQOS sticks as Modified Risk Tobacco Products (MRTPs). The applications covered the history and science, projections and past performance (FDA 2019, 2020).

Chapter 6

Improving Regulatory Policies

Summary

Tobacco harm reduction products can effectively facilitate smoking cessation, but access to the products is affected by the economic, tax, and regulatory policies a country adopts. This chapter examines the policy responses to THR and combustible products in ten countries and finds those responses vary greatly. Some nations, notably the United Kingdom, have recognized the potential of THR and implemented a raft of measures to encourage persistent smokers to switch to alternatives. Policy responses that acknowledge the existence of a continuum of risk, and then apply measures accordingly, incentivize persistent smokers to switch to alternatives. Under these regulatory frameworks, alternatives appear to reduce the harms of tobacco use while simultaneously allowing public health agencies to externalize the cost of smoking cessation. As countries have wrestled with how best to regulate alternatives to cigarettes, the evidence increasingly supports reducing harm for smokers through correcting misperceptions, communicating risk appropriately, replacing bans with risk-proportionate regulation such as taxes, and considering evidence on flavors and nicotine caps.



After a series of protracted negotiations, the FCTC was brought into force in 2005. In the 35 years that passed between the introduction of the first resolution at the WHO and the adoption of the FCTC, governments individually adopted policies to combat smoking. Coupled with rising awareness of the harms of smoking, the policies produced a marked decline in the number of smokers even before the FCTC was adopted. For instance, the proportion of Americans smoking decreased from 42.4% in 1965 to 20.1% in 2005 – and then to 14% in 2019 (CDC 2020). Similar declines were observed in Australia, Canada, and the United Kingdom, among other countries.

In recent years, however, progress toward eliminating smoking appears to have slowed, even stalled. The persistence of smoking likely reflects the complex interplay of factors, but more than 1 billion smokers are testimony that the traditional paradigm of cessation is not working. One potential reason is that the paradigm is binary (that is, people are either “smokers” or “non-smokers”). The reality is that the harms associated with tobacco exist along a continuum.

That fact is what made NRTs possible. Although nicotine can increase blood pressure and heart rate, its risks differ from those associated with the other compounds inhaled while smoking, such as tar. NRT-based smoking cessation products have worked exceptionally well for some and, over time, many of these products have moved from being regulated as prescription-only medicines to becoming widely available over-the-counter products. For many persistent smokers, however, NRTs fall short, lacking the titration opportunities and tactile feedback needed to substitute for traditional cigarettes. And, despite NRTs being on WHO’s Model List of Essential Medicines, few countries have included them among their own essential medicines, so smokers find it difficult to access and afford these therapies (Shah, in review).

In keeping with the reality of that risk continuum and to address the shortcomings of NRTs, alternative products such as e-cigarettes and HNB products have become natural catalysts for smoking cessation. Recent randomized controlled trials have corroborated these arguments. Such studies helped lead the U.S. Food & Drug Administration (FDA) to develop a nicotine-focused framework for regulation and public health (Gottlieb 2017). The FDA, under Commissioner Scott Gottlieb, recognized that the main health problem is not the addictive nicotine but the mechanism that delivers the nicotine, which, for cigarettes, involves combustion.

The insight of the FDA effectively provides an opportunity for health promotion, defined by the 1986 Ottawa Charter for Health Promotion, as “the process of enabling people to increase control over, and to improve, their health.” The declaration goes further, stating that “health promotion focuses on achieving equity in health. Health promotion action aims at reducing differences in current health status and ensuring equal opportunities and resources.... People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health” (WHO 1986).

Given that other nicotine-delivery systems provide a less harmful alternative to cigarettes, staying true to the principles of health promotion requires policies that empower individuals to choose alternatives over smoking. Those policies should necessarily focus on making THR products more accessible, more affordable, and tailored to the needs of the consumers. The FCTC requires modernization to address harm reduction technologies, to encourage their translation into national guidelines, and to invest in national and global R&D, innovation, and

science to promote THR over smoking (Yach 2020). This strategy could effectively be advanced through risk-proportionate policies such as taxation, better understanding of the role of flavors and nicotine, and addressing common misperceptions.

Examining the Spectrum of Policy Responses to Alternatives

In response to the development of new delivery mechanisms, more countries have had to wrestle with adapting their regulatory and economic policies to accommodate the role of less harmful nicotine products in smoking cessation. This section examines the specific policy responses of ten countries (Australia, Canada, China, Germany, India, Indonesia, Japan, Russia, South Korea, and the United Kingdom; see Appendix). Presented below are case studies from the Australia, Japan, and the United Kingdom to illustrate the full spectrum of policy responses. The impact of each of these responses is examined, and this assessment distills key lessons.

We find that engagement with alternatives is significantly affected by the economic, tax, and regulatory policies a country adopts. Policy responses that acknowledge the existence of a continuum of risk, and then apply measures accordingly, incentivize smokers to switch to alternatives. Under these regulatory frameworks, alternatives appear to reduce the harms of tobacco use while simultaneously allowing public health agencies to externalize the cost of smoking cessation. Such policies – when implemented effectively – appear to make both clinical and economic sense.

For each of the 10 countries, the Table in the Appendix compares policies for different alternatives to smoking across several areas using a traffic-light system: policy areas in which alternatives are more strictly regulated than smoking (e.g., taxes on alternatives are higher than traditional cigarettes) are red; policy areas in which alternatives and smoking are similarly regulated are yellow; and areas in which alternatives are less strictly regulated are green.

The analysis illustrates how policy responses run the gamut. At one end of the spectrum, Australia has largely treated alternatives as more harmful than traditional cigarettes and has erected barriers to their use. At the other end, the United Kingdom has embraced alternatives as less harmful than traditional cigarettes and has implemented policies to use alternatives as pathways for persistent smokers to reduce harmful use and eventually quit smoking altogether. In between those two extremes are countries like Japan, whose response has been mixed and, at times, contradictory. Australia, Japan, and the United Kingdom are examined in greater detail below in order to provide a better understanding of the nature and impact of these policies.

Australia

In Australia, alternatives have been met with a high degree of skepticism and suspicion. The Australian Department of Health, the Royal Australasian College of Physicians, and the Therapeutic Goods Administration (TGA) cite what they consider a dearth of evidence of any benefits from alternatives and have regulated alternatives even more strictly than traditional cigarettes (RACP 2019; Australian Government DoH 2020). The

Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons, for example, has designated nicotine a “dangerous poison” (Australian Government DoH 2020; DoH Australia 2019), and Australia has banned the sale and use of products containing nicotine unless those products can be smoked (e.g., traditional cigarettes) or approved for therapeutic purposes and obtained by prescription.

As a result, the Australian Institute of Health and Welfare found that fewer than 1.5%, 0.8%, and 0.2% of smokers, ex-smokers, and never smokers, respectively, over the age of 14 reported using e-cigarettes daily. Among smokers over the age of 14, only 4.4% reported using e-cigarettes at all. Among those who did use e-cigarettes, virtually all were smokers. Nearly a third of those over the age of 14 who did use e-cigarettes reported a desire to quit as their primary reason for using alternatives, and a fifth said that they believed alternatives were less harmful than traditional cigarettes (AIHW 2017). Even more reported a desire at least to reduce their consumption of traditional cigarettes.

Clearly, there exists in Australia a market of smokers who would benefit from the reduced harm of e-cigarettes or HNB devices, but the government has made the alternatives nearly impossible to access. By taking this precautionary approach, Australia has placed itself at one end of the policy spectrum. The government is more hostile to alternatives than it is to traditional cigarettes, and discourse about the issue has been severely limited.

Japan

In Japan, the response to alternatives has been mixed, with e-cigarettes being kept at bay while HNB products are easily available. E-cigarettes containing nicotine are currently categorized as a medicinal product and thus subject to regulation under the Pharmaceutical Affairs Act of 2010. That law effectively limits manufacture, marketing, import, and distribution by requiring government approval. To date, no manufacturers have attempted to obtain such approval, so there is a *de facto* ban on nicotine-containing e-cigarettes. By contrast, HNB products are *not* categorized as medicinal products. Instead, they are regulated by the Ministry of Finance in a near-identical regulatory framework as traditional cigarettes and are taxed the same.

With a relatively level regulatory playing field for both traditional cigarettes and HNB products, Japan provides a particularly good case study. Uptake of the HNB products has been swift, with an 11-fold increase in use by current smokers with an intention to quit by 28-fold (Hori 2019). Notably, studies have found a sharp decrease in cigarette consumption following the introduction of HNB products (Stoklosa 2019). This held true across all eleven regions in Japan with researchers finding that the best predictor of the decline in cigarette sales in a given region was the introduction of HNB products (Stoklosa 2019). Coupled with the fact that no other tobacco control policies or initiatives were enacted at that time, the timing appears to be more than coincidence. As further evidence of a causal link, Euromonitor found that annual cigarette consumption was declining at a rate of 1.8% annually in the years before HNB products became popular (i.e., 2011-2015) and then accelerated to 9.5% annually in the years after they became popular (i.e., 2015-2018) (Hampsher 2021). Moreover, Stoklosa et al (2019) assessed regional variation in the decline of cigarette consumption and found that smoking rates began to decline earlier in regions where HNB products first became popular.

Thus, Japan has responded to alternatives in a mixed manner. E-cigarettes were banned in ways that mirror the hostile policy response observed in Australia, but HNB products were placed on a level playing field with traditional cigarettes. Given a free, unbiased choice, Japanese smokers themselves are moving toward less harmful alternatives.

United Kingdom

In the United Kingdom, authorities appear to have closely examined the evidence and developed a policy framework that actively incentivizes a transition from traditional cigarettes. The British Medical Association, the House of Commons Science and Technology Committee, Public Health England, and the Royal College of Physicians have published statements and reports which underscore that THR products, while not risk-free, are far less harmful than traditional cigarettes. Accordingly, the Royal College of Physicians has recommended that alternatives be regulated in proportion to their harms, so that public policy pushes smokers toward less danger to their health over time (RCP 2021). The sale of alternatives is not merely permitted but promoted by the National Health Service and related government authorities in guidelines for smoking cessation.

A plethora of policies further distinguish alternatives from smoking products. Notably, alternatives are not formally licensed for medical use, physicians are not required to prescribe them, and though they are subject to the country's 20% value-added tax (VAT) – they are exempt from the tobacco excise tax and thus less costly (E-cigarette Intelligence). The U.K. Department of Health has also stated that, “routine bans of vaping products at the workplace or in public spaces should cease, to maximize the availability of safer alternatives to smoking” (DoH United Kingdom 2017) and Public Health England has produced model guidelines and policies for workplaces based on that guidance. Alternatives are also subject to the Tobacco Products Directive (TBD) ensuring that the devices are child proof and limiting nicotine content.

As a result of this relatively supportive and evidence-based policy response, alternatives have rapidly become the most popular quitting aid for current smokers in the United Kingdom (McNeill 2018). The increasing prevalence of e-cigarettes in the U.K. can be broadly correlated with the reduction in the smoking population. Between 2012 and 2019, the proportion of adults using alternatives rose from 1.7% to roughly 7.1%; during that same time, the Office of National Statistics reported that the percentage of smokers declined from 19.6% to roughly 14.1% (ASH 2021, ONS 2020). Nearly two-thirds of current vapers are ex-smokers (ASH 2021). Those who used alternatives cited a desire to reduce consumption of traditional cigarettes as a common reason for their use.

The data were roughly the same across age and gender and revealed that the proportion of those using e-cigarettes who reported no longer smoking has risen quickly. E-cigarette users who reported cessation increased from 33% in 2014 to 52% in 2017, and according to Action on Smoking and Health, e-cigarette users reporting that they still smoke decreased from 65% to 45% (Hampsher 2020).⁴ Multiple studies investigating

⁴ The case studies are informed by work carried out by BOTEC and commissioned by the Foundation for a Smoke-Free World.

predictors of smoking cessation found that greater use of e-cigarettes was associated with higher success rates (Beard 2020).

Several studies have also examined whether alternatives may have a gateway effect or whether they renormalize smoking. There is limited evidence of such effects among young people despite the rapid growth of e-cigarettes (Hallinburg 2020). Moreover, some argue that alternatives may not only displace but accelerate the end of smoking by “de-normalizing smoking” (McNeill 2015), often pointing out that youth experimentation with alternatives does not appear to be translating into regular use in the UK (Bauld 2017). ASH UK found that fewer than 1% of never-smokers are current vapers and that only 0.5% of those aged between 11-18 who have never smoked are using e-cigarettes less than weekly (ASH 2021).

The U.K. has responded to alternatives in a supportive manner by implementing a framework that effectively regulates these products in proportion to their harm while maintaining strict controls on combustible tobacco products. The result has been a relatively rapid growth of alternatives. Early evidence suggests that alternatives increase the frequency and success of quit attempts without necessarily creating a gateway effect or renormalization of smoking among never-smokers.

The 2021 report by the Royal College of Physicians recommends reducing taxation for alternatives. The report also recommends media campaigns that dispel misperceptions about nicotine, provide balanced information about THR products, and encourage switching as a quitting aid, thus pushing the country to be a global leader in aligning regulations with science, consumer demands, and data (RCP 2021).

Best Practices

The dilemma facing smoking cessation advocates is clear. A decades-old paradigm to promote smoking cessation has worked for many but not all. For those who continue to smoke, the toll remains devastating. Using the same policies and expecting different results for these persistent smokers make no sense. As countries have wrestled with how best to regulate alternatives to cigarettes, the evidence increasingly points toward a new approach to reducing harm for smokers:

1. **Correcting Nicotine Misperceptions** – For decades, nicotine and smoking have been interchangeable. The predictable result has been the conflation of the harms of nicotine with the harms of smoking. For example, a seven-country survey of more than 50,000 tobacco users by Rajkumar and colleagues (2020) found nearly two-thirds of adults erroneously believe that nicotine causes cancers. As noted by Fairchild and colleagues (2019), the gap between perception and reality about nicotine has hampered the adoption of science-based cessation and harm reduction strategies. Correcting these misperceptions appears to be an essential first step in reigniting the fight against smoking.
2. **Communicating Risks Appropriately** – In addition to correcting misperceptions about nicotine, publishing guidelines that appropriately communicate the risks of tobacco products is critical, and the U.K. has been a leader in doing so. Coupled with vigorous monitoring of all nicotine products, broad

communication appears to result in not just greater understanding of risks but more uptake of less harmful alternatives and less smoking.

3. **Developing Risk-Proportionate Regulation** – Traditionally, the one-size-fits-all approach to smoking cessation was partial to blanket bans in most forms. In keeping with efforts to correct nicotine misperceptions and communicate risks appropriately, bans should be replaced with risk-proportionate regulation. For example, experts have noted that taxes are among the most effective policy levers available for tobacco control. Taxing nicotine products in proportion to their harm (for example, by increasing taxes on cigarettes and lowering taxes on alternatives), can strongly discourage smoking and encourage switching to less harmful products. The price elasticity of demand for less harmful alternatives is found to be between -0.78 and -2.1. Those figures suggest that a 10% increase in pricing would reduce demand by 7.8% to 21%; conversely, a reduction in pricing would increase demand (Yurekli 2020). In the United States, for example, Pesko and Warman (2017) found that higher taxes on THR products reduced their use and increased cigarette use among adolescents. Multiple countries have already enacted policies to this effect with promising results. In addition to the U.K. (which has already been detailed above), Sweden encourages less risky use by having lower taxes on snus (a less harmful oral tobacco product). The product, as noted earlier, appears to have contributed to the country having one of the lower tobacco-attributable mortality rates in Europe. The evidence for risk-proportionate taxation appears strong. By adopting similar policies, countries can take steps to ensure that their policies align with the science and reflect the risks associated with various tobacco products.
4. **Evaluating the Role of Flavors and Limits on Nicotine Content** – Two areas requiring further evaluation include the role of flavors and nicotine limits in reducing harm. A cross-sectional study in Canada and the United States by Gravely and colleagues (2020) suggests that flavors may be popular among adults those who have switched or have quit smoking through the adoption of alternatives. If that is the case, then limiting or banning flavors may discourage current smokers from choosing THR alternatives. One natural concern with the availability of flavors is whether it encourages youth uptake. Notably, a study by Friedman and Xu (2020) found that flavored alternatives were not associated with increased uptake by young people but that flavored alternatives did increase the odds of smoking cessation by adults. Such findings align with the experience of countries like the United Kingdom. Another area for further evaluation involves increasing or removing limits on nicotine concentrations in alternatives. Titratability of nicotine content appears to help persistent smokers switch to alternatives, so higher doses of nicotine may be particularly valuable for the most persistent and heavy smokers, especially in the early stages of their conversion to THR products.

Chapter 7

Smoking and Children/Youth

Summary

Young people smoke at a far lower rate than adults, and youth smoking prevalence is declining in high-income countries (WHO 2019a). Still, too many teenagers continue to smoke cigarettes, especially in LMICs, where both national governments and international organizations have not addressed smoking among youth. The increased use of alternative nicotine-delivery systems raises concerns as well. “Nicotine isn’t a benign substance,” as former Commissioner of the FDA Scott Gottlieb has said. “This is especially true when it comes to children, and the effects that nicotine has on the developing brain” (FDA 2018a).

Banning sales to minors is a necessary step, taken by many countries in the world, but current prohibitions are ineffective, again particularly in LMICs, where enforcement is lax and children themselves are often sellers as well as users of cigarettes, bringing home essential cash to hard-pressed families (Tobacco Atlas 2020).

Data on youth cigarette smoking are spotty and inconsistent, with odd conventions, such as often defining young smokers as being aged 15 or under. The WHO has reported that 6.5% of adolescents overall are smokers, with the highest rates in Europe and upper-middle-income countries globally, because access to cigarettes requires access to money (WHO 2019a). Cigarette-smoking prevalence among youth has declined over the past 20 years but, at the same time, the prevalence of use of other tobacco products, including snuff, dip, cigars, pipes, and electronic cigarettes, increased or did not change (Ma 2021).

For both children and adults, there is a clear correlation between declining rates of smoking and rising rates of use of e-cigarettes and other alternatives (WHO 2019a). Although a policy of encouraging current adult smokers to switch to less harmful alternatives is productive to public health and the economy, the consensus view is that young people, like current non-smokers, should not initiate the use of any form of tobacco, including e-cigarettes. Demonizing e-cigarettes for youth, however, can have spillover effects for adults, discouraging them from switching and giving them an excuse to keep smoking (Parmar 2019).

In the past, large cigarette companies, viewing youth as a replacement market for aging smokers, have targeted a significant part of their marketing budgets toward minors (Cummings 2002). Today, these same firms have adopted clear, written policies of marketing only to adult smokers and appear to have abided by these restrictions (PMI 2019, BAT 2021). Some new e-cigarette companies, by contrast, have aggressively marketed to young people. Policy makers, the media, and interest groups have brought public pressure and, in some cases, legal and legislative action, to bear against such firms, but if this response is too broad (leading to bans on certain flavors, for example), the backlash may deter adults from switching to less harmful alternatives by limiting their choices.

Smoking by children is an emotional issue that can obscure the more clear and present danger, which is the imminent disease and mortality faced within the next 20 years by current cigarette smokers in their 30s, 40s, and 50s (Jha 2020). Conflating the dangers of tobacco and alternatives may make sense for adolescents, but for adults the spillover effects could lead to millions of needless deaths.

Rates of Children Smoking

More than 100 countries report youth tobacco use, but they do so inconsistently, in different years, and with varying definitions of both age group and smoking frequency. Surveys quickly grow outdated. The WHO's GYTS surveys focus on adolescents between ages 13 and 15, and results vary widely. In the WHO Europe region alone, cigarette smoking prevalence ranges from 1% in Tajikistan to 20% in Italy and Bulgaria (WHO 2020). Youth smoking is declining in most countries, while flat or rising in many others. Indonesia, the world's fourth largest most populous country, where about one-fifth of boys smoke cigarettes, had essentially no change in youth smoking rates from 2006 to 2015 (WHO 2019c). In LMICs, especially, data-gathering on youth tobacco use is inadequate to monitor the effects of different tobacco-control policies.

Unlike alcohol, which is involved in nearly one-fourth of fatal accidents for US teenagers (NHTSA 2015), and opioids and cocaine, which killed 4,000 young people in the United States through overdoses in 2019 (CDC), smoking does not kill minors but instead starts them on a path to addiction and premature mortality. There is a sizeable gap between the inception of smoking and severe disease and death from the behavior, which typically occurs in one's 50s and later. "Even quitting in middle age avoids much of the excess healthcare risk associated with smoking" (Fagerström 2002).

Prohibitions Ineffective

Nearly all countries ban marketing and direct sales of tobacco products to children, but in LMICs, especially, these prohibitions are not rigorously enforced. For example, a study of 107 retailers in Indonesia found that schools “are surrounded by cigarette retailers. Half of the retailers sell cigarettes at a price affordable by adolescents [just 70 cents US], attracting adolescents to initiate smoking.” Some 78.5% of students in Indonesia admit to having smoked at one time, including even 5% of boys aged seven and under (Dewi 2020).

Despite prohibitions in India, a study of areas around 243 schools in that country found that nearby vendors were displaying “tobacco products in ways that are appealing to children and youth. 91% of displays were at 1 meter – a child’s eye level. An estimated 54% of the points of sale had no visible health warning; and 90% of displays were beside candy, sweets and toys – items marketed to children” (Consumer Voice 2019).

Higher-income countries have developed sophisticated systems to prevent sales to minors, but LMICs receive little assistance from international organizations on ways to increase surveillance and enforcement. Education programs, including some taught by student peers themselves and others with a religious orientation, have demonstrated success in schools in such countries as Indonesia, and Turkey, but the extent of these programs in LMICs appears limited (Tahlil 2013, Bilgic 2018).

Alternative Nicotine-Delivery Systems

E-cigarettes, snus, and HNB products are far less harmful than cigarettes (National Academies of Sciences, Engineering and Medicine 2018), and young people have quickly adopted these nicotine-delivery alternatives when available, mainly in higher-income countries (Cullen 2019). Still, the reasonable principle that no one should start using *any* tobacco product has led to a ban on both smoking and alternatives for young people throughout the world – with prohibitions now ranging through age 25 in some countries (Tobacco Atlas 2020).

Vaping among youth has been called an “epidemic” in the United States and elsewhere (CDC 2019), but that may be an exaggeration, mainly because it ignores the propensity of young people to experiment. A British study found that just 0.4% of students who had never used tobacco vaped on more than 20 of the past 30 days. It concluded that regular use of e-cigarettes among those aged 11 to 16 was 3% or less and “remains largely confined to regular [cigarette] smokers.... [Y]outh experimentation is not currently leading to greater frequency of use” (Bauld 2017).

Vaping, nevertheless, is rising, and a clear correlation – and likely causation – has emerged between declining prevalence rates of cigarette smoking and higher rates of vaping and use of other alternatives. This correlation applies both to adults and young people. Between 2013 and 2019, the FDA reported that the proportion of high school students who smoked cigarettes in the preceding 30 days dropped from 13% to 6% while those who used e-cigarettes rose from 5% to 28% (FDA 2020a). Figures for 2020 were distorted by the EVALI controversy (see Chapter 8).

Young people try what's new, and the FDA noted that in its 2019 report, of the approximately 5 million middle and high school students who vape, 3.4 million do so fewer than 20 days out of the past month. Also, many young e-cigarette users vape flavorings without nicotine. In 2019, the University of Michigan's Monitoring and Future Survey found that among 10th graders, 20% vaped nicotine in the past 30 days while 13% vaped flavorings alone (Schaeffer 2019). In fact, a separate study found that in 2019, students who merely vaped flavorings without nicotine exceeded tobacco smokers. Sokol and Feldman concluded, "[T]he decline in current smoking among 12th graders has accelerated since e-cigarettes have become available. E-cigarette use is largely concentrated among youth who share characteristics with smokers of the pre-vaping era, suggesting e-cigarettes may have replaced cigarette smoking" (Sokol 2021).

It is notable that youth smoking in Australia declined sharply from 1996 to 2012 but then, unlike in the United States and the United Kingdom, levelled off (Cancer Council 2019). Australia effectively bans e-cigarettes, even for adults (see Chapter 6), so young people have a difficult time substituting them for combustibles. Similarly, in the Philippines, vaping has been aggressively discouraged, and youth smoking rates are high, at 12% for ages 13 to 15, while e-cigarette use is low, at 2.5% (Campaign for Tobacco-Free Kids 2021). (The legislature in the Philippines recently approved vaping under tight controls, so the country could provide a test case in the future).

Unfortunately, recent data comparing vaping and smoking rates among young people in LMICs are mostly unavailable, in large part because alternatives have only recently begun to penetrate these markets.

A Policy Conundrum

A particular policy challenge is preventing young people from using any sort of nicotine delivery system while at the same time encouraging adult smokers who cannot quit to switch to alternatives. "What primarily causes death and disease from tobacco use," said former FDA Commissioner Scott Gottlieb, "isn't the nicotine in these products. It's the act of lighting tobacco on fire to free that drug for inhalation" (FDA 2018a). Gottlieb later wrote, "E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products and onto nicotine delivery products that may not have the same level of risks associated with them" (FDA 2018b). As noted in Chapter 5, the FDA in 2019 approved Swedish Match snus smokeless tobacco as an MRTP, stating that "using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis" (FDA 2019). In July 2020, the FDA also awarded MRTP status to IQOS, the HNB product from PMI (FDA 2020b).

With the growing acceptance of less harmful nicotine-delivery systems, there is a danger that if policy makers aggressively demonize alternatives in their attempts to stop adolescents from vaping, they may frighten adult smokers away from switching to far less risky practices. In addition, policy makers often make decisions about tobacco without regard to possible effects on the use of marijuana, which can be easier to access and, according to the CDC, lead to mental health problems, including psychosis, and a decline in school performance (CDC 2017).

Responsibilities of Tobacco Companies

In the past, tobacco companies marketed cigarettes to youth. As a memo to the president of Lorillard said in 1978, “[T]he base of our business is the high school student” (Lorillard 1978). Today, many of the larger private companies have policies of marketing all products, including alternatives, only to adult smokers. PMI, for example, states on its website, “[W]e do not use images or promotional materials that have particular appeal to minors, including youth-oriented celebrities or cartoons, or brands, toys or other merchandise which are primarily for, or used by, minors,” and “we do not use models who are or who appear to be under the age of 25” (PMI 2019). BAT’s website states, “A fundamental requirement of our marketing principles is that our marketing is aimed only at adult consumers and is not designed to engage or appeal to children.” The company has a “youth access prevention” policy that features “engagement with governments to adopt minimum age laws of 18 for tobacco sales where none exist and, where they do, to effectively enforce them” (BAT 2021).

Some companies, however, have shamelessly marketed e-cigarettes directly to younger audiences, appealing to young people with ads emphasizing kid-associated bright pinks and blues, young models, and scenes of fun, coolness, and relaxation (Keller 2018). Flavorings for products with names like Candy King Batch are also enticing to young people (but banning flavors like mint and menthol could deter adult smokers from switching to less harmful alternatives).

A lawsuit brought by the Commonwealth of Massachusetts against Juul Labs in 2020 noted that the company launched e-cigarette advertising during 2015-2016 on youth-focused websites, including those of Nickelodeon, the Cartoon Network, and Seventeen magazine (Mass.gov 2020). The company was accused of using provocative models and images with express appeal to young people and of trying to recruit celebrity endorsers such as Miley Cyrus with underage followers. Stanford researchers in 2018 produced a trove of images from launch parties and other Juul promotions aimed at young people (Brodwin 2018).

Education and Reasonable Dialogue

The CDC recently listed “strategies to reduce e-cigarette use among youth” (CDC 2020). Several of those strategies would also affect adults and may cause current smokers to hesitate to make a switch to harm-reducing alternatives, including “increasing price” and “implementing comprehensive smoke-free policies that include e-cigarettes.” But the CDC, which is influential globally, also called for “developing educational initiatives targeting young people,” a policy for all forms of tobacco products.

Education programs are necessary, but they require a commitment and an expenditure that LMICs, especially, have been reluctant so far to adopt. Support from high-income governments and charitable organizations – similar, for example, to the educational effort against HIV/AIDS in Africa – could go a long way toward reducing smoking prevalence, especially in LMICs, home to half the world’s smokers between ages 13 and 15 (WHO 2019a).

In general, the issue of youth smoking would undoubtedly benefit from more rational dialogue. As politicians have learned, raising the specter of harm to children, sometimes called the “Kidification” of an issue, is a good way to get a favorable hearing, but it can cloud a serious policy matter with emotionalism. Certainly, the risks to young people from alternative nicotine-delivery systems are greater than to adults. But by focusing on children, policy can produce unintended effects that discourage adults from adopting new technologies that will allow them to live longer and healthier.

Chapter 8

Learning from the COVID-19 Pandemic

Summary

The Coronavirus Disease 2019 (COVID-19) pandemic has brought new levels of glory and scrutiny to health policy. Individuals have come to appreciate the impact of public health initiatives, and officials are rethinking how best to manage global health threats. In doing so, the pandemic has offered three lessons relevant to the future of tobacco control.

Lesson 1

The Value of Public-Private Partnerships (PPP)

- The success of US vaccine development demonstrates the power of multi-sectoral engagement and PPPs.
- Despite bad actions in the past, the tobacco industry is well positioned to contribute to tobacco control through innovation in THR products, just as the pharmaceutical industry innovated with vaccines and therapeutics to fight COVID.
- Strong PPP will be necessary to make THR products accessible and affordable to LMICs and marginalized communities.

Lesson 2

The Need to Correct Misinformation

- The pandemic underscores challenges in health communications and the need to rethink strategies in this sphere.
- Tobacco communicators (like public health officials battling COVID) must contend with misinformation campaigns, as well as sensational media portrayals – particularly with respect to e-cigarettes. In conveying messages about tobacco control, it is necessary not just to provide information, but to make it resonate on an emotional level.

Lesson 3

Perils of the Precautionary Principle

- Some vaccine hesitations can be attributed to the precautionary principle – the belief that a new intervention should be avoided until its long-term effects are conclusively known.
- Aversion to THR can also be attributed to this type of thinking.
- In both cases, however, the potential risks are far outweighed by certain benefits.

The COVID-19 experience can help us rethink how to fight the tobacco crisis. When the pandemic arrived, the world largely understood the urgency of the problem and proceeded accordingly. There was global sentiment of agony and rage that motivated life-saving measures and vast government spending. Stakeholders in the field of tobacco control must cultivate a similar sense of urgency.

Lesson 1

The Value of Public-Private Partnerships

The COVID-19 pandemic teaches that global crisis demands global solutions. These answers entail collaboration not just among countries, but across sectors. The successful and speedy development of vaccines against COVID-19 was a direct result of PPPs at an unprecedented scale. The pharmaceutical industry, in some cases with research support from government agencies and universities, provided the necessary scientific and technological innovation while governments offered critical financial and infrastructure support (NIH 2020). This process, though imperfect, demonstrated the power of multi-sectoral engagement.

Efforts toward tobacco cessation and THR could also benefit from PPP of this kind. For example, THR products like e-cigarettes have great potential to reduce tobacco-related deaths; however, realizing the full benefits of these tools will require government assistance in development and consumer education. Unfortunately, such partnerships do not currently exist, thanks to the wholesale banishment of industry from relevant conversations (Ballin 2018). Certainly, the tobacco industry earned a poor reputation through years of deceit. Still, it is possible both to acknowledge an industry's dark history and recognize how it has changed and may now contribute to the public good. Here, again, the pharmaceutical industry offers precedent.

In recent decades, the public has come to view the pharmaceutical industry in a negative light – a reputation exacerbated by revelations regarding the complicity of some companies in the opioid crisis, price-gouging and price-fixing. Yet, when the COVID-19 pandemic took hold, the world understood that any innovation in drug development would necessarily come from the industry that develops drugs (Caliber 2020). Likewise, it should be clear that the tobacco industry has the expertise necessary to drive innovation in the field of tobacco cessation and THR. The evidence is already there (PMI 2021).

For these products to achieve the maximum benefit, however, governments will have to recognize the potential of THR product innovation and develop policies to support it by, for instance, regulating and taxing tobacco products in a way that is proportionate to the health risk they pose (Yurekli 2020). Strong PPP will be necessary to ensure equitable access to new cessation and harm reduction tools. Equitable access, in turn, may require collaboration between government and industry to reduce the cost of products and perhaps even to provide free licensing of intellectual property.

Lesson 2

The Need to Correct Misinformation

Like the virus itself, misinformation about COVID-19 has spread rapidly, often foiling the efforts of responsible health communicators. The pandemic teaches that it's not enough to have the facts on your side. Important messages must be accompanied by a sound strategy for their dissemination (Finset 2020). Too often, health communicators subscribe to a "knowledge deficit" model – a strategy that assumes individuals merely lack access to accurate information (Simis 2016). This model neglects a slew of emotional and cultural factors that might render individuals unreceptive to particular facts.

More successful communications approaches consider why messages may not resonate in certain communities and how to surmount these obstacles. For example, the Center for Public Interest Communications developed vaccine education guidelines that emphasize the role of trust (see Table 8-1). These approaches can be applied to many areas of public health communications, including tobacco control.

Table 8-1:

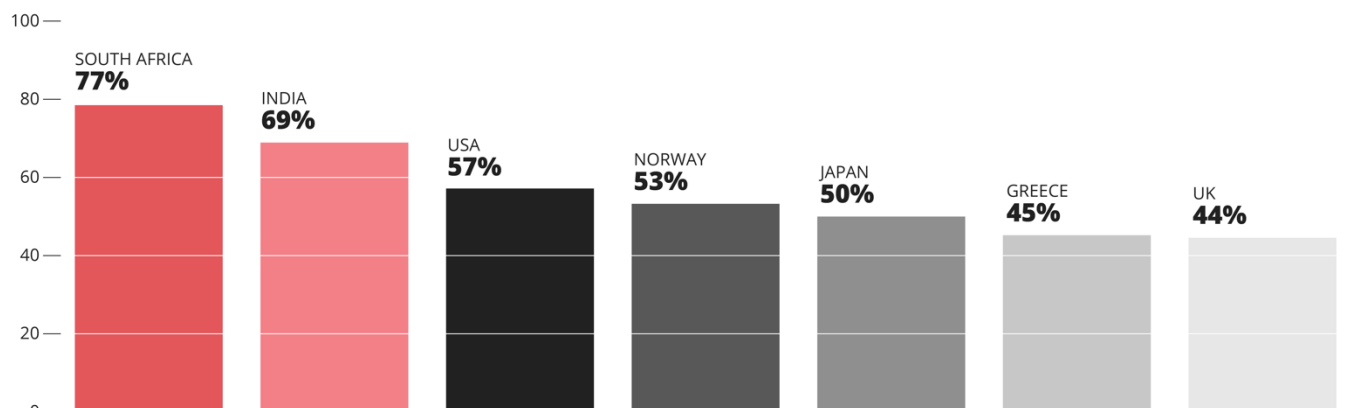
Approaches for Sharing Vaccine Information

- Work within worldviews, identities, and moral values
- Use timing to your advantage
- Make your content concrete, supply a narrative, and provide value.
- Recognize that communities have different relationships with vaccination.
- Change social norms to help gain acceptance.
- Evoke the right emotions.
- Be explicit and transparent about your motivations.

Communication challenges are particularly profound in the case of tobacco and nicotine discourse, where emotions run high, and information can be lacking. Poor messaging in this sphere yields widespread misperceptions that directly affect individual and public health. For example, as noted earlier, many smokers believe that nicotine is the primary driver of tobacco-related cancer and that e-cigarettes are even more harmful than combustible tobacco. Both views may prevent smokers from switching to lifesaving THR products (Figures 8-1 and 8-2) (Bate 2019; Rajkumar 2020).

Figure 8-1:

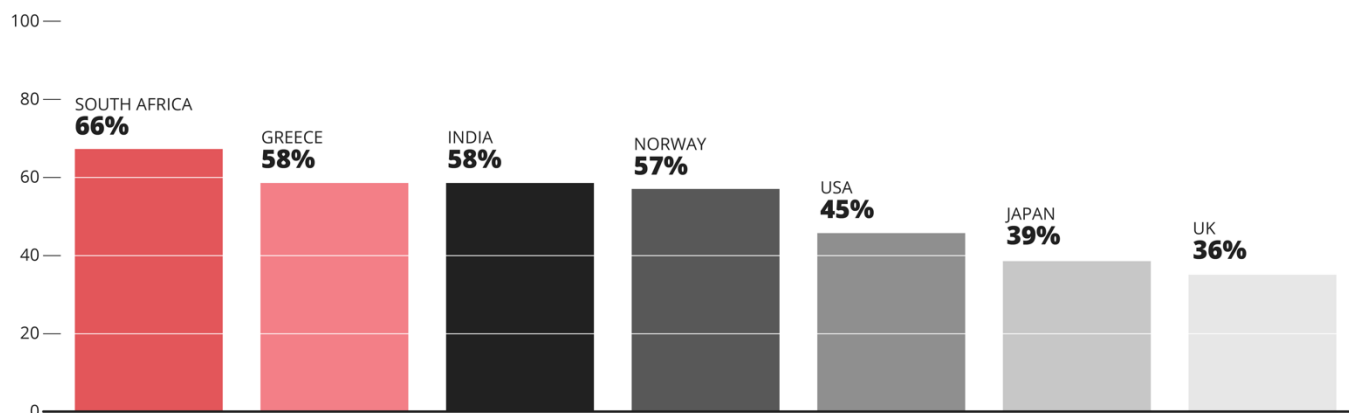
Percentage of Survey Respondents Who Answered “Yes” When Asked if Tobacco-Related Cancer Is Primarily Caused by Nicotine



Source: Rajkumar 2020.

Figure 8-2:

Percentage of Survey Respondents Who Answered That They Believe E-Cigarettes Are Equally or More Harmful Than Combustible Tobacco



Source: Rajkumar 2020.

These widespread misperceptions can be attributed, in part, to misleading representations in the media (Morphett 2020). This phenomenon was apparent in the wake of the 2019 EVALI outbreak. Media outlets were quick to attribute deaths to e-cigarettes, or to conflate THR products with illicit THC products. Emotional headlines like “If He Smoked Cigarettes, He’d Still Be Here” even implied that e-cigarettes posed a greater health risk than combustible tobacco (Howerton 2019). Dave et al found that EVALI outbreak sharply increased the fraction of people who think that vaping is more harmful than smoking (Dave 2020).

False beliefs are often encouraged by vaping opponents and nonprofit groups that overstate the harmfulness of e-cigarettes (Patel 2020). For instance, Michael Bloomberg, whose philanthropies fund anti-vaping initiatives,

often conflates smoking and e-cigarette use. Like others, Bloomberg focuses on the risk of youth uptake to malign the class of products generally, thus discouraging adult smokers from switching. In 2019 he stated, “E-cigarette companies and the tobacco companies that back them are preying on America’s youth.... [T]he result is an epidemic that is spiraling out of control and putting kids in danger of addiction and serious health problems” (Newman 2019). Bloomberg does not elaborate on what these illnesses might be, and he fails to mention the proven benefits of e-cigarettes for adult smokers.

The COVID-19 pandemic has taught us that, to overcome misinformation, health communicators must address concerns specific to communities, ages, and political groups (Cerise 2021). In the United States, for example, the reasons for vaccine skepticism in the black community may differ dramatically from those among white Republicans (Bajaj 2021). Similarly, effective communication about tobacco and nicotine requires meeting communities where they are, ideally through tailored messages and messengers (Sellers 2020).

No panacea exists for online misinformation; however, correcting false messaging starts with confident and unambiguous communication from public health experts. At the beginning of the COVID-19 pandemic, U.S. government officials failed to offer a consistent stance on face masks – a misstep that contributed to later mask skepticism and low adherence to guidelines in general (Kolstoe 2020). Currently, there is similar confusion regarding THR products, with some countries acknowledging their benefits and others banning the products outright. Any hope of effectively communicating the relative risks of various tobacco and nicotine products requires a strong consensus from the global health community.

Lesson 3

Perils of the Precautionary Principle

For months, the world held its breath, hoping for an effective vaccine against the coronavirus. In an amazing feat of science, this call was answered in record time. Then came skepticism. Despite rigorous clinical trials and endorsements from health officials, there was considerable anxiety about unintended and adverse effects of the vaccines. *Sure, they seem to work, but how do we know the vaccines aren't slowly killing us? Shouldn't we wait and see before taking new medicines?*

This attitude, based on what is known as the precautionary principle, holds that, without exhaustive long-term data, adopting a new intervention is too risky and thus ill-advised (Ricci 2013). Although erring on the side of caution is often a practical approach, such a stance fails to account for instances in which the consequences of inaction are grave. In the case of the COVID-19 vaccine, for example, waiting for decades of clinical data before making the vaccine available would have been more reckless than cautious.

In the field of tobacco control, the choice seems the same. Adherence to the status quo ensures that millions of people will continue to die from smoking. By contrast, the adoption of THR products presents a means to reduce death and disease dramatically. Rather than embrace new technologies as a remedy to the tobacco crisis, proponents of the precautionary principle reject demonstrated benefits based on hypothetical risks.

The best way to assuage these concerns is with transparency: for example, giving the public access to exhaustive data on the safety of emerging THR products. Indeed, Pfizer took this approach with its COVID-19 vaccine, releasing an unprecedented amount of safety data ahead of product approval (Firing Line 2020). Unfortunately, in the field of harm reduction, scholarly journals often block the publication of industry research. For instance, all publications under the umbrella of the *British Medical Journal* (BMJ) “no longer consider for publication any study that is partly or wholly funded by the tobacco industry” (Godlee 2013). Such policies run contrary to the principles of Open Science and may promote a kind of academic confirmation bias: because prominent journals do not publish industry data about THR products, scientists may continue to believe that data about their use are insufficient.

Entangled Crises

The links between COVID-19 and the tobacco epidemic transcend mere analogy: A history of smoking may predispose individuals to hospitalization and death from the virus, and surveys show that as many as 40% of tobacco and nicotine users increased consumption because of lockdown conditions (Lowe 2021; FSFW 2020). Further, there is legitimate concern that the swell of resources allotted to the COVID-19 pandemic response will lead to neglect of noncommunicable diseases, including those caused by tobacco use.

Michael McGinnis and William Foege identified this problem when they wrote, “One of the most difficult challenges is to ensure that the urgent does not crowd out the important. In health, this challenge is especially difficult because urgent matters can be so riveting” (McGinnis 2004). At present, COVID-19 is proving more riveting than the tobacco epidemic. It is not, however, more important. Smoking was the leading cause of preventable death heading into this pandemic and it maintains that status today. During the pandemic, smoking has killed more than twice as many people worldwide as COVID-19.

The COVID-19 experience can help us rethink how to fight the tobacco crisis. When the pandemic arrived, the world largely understood the urgency of the problem and proceeded accordingly. There was a global sentiment of agony and rage that motivated life-saving measures. It is time to motivate stakeholders in the field of tobacco control to a similar sense of urgency.

Recommendations

Chapter 9 Vision on How to End Smoking

The possibility of finally bringing an end to smoking has emerged with new technologies that deliver nicotine without combustion. By coupling the best science to intelligent public policy, the scourge of smoking can be eliminated by acting upon the insights and recommendations below.

- The effort to end smoking now has the most powerful tool in history at its disposal: technology that delivers nicotine without the dangers to health caused by the combustion of tobacco. With the support of extensive research, development and deployment of this technology must be encouraged and enhanced by government, tobacco industry, and non-profits.
- Cessation efforts must focus on LMICs, where most smokers are located. LMICs have been neglected for far too long. In the spirit of the original FCTC, these countries require the resources and capacity to end smoking, including research recognizing their unique cultures and histories (for example, the widespread use of toxic forms of smokeless tobacco in parts of Asia). The size of the financial gap to fill must be determined, and funding mechanisms to implement effective tobacco control in LMICs must be devised.
- The history of smoking cessation indicates clearly that physicians have played a critical role, beginning with the original report of the Royal College of Physicians on Smoking and Health in 1962. Today, many physicians are unaware or misinformed about the harms of nicotine and, especially in LMICs, they are still smoking themselves. Their role in cessation must be revived and enhanced through education and compensation for the time necessary to advise patients.
- Currently, in all but a few countries, regulatory policy toward tobacco is confused and contradictory and not based on the best science. Public policy must enable persistent smokers to switch to less harmful nicotine-delivery devices and eventually to quit completely. Backed by research, risk-proportionate policies are the best way to reach that goal.

- Consumers are the most powerful force in creating change. Consumer voices must be lifted up. Understanding the perceptions and lived experiences of those most affected by tobacco use harms (or those who have switched to tobacco harm reduction products or quit) requires consumer research.
- The best ideas come from the broadest stakeholder engagement. Industry representatives, including researchers supported by industry, must not be excluded from fora and discussions of smoking cessation. Debate must be conducted with civility and respect for different points of view.
- Young people must not smoke or use tobacco harm reduction products, and nearly all countries have prohibitions. Technology must be deployed to make those bans more effective. But policies to discourage youth THR use, such as marketing restrictions, must be distinct from policies that encourage current adult smokers from switching to THR.

Global Tobacco Use Trends

1. Research institutions should quantify the size of the financial gap and the funding mechanisms to implement effective tobacco cessation and harm reduction in LMICs.

Cessation Efforts Stall

2. Undertake multi-national, multi-disciplinary and participatory foresight studies (an analysis of alternative futures), especially in LMICs to identify optimal policy responses needed to end smoking and its health impacts, the impact of technological innovations and how these innovations may reshape the landscape over the next 20 years.

Emergence of Technological Innovation

3. Develop private-public partnerships in selected LMICs to improve access, affordability, and local acceptability for cessation and THR products, drawing inspiration from two decades of experience for infectious diseases.
4. Expand access to tobacco harm reduction products in LMICs. Because these products can be expensive, THR patents must be shared by their owners with companies that have weaker R&D capacity but can manufacture products locally.
5. Support development of more effective biomarkers of exposure to the wide range of tobacco products available, as well as biomarkers of early health outcomes that can predict long-term morbidity and mortality outcomes.

Mobilizing Physicians

6. Encourage medical bodies such as the Royal College of Physicians and the World Medical Association to re-establish the leadership role of doctors in ending smoking in LMICs.
7. Determine doctors' knowledge, practice, personal views, and behaviors (for example, do they personally smoke) vis-à-vis nicotine on a periodic basis using digital technologies. Based on those insights, develop and promote evidence-based programs tailored to their knowledge base, practices, and regions to discover what works to end smoking in adults.
8. Support research to design more effective ways of ending smoking in high-risk patients who smoke, including patients with mental health conditions, tuberculosis, heart disease and early-stage chronic lung disease.
9. Support development of easy-to-access, up-to-date information for physicians on three aspects of nicotine: emerging science and knowledge about the health effects, consumer perceptions and how they affect product use, and trends in the creation of future products to end smoking.

The Proper Role for the Industry

10. Encourage tobacco companies (multi-national and local) and state tobacco monopolies to have a clear plan to phase out high-risk combustible products. The plan should include performance metrics for CEOs and senior management to achieve this goal.
11. Find the best ways for tobacco manufacturers and public health agencies to work with social media companies to develop and implement guidelines to detect, reduce and counter disinformation on THR and the role of nicotine.

Improving Regulatory Policies

12. Advocate for risk-proportionate regulations as a means of making it easier for smokers to switch from combustibles and quit.
13. Fund research aimed at documenting the early and medium-term health effects (five years) of smokers switching completely or partly to THR products or cessation in large populations of adult users matched to smoking controls.
14. Support research to adapt profitable business model designs used by leading multi-national companies with large THR portfolios to state-owned tobacco monopolies.
15. Develop mechanisms to assess the impact of recently introduced risk-proportionate policies on switching from combustibles to THR and on cessation. Those policies include changes involving the treatment of pricing and taxation, flavors and nicotine levels, and health messages.
16. Leverage multi-national, multi-disciplinary and participatory foresight studies to identify health gains from optimal policy responses needed to end smoking.

Smoking and Children/Youth

17. Support development of a global multi-company alliance that endorses and commits to enforce a common set of the highest voluntary standards, which include responsible marketing practices to restrict combustible tobacco and THR product access to those under the of age 21. Require a third party to evaluate and monitor compliance.
18. Advocate for governments to mandate the use of technologies to verify the age of prospective purchasers of cigarettes and THR products at the point of sale and online. These technologies already exist in nascent form in high-income countries, but government and industry support and additional research are needed for faster development, especially with an eye to adapting the tools to the needs and realities of LMICs.

Considerations from COVID-19

19. Adopt best practices to combat misinformation and build a healthier information environment for tobacco harm reduction. Identify leading sources of misinformation, harnessing technology to slow the spread of falsities and to share accurate information. Encourage trusted messengers such as doctors to disseminate clear information. Also fund research into understanding sources of misinformation, identifying evidenced-based interventions, and work closely with consumer and media advocates to reach communities disproportionately affected by misinformation.

Appendix

Analysis of Regulation of Alternative Products Versus Cigarettes⁵

An analysis of the policy responses to THR alternatives in the ten representative countries to smoking is summarized below. For each of these countries, the table compares policies for two different alternatives with those for smoking across four areas. We use a traffic-light system: policy areas in which alternatives are more strictly regulated than smoking (for example, taxes on alternatives are higher than taxes on traditional cigarettes are red; those in which alternatives and smoking are similarly regulated are yellow; those in which alternatives are less strictly regulated are green; and gray means that the information is unavailable for various reasons).

The analysis ultimately illustrates how policy responses run the gamut. At one end of the spectrum, countries like Australia have largely treated alternatives as more harmful than traditional cigarettes and have erected barriers to their use. Similarly, India has banned less harmful alternatives while regulations on cigarettes remain light – for instance, online sale of cigarettes is allowed, few retail restrictions for cigarettes exist, and flavored cigarettes are permitted.

At the other end, countries like the United Kingdom have embraced alternatives as less harmful than traditional cigarettes and have implemented policies to use alternatives as glide paths for persistent smokers to reduce harmful use and eventually quit smoking altogether. In between those two extremes are countries like Japan, whose response has been mixed and, at times, contradictory.

| Country | Policy area | Vaping products | Heated tobacco | Overall assessment by policy area |
|-----------|-------------------------|-----------------|----------------|---|
| Australia | Product and ingredients | | | Alternatives to traditional combustible products are de facto banned. Nicotine is regulated as a medicinal product in Australia; alternatives require a prescription and are not allowed to be sold as consumer goods. A license is now necessary for personal imports of vaping HNB products, and nicotine pouches. Personal imports of oral tobacco are not allowed. In comparison, cigarettes can be sold but are subject to significant restrictions in terms of plain packaging, warning labels, tax, advertising, sale, and age restrictions. |
| | Advertising | | | While cigarettes advertising is strictly controlled, advertising of all other products is banned. |
| | Retail channels | | | Cigarettes continue to be sold in retail channels (despite heavy restrictions) while no alternatives may be sold without a medical prescription. |
| | Taxation | | | Taxes are not applicable for tobacco alternatives and nicotine products; tax is due if imported for personal use. |
| Country | Policy area | Vaping products | Heated tobacco | |
| Canada | Product and ingredients | | | All tobacco products are subject to plain packaging and flavor restrictions, which do not apply to e-cigarettes (however, as of July 2021, a nicotine cap of 20mg/ml and a ban of flavors is under consideration). Nicotine pouches are not allowed unless licensed as a prescription or natural medicine. |

⁵ This table is a snapshot in time and will be updated as regulations in the countries covered evolve. It was last updated on 18 August 2021.

| | Advertising | | | The law makes no distinction among types of tobacco products, while vaping products are allowed to be advertised with minor limitations. Pouches cannot be advertised. |
|---------|-------------------------|-----------------|----------------|---|
| | Retail channels | | | The law makes no distinction for retail restrictions among types of tobacco products. E-cigarettes may be sold across provinces. |
| | Taxation | | | Effective taxes are substantially higher for cigarettes than for oral and heated tobacco. E-cigarettes are not taxed (in 2022, a tax may enter into force if a pending proposal is approved). |
| Country | Policy area | Vaping products | Heated tobacco | |
| China | Product and ingredients | | | China's tobacco sector is strictly monopolized and controlled through several state-wide tobacco companies making up China National Tobacco. Cigarettes, HNB devices, and oral tobacco products are considered part of the monopoly, and it is illegal to commercialize the products unless approved by the monopoly. E-cigarettes and pouches do not have substantial product/labelling rules; heated tobacco is restricted; and oral tobacco products are subject to similar (lenient) rules as cigarettes. |
| | Advertising | | | Chinese law does not distinguish among tobacco-containing products, and alternatives are subject to the same restrictions as cigarettes. Nicotine pouches are not specifically restricted. Vapor products are de facto treated as tobacco products, although there is no specific legal basis for this treatment (this is about to change). |
| | Retail channels | | | The sales channels for vapor products are as limited as other tobacco products but no license is required. Tobacco-containing products require the same license as cigarettes, and nicotine pouches have no specific controls (although we consider they could be treated the same as oral tobacco). |
| | Taxation | | | Only legal tobacco-containing products are taxed. The tax on oral products is substantially lower than for cigarettes. |
| Country | Policy area | Vaping products | Heated tobacco | |
| Germany | Product and ingredients | | | Alternative tobacco products are subject to fewer restrictions than cigarettes; in particular, flavors are allowed. Nicotine pouches are considered a banned food product in Germany. Nicotine-containing e-cigarettes are regulated as tobacco-related products and Tobacco Products Directive (TPD) restrictions common to the whole European Union apply, including a limit on nicotine concentration to 20 mg/ml. |
| | Advertising | | | Advertising for alternative tobacco products has been restricted recently to the same extent as cigarettes in Germany. Nicotine pouches cannot be advertised. |
| | Retail channels | | | Retail channels for alternative tobacco products have been restricted recently to the same extent as cigarettes in Germany. Nicotine pouches cannot be sold. |
| | Taxation | | | All alternative products are effectively taxed at a lower rate than cigarettes; e-cigarettes are not taxed (however, this will change in July 2022 when a tax of €0.16 per ml of e-liquid will apply). |
| Country | Policy area | Vaping products | Heated tobacco | |
| India | Product and ingredients | | | E-cigarettes and HNB products are banned. Tobacco-containing products are regulated identically. Pouches are unregulated. Regulations around oral tobacco remain unclear, but food products containing nicotine such as <i>gutkha</i> are banned. No major restrictions apply to the ingredients or content that may be used on legal tobacco products. |
| | Advertising | | | E-cigarette and HNB advertising are banned. Advertising of other tobacco products is regulated identically. Pouches are unregulated. |
| | Retail channels | | | E-cigarettes and HNB products are banned. Restrictions on retail sales of other tobacco products are regulated identically. |
| | Taxation | | | Pouches are untaxed. The tax burden imposed on oral products is lower than cigarettes. |
| Country | Policy area | Vaping products | Heated tobacco | |

| Indonesia | Product and ingredients | | | All tobacco-containing products are regulated in the same way as cigarettes. There are also no specific labelling or packaging regulations applicable to e-cigarette hardware or e-liquid. According to the National Agency of Drug and Food Control, e-cigarettes are not catalogued as tobacco products except for tax purposes. Therefore, because no other product-specific laws exist, only general and consumer product regulation apply. There are no bans on flavors or additives. |
|-------------|-------------------------|-----------------|----------------|---|
| | Advertising | | | The advertising of tobacco-containing products is treated similarly to cigarettes with only limited restrictions. Nicotine-containing product advertising is unrestricted. |
| | Retail channels | | | Restrictions on the sale channels for tobacco-containing products is the same as cigarettes (only limited restrictions). Nicotine products are unregulated. |
| | Taxation | | | Taxes on oral tobacco, e-cigarettes, and pouches are effectively lower than cigarettes; heated tobacco taxes are higher. |
| Country | Policy area | Vaping products | Heated tobacco | |
| Japan | Product and ingredients | | | Nicotine-containing products are banned (although non-nicotine vape products are treated as consumer products). All tobacco-containing products are regulated in the same way as cigarettes; restrictions are mild. In contrast, nicotine-containing products are heavily restricted: Japan has banned e-cigarettes other than as pharmaceutical products, an approach that has not been followed by other East Asian nations. Content of heated tobacco consumables is not regulated. No specific restriction applies to the ingredients and flavors that may be used in tobacco products. |
| | Advertising | | | Tobacco control laws in Japan, especially in terms of advertising or flavor availability, are more lenient than in many other countries allowing advertising, which may be seen as a contributing factor to the success of the heated tobacco market. |
| | Retail channels | | | Nicotine-containing products are banned, and any tobacco-containing products are regulated in the same manner as cigarettes. |
| | Taxation | | | Alternative tobacco products are effectively taxed at a lower rate than cigarettes. |
| Country | Policy area | Vaping products | Heated tobacco | |
| South Korea | Product and ingredients | | | Nicotine and tobacco products are all regulated the same way under the same framework. For vapor products, nicotine strength is limited to 1%. In contrast to Japan, nicotine-containing e-cigarettes are legal, but are regarded as poison (thus, requiring a license). The development of the South Korean vaping market is constrained by a strict cap on nicotine concentration, at a maximum of 10 mg/ml – considered among the lowest tolerance limits in the world. |
| | Advertising | | | Advertising restrictions for all tobacco and nicotine products are the same as cigarettes. |
| | Retail channels | | | Retail restrictions apply equally for all tobacco and nicotine products. |
| | Taxation | | | Oral products and pouches are effectively taxed at a much higher rate than cigarettes; vaping is taxed at a much lower rate, and heated tobacco at a slightly lower rate, compared with cigarettes. |
| Country | Policy area | Vaping products | Heated tobacco | |
| Russia | Product and ingredients | | | Although product restrictions are now applied equally to tobacco- and nicotine-containing products, no technical standards have yet been developed for vaping and heated tobacco, and thus regulation is lower compared to cigarettes. Chewing tobacco is treated similarly to cigarettes; all other oral products and nicotine pouches are banned. |
| | Advertising | | | The Russian legal framework envisages the same advertising and sponsorship restrictions for cigarettes as alternatives. |
| | Retail channels | | | The Russian legal framework envisages the same retail restrictions for cigarettes as for nicotine-containing products. |

| | Taxation | | | New alternative products are effectively taxed at a lower rate than cigarettes, particularly vapor products; the effective tax rate for oral products' (chewing tobacco) is higher than cigarettes. |
|----------------|-------------------------|-----------------|----------------|--|
| Country | Policy area | Vaping products | Heated tobacco | |
| United Kingdom | Product and ingredients | | | The United Kingdom regulates products according to risk profile: While cigarette regulation is among the strictest in Europe (including plain packaging and flavor bans), vapor and other THR products are regulated less onerously. |
| | Advertising | | | All tobacco-containing product advertising is heavily restricted, with very few options allowed; pouches are allowed to be advertised freely, and vaping advertising have some limitations. |
| | Retail channels | | | Products can be sold in all retail outlets, except for vending machines. The main difference between tobacco and alternative nicotine products is that tobacco products may not be openly displayed in any shop other than tobacconists. |
| | Taxation | | | Alternative tobacco products are effectively taxed at a lower rate than cigarettes; nicotine-containing products, including vape and nicotine pouch, are untaxed. |

Source: E-Cigarette Intelligence, Foundation for a Smoke-Free World.

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CHAPTER 3: EMERGENCE OF TECHNOLOGICAL INNOVATIONS

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