



GLOBAL STATE OF TOBACCO HARM REDUCTION

2022

2020

2015

2000

1970

1930

1880

THE RIGHT SIDE OF HISTORY



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**GLOBAL STATE OF TOBACCO
HARM REDUCTION**

2022

**THE
RIGHT
SIDE
OF
HISTORY**

The Right Side of History: The Global State of Tobacco Harm Reduction 2022

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An accompanying GSTHR Briefing Paper summarising the findings and key messages of the report is also available at <https://gsth.org>. The Briefing Paper will also be available in Arabic, Chinese, French, German, Hindi, Indonesian, Japanese, Polish, Portuguese, Russian, Spanish and Swahili.

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Report summary and key messages

Introduction: The threat of disruption

Tobacco harm reduction encourages people who smoke or use risky tobacco to switch to the use of safer nicotine products. The adoption of a harm reduction approach is complementary to existing tobacco control interventions. **The emergence of safer nicotine products, especially vaping, has brought seismic disruption to the commercial, clinical, public health, and legislative landscapes.** This disruption has dominated the history of tobacco harm reduction so far.

Chapter 1: Dying for a smoke

Humans have smoked tobacco for thousands of years. In the 19th century, a mass consumer market developed after the invention of the cigarette rolling machine. In the 1950s, the severe health risks of smoking became evident; tobacco control efforts began from the 1960s onwards. **Despite decades of tobacco control, over one billion people still smoke around the world and each year, eight million people lose their lives to smoking-related diseases.** The populations of many low- and middle-income countries, and vulnerable and disadvantaged groups in high-income countries, are disproportionately impacted.

Chapter 2: The genesis of tobacco harm reduction

Throughout the 20th century, tobacco companies misrepresented filter and light cigarettes as 'safer' – but cigarettes remained deadly. **By the 1970s, health researchers understood that people smoked to obtain nicotine, and that nicotine was not the cause of the most severe smoking-related harms.** Health researchers began to explore the concept of tobacco harm reduction, noting that some forms of nicotine delivery, for example Swedish-style snus or US smokeless tobacco, were less harmful to health than smoking while being palatable to consumers.

Chapter 3: A stuttering evolution towards the quiet revolution

The search for safer ways of consuming nicotine beyond combustible cigarettes continued: the tobacco industry persisted, but ultimately failed. **It was individuals working outside the tobacco industry who pursued innovations that began the journey towards modern safer nicotine products.** A Chinese pharmacist developed the vapour technology that would kickstart a quiet revolution in safer nicotine consumption: the e-cigarette. A new industry sprang up in the city of Shenzhen in China in the 2000s – and consumers worldwide began to adopt the products.

Chapter 4: Community innovation – and commercial expansion

In the first decade of the 21st century, people began sharing their experiences of switching from smoking to vaping products. Supportive vaping communities sprang up, both online and in person. Some consumers developed new innovations in vaping technology, subsequently commercialised by agile manufacturers based in China and, increasingly, other countries as well. **Consumers began advocating for their right to switch from smoking to safer products as regulators considered reducing access to them.** The tobacco industry was late to act on the disruptive threat posed by vapour technology to their core business.

Chapter 5: 'Fear, Uncertainty and Doubt'

Public health and traditional tobacco control were wrongfooted by the disruption of the vaping revolution; the arrival, from the 2010s, of some tobacco industry players into the market reasonably led to concerns. Nevertheless, a significant and independent evidence base in favour of the role of safer nicotine products in tobacco harm reduction was developing at pace. Yet many in public health failed to adapt. **Some health organisations have deployed the tactics of fear, uncertainty, and doubt that**

the tobacco industry was once, rightly, criticised for – including a refusal to engage with emerging scientific evidence. This has, in many instances, drifted into outright disinformation.

Chapter 6: Follow the money

It is unarguable that scrutiny and debate about new products and nicotine-using behaviours is essential. Yet kneejerk opposition, without regard to evidence, or a willingness to discuss the role of effective tobacco harm reduction in reducing smoking-related death and disease, has led to facts falling victim to dogma. **The foundations for this can be traced to the financial dependency of the WHO's global tobacco control interventions – and related organisations and campaigns – on funding from individual billionaires, with Bloomberg Philanthropies holding a dominant role.**

Chapter 7: Regulating for health

State and public health bodies have a duty to help ensure safer nicotine products are properly tested, assessed, regulated, and controlled – for example, by preventing their sale to children. But the use of the law to influence individual behaviours involves consideration of key human rights; balancing individual rights against centrally determined benefits is essentially fraught. When the state or international organisations legislate and enforce, the intention is to reduce harms and risks. **In many countries in 2022, significantly safer nicotine products are banned or restricted, while cigarettes, the most dangerous means of using nicotine, remain universally legal.** In many cases, cigarettes are even being produced by state-owned or state-benefiting enterprises.

Chapter 8: The right to use and the right to choose

People who smoke should have the right to access lower risk products that evidence shows are amongst the most effective tools for cessation. To this end, consumer advocacy organisations have formed worldwide, and have had some notable successes in retaining that right in some countries and regions. Yet at the highest levels of international policymaking, these people are barred from participation in decisions that directly affect their health. The Framework Convention on Tobacco Control includes harm reduction, but the approach has been ignored in its implementation to date. **In light of new developments in nicotine consumption, and in consideration of the fundamental human right to health, harm reduction now can and should be incorporated into international and national tobacco control efforts.**

Chapter 9: Future shoot

The genie is out of the bottle: a major disruptive force is at play. A range of safer nicotine products have established both an evidence base for reduced harm in comparison to smoking cigarettes and consumer popularity, with an estimated 112 million safer nicotine product users globally in 2021. But divisions within both the public health and political worlds are blocking progress. Prohibition of safer products, while deadly combustibles remain on sale, is illogical. It will ultimately fail. Meanwhile, with over a billion customers for cigarettes, the tobacco industry's core business is rock solid; it can afford to watch the battle over tobacco harm reduction play out. **Effective harm reduction interventions, at minimal cost to governments and health agencies, can end smoking within a generation.** The alternative is a continuation of approaches that will continue to fail those most in need. The price will be counted in the millions of lives that could have otherwise been saved.

About the report

The Right Side of History: The Global State of Tobacco Harm Reduction 2022 is the third of our biennial Global State of Tobacco Harm Reduction (GSTHR) reports. Since 2018, the series has been charting progress in the adoption of tobacco harm reduction (THR), an approach which encourages people who smoke or use risky tobacco to switch to the use of safer nicotine products (SNP). These products include nicotine vapes, Swedish-style snus, nicotine pouches and heated tobacco products. The adoption of tobacco harm reduction is complementary to existing tobacco control interventions.

In these reports and other publications, we have gone into great detail about the global landscape of tobacco harm reduction (THR). We have explored what the products are, how they work and how they differ from combustible cigarettes. We have heard from some of the people who use safer nicotine products, who now number over 100 million. We have considered the 'right to health' imperative of THR, the significant and growing independent evidence in support of THR, and its vast potential in addressing the public health harms caused by tobacco.

Since 2018, we have also exposed compromised science designed to undermine confidence among smokers and health professionals about switching to SNP. We have revealed the global funding streams that are biased against THR, among whose beneficiaries is the World Health Organization (WHO). We have described the 'no platform' culture which has excluded researchers, clinicians and SNP consumers from the international tobacco control stage. Finally, we have shown how disinformation leads to forms of regulation and control that work against the interests of public health.

The report you are reading now does not seek to replicate or revisit the previous reports in detail. Instead, it steps back and casts an eye over the history of THR. Where did this history begin? And how has it developed? We bring the story right up to date with a final section that attempts to look into the near future.

Information for this report has been gleaned from numerous sources including academic journals and books, tobacco policy papers and research, market analyses, government websites, mainstream and specialist journalism, and social media commentary. We are grateful for the time and expertise offered by a number of key individuals who provided information during the writing process through conversations, email exchanges, and the supply of documents. Some of those who contributed wish to remain anonymous, including former WHO employees and those working in the tobacco industry, both past and present. Our thanks go to all of these people for their input. We are also pleased to acknowledge the assistance of the following individuals:

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Foreword: The Right Side of History

Gerry Stimson

Director, Knowledge•Action•Change, Emeritus Professor Imperial College London

The beginning of the end for smoking?

It is now well over a decade since I first came across a technological innovation which enabled people to consume nicotine without having to burn tobacco. The potential of vaping products was obvious and exciting. Here was an opportunity to massively reduce the burden of premature death and ill health caused by smoking cigarettes.

I was further encouraged to learn that there was already a vibrant community of people adopting this new technology, who were actively seeking to support friends and family who still smoked to switch. I looked forward to this combination of innovation and consumer activism helping to rapidly hasten the end of smoking. We appeared on the cusp of a mass global health issue being consigned to the history books.

As a social scientist working for a long time on health issues, what struck me was that the switch away from smoking was being driven by consumers and new products, not by public health and tobacco control advocates. This was a revolution in public health driven by people affected by smoking, rather than by public health institutions.

New technology and established harm reduction principles

The necessity of understanding and communicating the possibilities offered by these innovative products was clear. Along with my long-time colleague Paddy Costall and others experienced in delivering harm reduction approaches for those using drugs, in 2011 we established Knowledge•Action•Change (K•A•C) to promote harm reduction as a key public health strategy.

We had a track record in helping to facilitate policy developments that demonstrably reduce disease and mortality. Our previous experience had taught us the importance of engagement with all of the key stakeholders. The team we brought together were skilled at building networks, and involving people with lived experience, including people who use drugs, those affected by HIV/AIDS, those caught up in the criminal justice system, who are homeless or who live with poor mental health. Our team also shared strong international links with those involved in the existing areas of harm reduction, those working in public health and the related research and academic arenas. Our aim was to transfer these insights and skills to promoting tobacco harm reduction as something that might dramatically improve individual and community health and wellbeing.

K•A•C's work on tobacco harm reduction began in the UK, with meetings, small events and seminars, at which we discussed the potential these new nicotine technologies offered public health. The meetings were attended by a potent mix of researchers, academics, smoking cessation practitioners, service commissioners, and crucially, the people who were discovering and using these new devices. We listened, we shared information, and we began to build networks.

Challenges emerge

Aware of the growing international interest in the topic, 2014 saw the launch of the first Global Forum on Nicotine (GFN) in Warsaw. The conference proved very popular: deliberately multi-sectoral, it enjoyed input from a diverse mix of professionals and individuals with an interest in nicotine, including academics from various disciplines, policy analysts, public health experts, consumers and product manufacturers. We believed – and still do – that it was important to bring all stakeholders to the table. GFN

We appeared on the cusp of a mass global health issue being consigned to the history books

Our aim was to transfer these insights and skills to promoting tobacco harm reduction as something that might dramatically improve individual and community health and wellbeing

– now organised by our events company K•A•C Communications – celebrates its tenth year in 2023.

It soon became clear that rather than an overnight revolution, the move towards large scale adoption of tobacco harm reduction was going to be a longer, more complex uphill battle. We learned early on that those in favour of tobacco harm reduction could not count on broad support from those working in tobacco control or in the public health field, many of whom remain either ambivalent or hostile today.

It feels particularly frustrating that many professionals in other areas of harm reduction were and remain reticent, too, and that many continue to largely ignore smoking. This, despite the huge numbers of people accessing harm reduction services for substance use who die each year as a direct result of smoking-related illness, while effective harm reduction approaches are now available.

But way beyond the reach of our work, a negative atmosphere was being created around tobacco harm reduction by key international organisations that were early to express hostility toward the whole notion. Most notable among these institutions is the World Health Organization. This is in spite of the fact that ‘harm reduction’ is named as the third pillar of a tobacco control strategy, alongside demand and supply reduction, in the opening words of the WHO’s Framework Convention on Tobacco Control (FCTC).

It is not just within public health that novel safer nicotine products have provided a challenge to the status quo. The rise of vaping products, which began life in small start-up companies, often in China, caused disruption, concern and confusion amongst the major tobacco industry players. Huge companies producing billions of cigarettes per year were wrong-footed. This new technology didn’t emerge from their research and development facilities, nor could it be claimed by public health.

But the evidence matters – and there is a growing mountain of it relating to the greatly reduced risk associated with safer nicotine products. Fortunately, a number of countries could see the benefits of enabling their smoking population to switch from the dangers of smoking cigarettes to much safer products. Public Health England, whose function is now within the Office for Health Improvement and Disparities, is one example of a national health body which recognises these benefits. Countries which have adopted positive policies to safer nicotine products, or even just avoided counter-productive legislation or regulation, have seen the benefits in significant reductions in the number of people who smoke.

Scaling up

If we were to support tobacco harm reduction to flourish, we knew that decision-makers needed access to independent, high-quality research and policy guidance, as well as the ability to hear from the growing networks of both professionals and individuals, and affected populations building the evidence-base for the approach. Work like this is time-consuming, often challenging and it requires financial resources. Funding is yet another area in which tobacco harm reduction is drastically underserved by mainstream sources.

Harm reduction programmes are not always an easy sell when it comes to major funding organisations. But even those philanthropic foundations which provide generous financial support for substance use harm reduction have, to date, balked at supporting tobacco harm reduction. One actively works against it. These foundations are missing an opportunity to support an approach which could deliver impact on a scale that is virtually unparalleled in public health: eight million people die globally every year from smoking-related disease. That’s three times more than the number of deaths from HIV/AIDS, tuberculosis and malaria combined. It is ten times greater than all deaths related to state-banned drug use.

“It soon became clear that rather than an overnight revolution, the move towards large scale adoption of tobacco harm reduction was going to be a longer, more complex uphill battle

“The rise of vaping products [...] caused disruption, concern and confusion amongst the major tobacco industry players

“Harm reduction programmes are not always an easy sell when it comes to major funding organisations

In 2017, therefore, the launch of the Foundation for a Smoke-Free World (FSFW), established with a mission to end smoking in this generation, provided the potential to obtain funding for further work in this arena. At K•A•C, we recognised the vital importance of mapping the global, regional and national availability of safer nicotine products, alongside the regulatory responses to them. So was born the Global State of Tobacco Harm Reduction (GSTHR) programme, of which this report is one part. The database and publications produced by the GSTHR have become a highly valued resource accessed by many thousands globally each month.

As an organisation we also wanted to help expand research capacity and understanding in relation to the principles and delivery of tobacco harm reduction. To achieve this, we established the Tobacco Harm Reduction Scholarship Programme (THRSP), again funded by the FSFW. Scholars from across the world have worked on a wide range of topics, helping improve professional and community understanding, with outputs including articles published in peer-reviewed journals, the establishment of regional networks, podcasts and films. Graduates of the THRSP will play vital roles in the ongoing struggle to expand and improve THR.

Potential yet to be realised

It is impossible to pretend that things have progressed as I had hoped and expected over the last ten years. Massive obstacles and barriers remain. In some areas the situation has actually worsened, even while the scientific evidence in favour of tobacco harm reduction has strengthened. Too many in public health remain wedded to traditional approaches which fail to recognise the potential of safer nicotine products while continuing to fail those most in need.

As I reflect on the situation in 2022, the great promise and potential of tobacco harm reduction remains to be realised. The trajectory is in the right direction, driven by good products and consumer interest. There has been progress. Recent GSTHR research estimates that there are now 82 million people vaping worldwide, with another 20 million using heated tobacco products and around 10 million using snus or other smokeless products. That is over 100 million people who are avoiding the extremely high risks of smoking tobacco. But these figures are dwarfed by the 1.1 billion who continue to smoke daily, with no indication that traditional tobacco control policies will have a significant impact anytime soon.

Tobacco harm reduction provides a pragmatic response, one that can provide significant gains for minimal investment from under-resourced health budgets. It can help address the issues of countries and communities being left behind by the health gains experienced by others.

We need an openness to new thinking and a critical but balanced evaluation of the science. We should also recognise the principle of ‘nothing about us, without us’ – that people with experience of switching from smoking to safer nicotine products, and the advocacy organisations many have formed, can be tremendous assets and should be listened to.

And we need to get all stakeholders working together. Together, there is so much that can be achieved in the coming years – and history will surely not deal kindly with those who fail to grasp this opportunity.

the great promise and potential of tobacco harm reduction remains to be realised

Tobacco harm reduction provides a pragmatic response, one that can provide significant gains for minimal investment from under-resourced health budgets

Preface: The war against better health

Harry Shapiro

Report author; Executive Editor, The Global State of Tobacco Harm Reduction

Imagine for a moment that it's your first day as Director-General of the world's leading public health agency. You're being briefed by a stream of officials about the greatest health challenges facing humankind. Amid the dizzying amounts of data being pushed across your desk, one set of figures catches your eye. 1.1 billion smokers in the world, 80 per cent of whom live in low- and middle-income countries (LMIC).¹ Eight million smoking-related deaths annually, and a total of a billion deaths forecast for 2100, an estimate unchanged since 2001. Half of all current smokers to die from a smoking-related disease. Half of those deaths will occur in middle age. Nearly 200 million disability-adjusted life years wiped out, at a global cost of nearly \$2 trillion a year, roughly 2% of the world's gross domestic product.² How did we get here, you ask – and what is being done about it?

The WHO Framework Convention on Tobacco Control (FCTC) came into force in 2005, and in 2006, the WHO implemented a package called MPOWER, which sets out to monitor tobacco control progress. Yet the WHO's own data show that, in fact, there is little if any progress. By 2006 in high-income countries, smoking rates were already declining, but prevalence rates were beginning to plateau. And today, just as in 2006, most smoking and smoking-related deaths occur in LMIC. It is also largely these countries who have taken their cue from the articles of the FCTC to enact domestic tobacco laws. But weak infrastructure and political inertia mean enforcement is variable. Many states also rely on tobacco taxes, tobacco export revenues in tobacco-producing economies, and even direct state involvement in the domestic tobacco industry.

Going right back to the creation of the United Nations in 1948, and in landmark international treaties since, is the recognition that the right to health is one of the fundamental human rights citizens can expect of the state. The global agency charged with promoting the right to health as a basic human right is the World Health Organization (WHO). To date, however, the WHO, has done little to promote a human rights approach to public health. As Professor Benjamin Meier has asserted in the *Stanford Journal of International Law*, the WHO has taken a functional, technocratic, overly medicalised approach to treaty obligations.³

What this means in practice is a failure to empower citizens to take control of their own health, contrary to the ambitions outlined both in the WHO Declaration of Alma Ata in 1978 focused on primary health care goals and in the WHO Ottawa Charter of 1986 on health promotion.^{4,5} At a macro level, this medicalised approach recognises only the role of bureaucratic healthcare systems. At a micro level, it can be characterised as 'doctor knows best'. And understandably, what all health professionals want is to cure people – or at the very least 'do no harm'.

Half of all current smokers to die from a smoking-related disease

the WHO, has an unenviable record of doing little to promote a human rights approach to public health

¹ WHO. (2022, May 24). *Tobacco factsheet*. World Health Organization. <https://www.who.int/news-room/fact-sheets/detail/tobacco>.

² *Commission Report: Reignite the Fight Against Smoking*. (2021). The International Commission to Reignite the Fight Against Smoking. <https://www.fightagainstmoking.org/>, p. 9.

³ Meier, B. (2010). Global Health Governance and the Contentious Politics of Human Rights: Mainstreaming the Right to Health for Public Health Advancement. *Stanford Journal of International Law*, 46, 1, p. 50.

⁴ By 1988, the WHO admitted that the 'Health for All By 2000' goal was impossible and dropped the target from subsequent Health For All campaigns. *Declaration of Alma-Ata*. (1978, September 6). International Conference on Primary Health Care, Alma-Ata, USSR. <https://cdn.who.int/media/docs/default-source/documents/almaata-declaration-en.pdf>; Meier, 2010, p. 48.

⁵ WHO. (1986, November 21). The Ottawa Charter for Health Promotion. *First International Conference on Health Promotion*. First International Conference on Health Promotion, Ottawa. <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>.

‘curing people’ is not always the most important public health imperative. Saving lives is what counts

A principle that some can find challenging about harm reduction is that ‘curing people’ is not always the most important public health imperative. Saving lives is what counts. As the HIV/AIDS crisis first emerged, the distribution of condoms and safer injecting equipment was undertaken by those on the frontline of affected communities, who were outside of formal medical or public health structures. Similarly, in the first phase of the safer nicotine product revolution, many people who had previously failed to quit smoking became early adopters of emerging vaping products. Some even made their own at home. As Gerry Stimson noted in his foreword, people exchanged information online with their peers about all aspects of the new technology, way ahead of any small or large corporate industry involvement. These early adopters didn’t consult an academic evidence-base; hundreds of online threads told the story of lives improved by switching to vaping, testimony which is replicated in stories shared among vapers to this day.

After years of dedicated advocacy, harm reduction has now been integrated into the strategic global public health response to substance use and HIV/AIDS, albeit grudgingly in some cases, and with variations in implementation across countries. But the evidence-base in favour of its role is overwhelming. When it comes to the demand reduction element of tobacco control, the WHO admits that globally 70% of smokers have no access to stop-smoking services.⁶ There are harm reduction options that were not available when original agreements and protocols were drawn up now providing people who smoke with safer alternatives. They bring the promise of swift gains for individuals and reducing global health inequalities. But even as the numbers of people using all forms of SNP has increased to over 100 million worldwide, adults who smoke and who want to switch away from smoking or quit altogether are facing significant opposition, including from within the WHO.⁷

From a war against tobacco and the industry that produces it, it appears as if there is now a global war on nicotine

Unfortunately, the WHO, its NGO and academic allies and philanthropic funders have no answer to the evidence base in favour of using safer nicotine products in harm reduction. To deflect attention away from the independent evidence, they claim that the tobacco industry has corrupted all who advocate in favour of the approach. From a war against tobacco and the industry that produces it, it appears as if there is now a global war on nicotine. If we’ve learned anything in over five decades of the ‘war on drugs’, we’ve learned that you cannot wage war against a substance. All such wars are civil wars against people.

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Tobacco harm reduction is already helping millions of smokers switch away from the most dangerous way of consuming nicotine, protecting families and bystanders from the harms of tobacco smoke. It needs to be integrated into existing global tobacco control strategies. ‘Harm reduction’ is already named as a pillar of tobacco control in the preamble to the FCTC. But still the WHO and others prevaricate. This report considers the history of tobacco harm reduction and the disruptive forces set loose by the emergence of SNP. Disruption is not always comfortable. But surely, everyone should be able to agree that the ultimate goal is to hasten the end of the death and disease caused by smoking as quickly as possible, *using whatever means necessary*, and ensuring the right to health for all, with nobody left behind.

⁶ WHO. (2019). *WHO report on the global tobacco epidemic 2019. Offering help to quit tobacco use*. World Health Organization. <https://www.who.int/publications/i/item/WHO-NMH-PND-2019.5>, p. 10.

⁷ Global State of Tobacco Harm Reduction. (2022a). *82 million vapers worldwide in 2021: The GSTHR estimate* (GSTHR Briefing Papers). <https://gsth.org/briefing-papers/82-million-vapers-worldwide-in-2021-the-gsth-estimate/>.

Introduction: The threat of disruption

“New ideas are not only the enemy of old ones, they also appear often in an extremely unacceptable form.”

Carl Gustav Jung

Three key themes run through the history of tobacco harm reduction (THR). To the casual observer, the increasing number of adult smokers who are taking control of their own health and switching to safer nicotine products (SNP) is one very visible sign of change. Fewer people are aware of the concerted global efforts to deny them that right. We will return to both in more detail.

However, it is arguably the continuing and seismic disruption wrought by SNP across commercial, clinical, public health, and legislative landscapes that dominates the trajectory of THR. The key elements of these multiple disruptions can be itemised as follows:

Consumers

For over 100 years, the cigarette has dominated global smoking culture. Smoking a cigarette couldn't be easier; many find there is an engaging sense of ceremony about the process. Snap the cellophane, open the packet, draw out the cigarette, tap the end, and light up. Apart from the nicotine hit, smoking was and still is regarded as a social activity. A cigarette after sex became a movie cliché; cigarettes are shared among friends or represent a welcoming gesture to strangers. For a long time in the twentieth century, smoking was 'cool'.

That said, in full knowledge of the dangers, most smokers declared their intention to quit, or at least declared their desire to want to quit. Medical reports and government campaigns told smokers they were 'addicted' to nicotine, with all the guilt associated with being labelled 'an addict'. Many felt compelled to try pharmaceutical products. Many had little success.

And then e-cigarettes became available. These were not, perhaps, seen as so much of a threat – nobody was taking cigarettes away, although the new products did require significant adjustment from those who wanted to try them. To an extent, the sharing element of cigarette smoking was still there: different bits of kit and flavours could be compared, especially as vaping events started to emerge. But, in the early days at least, vaping was nowhere near as convenient as lighting a cigarette. Despite this, the global vaping community grew rapidly, with multiple online forums and discussion boards, and in-person vape meets and shows. This groundswell created support networks and product development opportunities – while offering new choices, in terms of devices and flavours, that were unavailable to those who continued smoking.

As time went on, evidence emerged which demonstrated that switching from cigarettes to vaping eliminated nearly all the dangers of smoking, confirming that nicotine was not the source of death and disease. Yet – never missing an opportunity to share bad news – much of the world's media has diligently focused on any evidence of the risks potentially posed by vaping. Such reporting rarely considers the significantly reduced risks associated with vaping in relation to the risks of continued combustible tobacco

“the continuing and seismic disruption wrought by SNP across commercial, clinical, public health, and legislative landscapes ... dominates the trajectory of THR

“the global vaping community grew rapidly, with multiple online forums and discussion boards, and in-person vape meets and shows

people banded together in advocacy groups to protect the use of a consumer product, in ways that might be unprecedented in the history of consumer rights activism

With legal commitments to shareholders, debates rage within companies about whether it makes commercial sense to pursue a 'smoke-free future'

the advent of SNP also poses a threat to the profits of the pharmaceutical industry

use, which we know leads to the death of half of all users. Unsurprisingly, the media has often unquestioningly replicated information from apparently reputable sources – sources that for one reason or another, have an interest in maintaining the status quo.

Most users of SNP were content to remain consumers. But faced with overly restrictive regulatory proposals or limitations to product access, some people banded together in advocacy groups to protect the use of a consumer product, in ways that might be unprecedented in the history of consumer rights activism. Traditional consumer activists have been engaged in attempting to ban or control products that are perceived as dangerous in the service of consumer protection. THR activists were engaged in advocating for access to SNP in the service of public health.

Commercial interests

Sales of cigarettes account for over 90% of global tobacco revenues. For companies to retool their operations and logistics to switch over to vaping or heated tobacco products is a hugely expensive undertaking. With legal commitments to shareholders, debates rage within companies about whether it makes commercial sense to pursue a 'smoke-free future', especially as they are legally restricted over what they can say about how much safer these products are than smoking.

But there is evidence that disruption on a major scale is already taking place. In Japan, for example, cigarette sales fell 47% between the first quarter of 2016 and the same quarter in 2022 in the face of competition from heated tobacco products (HTP).⁸ That is the kind of market shift that makes even the most sceptical executives and shareholders take notice.

Beyond the tobacco industry itself, the advent of SNP also poses a threat to the profits of the pharmaceutical industry and a \$50 billion dollar market in nicotine replacement products and medicines.⁹ For many years, the pharmaceutical industry has sponsored international tobacco control activities and related health events. In December 2020, the world's largest healthcare company Johnson & Johnson and Cipla, a major Indian multinational pharmaceutical company, were both named as "partners" and "private sector companies that have offered support" for the WHO's 'Commit to Quit' campaign.¹⁰

But, while effective for some people, nicotine replacement products come nowhere close to replicating the experience and behaviours of smoking, which can be key to a successful switch from combustible cigarettes to SNP. Independent research demonstrates that vaping products are a more effective way out of smoking for many people.¹¹

⁸ Tobacco Intelligence. (2022, August 16). *Could Japan be leading the way towards the end of the combustible cigarette?* Business Insights – Intertabac. <https://www.business-insights.intertabac.de/could-japan-be-leading-the-way-towards-the-end-of-the-combustible-cigarette>.

⁹ Maximise Market Research estimates this figure will rise to \$124.58bn by 2027. The analysts include vaping and heated tobacco products in the 'nicotine replacement' category, reporting that "in 2020, e-cigarettes had the highest market share of 52.23%. E-cigarettes are becoming increasingly popular, and they are commonly recognized in the majority of nations. E-cigarettes have an adherence rate of around 17%, which is greater than the average abstinence rate of 9.7% for comparable NRT products."

Source: *Nicotine Replacement Therapy Market—Global Industry Analysis and Forecast (2022-2027)*. (2022). Maximize Market Research. <https://www.maximizemarketresearch.com/market-report/global-nicotine-replacement-therapy-market/119526/>.

¹⁰ *WHO launches year-long campaign to help 100 million people quit tobacco*. (2020, December 8). <https://www.who.int/news/item/08-12-2020-who-launches-year-long-campaign-to-help-100-million-people-quit-tobacco>.

¹¹ The Cochrane Review came to this conclusion in its 2020 evaluation comparing e-cigarettes with NRT for cessation purposes. Source: Hartmann-Boyce, J., McRobbie, H., Lindson, N., Bullen, C., Begh, R., Theodoulou, A., Nottley, C., Rigotti, N. A., Turner, T., Butler, A. R., Fanshawe, T. R., & Hajek, P. (2020). Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews*, 10. <https://doi.org/10.1002/14651858.CD010216.pub4>.

Government interests

Governments around the world rely heavily on the tax revenue from tobacco sales, either in domestic taxation or, in many places, the revenues earned from tobacco exports. In 18 countries, the government itself has a significant or even monopoly stake in the domestic tobacco industry.¹² Foreign imports of SNP are particularly unwelcome in some jurisdictions and may partly account for over-zealous regulation.

Alongside the need to protect tax revenues is the threat to the livelihoods of thousands of people working in tobacco-growing countries. This does not only relate to the manufacturers of commercially produced cigarettes, but also to more regionalised, small-scale industries that produce traditional oral as well as combustible tobacco products in Africa, India, and other parts of Asia.

From a legislative perspective, life was much easier when governments only had to deal with traditional tobacco products. The evidence of harm was clear: tobacco control was all about protecting citizens from the effects of tobacco smoke and from the influence of an industry providing and promoting dangerous products.

This certainty was shattered by the emergence of non-combustible nicotine products, which have divided the public health community over issues relating to product safety, flavourings, the products' appeal to young people, and concerns about nicotine dependency. Policymakers and legislators are left confused, leaving open every opportunity for bad decision-making.

Global health community

The advent of SNP has seen the biggest shake-up of the tobacco industry since the invention of the cigarette. But the degree to which the industry has responded is based on identifiable metrics such as returns on investment, profit and loss accounts, consumer demand, and the legislative environment. The disruption among health professionals and allied NGOs has been profoundly more disturbing.

The tobacco wars have been fought off the back of decades of undeniable evidence of the dreadful toll caused by smoking. Despite evidence to the contrary from the mid-1970s onwards, the assumption had always been that all the ingredients of a cigarette were equally dangerous. Clinical studies on new products – and on older smokeless products like snus – showed that consuming nicotine outside of a combustible cigarette was more than 90% safer.

Disaggregating nicotine from cigarettes has thrown the debate about smoking into disarray. Citing the new evidence are those who advocate support for the new products based on the principles of harm reduction and the right to health. The continued and significant impact of smoking on global health – and the slow rate of progress of 'traditional' tobacco control activities – lead many to believe these new products have a significant role to play in hastening the end of smoking.

Others are far more sceptical. Careers have been built, funding acquired, and organisations founded on the premise of the dangers of smoking and the need to campaign against the tobacco industry. For many, this has led to the adoption of positions against tobacco harm reduction, with a range of publicised views from insistence on the lack of long-term evidence of the safety of SNP to the belief that

In 18 countries, the government itself has a significant or even monopoly stake in the domestic tobacco industry

The disruption among health professionals and allied NGOs has been profoundly more disturbing

¹² Malan, D., & Hamilton, B. (2020). *Contradictions and Conflicts: State ownership of tobacco companies and the WHO Framework Convention on Tobacco Control*. Just Managing Consulting. <https://www.smokefreeworld.org/wp-content/uploads/2020/09/Contradictions-and-Conflicts.pdf>.

“**global public health is being harmed because those charged with promoting public health oppose approaches that are proven to reduce harm**

“**among those advocating for THR within the scientific community, there remains disagreement about the nature of nicotine addiction**

new products are simply the result of the tobacco industry compensating for falling cigarette sales in developed countries. Those opposed to THR have coalesced into a well-funded, well-organised lobby with global reach. Sadly, one oft-repeated tactic of this lobby is its determination to tar any advocates for tobacco harm reduction – be they academics, doctors, or consumer activists – with the taint of ‘industry shill’. We have arrived at a truly bizarre point in tobacco control history where global public health is being harmed because those charged with promoting public health oppose approaches that are proven to reduce harm.

Of course, there are also debates among those in favour of tobacco harm reduction. In 2015, the UK’s Royal Society of Public Health went on the record with a public statement that “nicotine is no more harmful than caffeine”, calling for “public confusion over nicotine” to be addressed in order to encourage “smokers to use safer forms of the substance” – with vaping products explicitly named alongside NRT.¹³ But among those advocating for THR within the scientific community, there remains disagreement about the nature of nicotine addiction.

The emergence of tobacco-free synthetic nicotine adds another twist to the tale, as does the promise of new treatments using nicotine to treat diseases of cognitive impairment such as dementia. Medical advances like these may yet assist in bringing nicotine in from the cold.

Ultimately, the disruption for the adult smoker who wants to try switching rather than quitting has been multi-faceted: from getting used to new ways of consuming nicotine – vapes, heated tobacco or oral products – to the challenge of weighing up all the conflicting and confusing evidence.

¹³ Royal Society of Public Health. (2015, August 13). *Nicotine “no more harmful to health than caffeine”*. <https://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html?s=03>.

Chapter 1: Dying for a smoke

A First Nation tradition catches the attention of Western explorers

Indigenous Americans have used tobacco for spiritual and medicinal purposes for many centuries. In many such communities, it remains central to culture, spirituality and healing to this day.¹⁴ Yet when Columbus and his crew made landfall in what is now the Bahamas in October 1492, they were astounded to find the people they encountered there putting rolled up leaves in their mouths, setting the leaves on fire and then inhaling the smoke.

Columbus was appalled, although it was clear his crew thought differently. “It was not within their power to refrain from indulging in the habit,” he reported.¹⁵ Outside of the oral traditions of these indigenous communities, this was the first documented incidence of the reinforcing properties of the nicotine contained in tobacco leaves.

The plant that had been observed in the Bahamas by Columbus and his men was later named for French diplomat and scholar Jean Nicot de Villemain. Nicot encountered it while serving as the French ambassador to Lisbon around 1560, sending tobacco seeds to the French court. On his return to Paris, he brought tobacco leaves, advocating the inhalation of powdered leaves as a headache remedy. Tobacco powder became popular among the nobility and gained the name ‘snuff’ in England in the 17th century. In 1753, Carolus Linnaeus named the genus of tobacco cultivars *Nicotiana*, recognising Nicot’s role in spreading the plant’s popularity.¹⁶



Raleigh's first pipe in England
Source: George Arents Collection, The New York Public Library. (1745–1865).

¹⁴ *Traditional Tobacco | Keep It Sacred.* (2015). The National Native Network. <https://keepitsacred.itcmi.org/tobacco-and-tradition/traditional-tobacco-use/>.

¹⁵ Kluger, R. (1997). *Ashes to Ashes: America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris* (1st Vintage Books ed edition). Vintage, p. 9.

¹⁶ Rogers, K. (n.d.). Jean Nicot | French diplomat and scholar | Britannica. In *Britannica*. Retrieved 26 September 2022, from <https://www.britannica.com/biography/Jean-Nicot>.

Smoking was lauded and condemned in equal measure

state punishments for using or selling tobacco ranged from the deeply unpleasant to the death penalty

When not used as a powder, tobacco leaves were burned in pipes and the smoke inhaled. Lacking a word for smoking, people were said to be ‘drinking’ smoke. With little knowledge of medical science, early physicians and alchemists hailed tobacco as a miracle cure for a whole range of maladies. Most famously, herbalist Nicholas Monardes published his *Medicinall historie of things brought from the West Indies in 1580*. The influential treatise described more than 65 conditions that he claimed could be cured by tobacco.¹⁷

Smoking was lauded and condemned in equal measure. James I of England was not impressed with the habit. He penned his famous *Counterblaste to Tobacco* in 1604 with some prescient complaints about its baleful effects being “dangerous to the lungs”.¹⁸ Christian and Muslim leaders condemned smoking as symptomatic of the evils of the rival religion. Through to the end of the 17th century, state punishments for using or selling tobacco ranged from the deeply unpleasant to the death penalty. Such draconian responses had little if anything to do with health concerns, but were instead derived from religious and moral beliefs about ‘intoxication’ and fears that men would gather to smoke, drink coffee, newly arrived from Africa, and plot treason.

From prohibited product to taxable commodity

By the end of the 17th century, however, governments had largely given up trying to enforce prohibition. Clearly, whatever penalties were in place, people continued to smoke. James I and other European monarchs were engaged in an endless round of ruinously expensive wars which were emptying their treasuries. Therefore, tobacco became heavily taxed.

This threw up another paradox – one that appears lost on many in today’s tobacco control establishment. If you have a product that people feel compelled to use and then make it too expensive through high taxation, criminal elements will get rich through smuggling. This is exactly what happened in England and elsewhere. Smugglers were frequently regarded as local heroes for selling tobacco at prices people could afford and as such were given haven. Government excise men were hated and attacked.

For centuries, then, smoking had been ubiquitous among First Nation people in the Americas, while sailors from Portugal and Spain brought tobacco to much of the rest of the world, including Africa and Asia. Until the mid-19th century, tobacco was primarily consumed in pipes, hookahs, as snuff, chew, or in cigars.

Hand-rolled cigarettes grew in popularity among soldiers fighting the Crimean and American Civil Wars as a quick way to get a nicotine hit under fire. While manufactured hand-rolled cigarettes were available, soldiers often bought tobacco shreds and rolled their own. In the US, pipe smoking and tobacco chewing had previously predominated, cigarettes being regarded as a foreign and rather effeminate import. Then came three innovations that transformed the history of tobacco and laid the foundations of the industry which exploded in the 20th century.

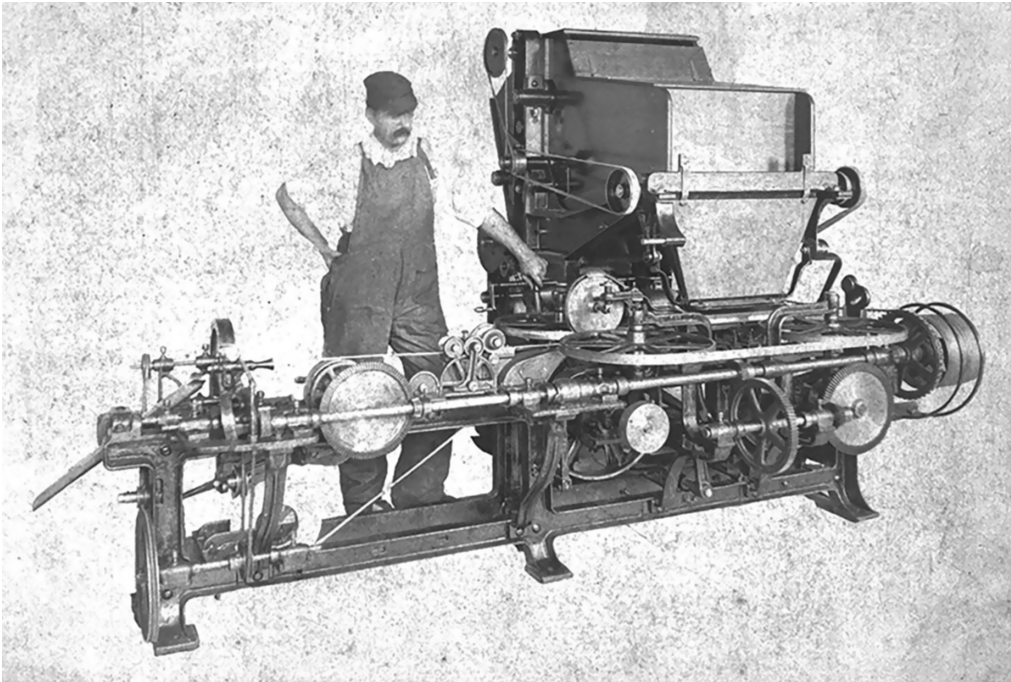
The first two are little mentioned. Using various combinations of chemicals, attempts to create a safe way to burn tobacco directly without equipment (such as pipes) had been underway since the 17th century, with little success. The mid-19th century saw the development of flue-cured tobacco for use in cigarettes. It was milder and sweeter than

¹⁷ ‘This vile custome’: A history of tobacco’s medical interpretations. (2015, December 22). [Text]. Royal College of Physicians of Edinburgh. <https://www.rcpe.ac.uk/heritage/vile-custome-history-tobaccos-medical-interpretations>.

¹⁸ King James I, *His Counterblast to Tobacco*, 1604. (n.d.). Document Bank of Virginia. Retrieved 27 September 2022, from <https://edu.lva.virginia.gov/dbva/items/show/124>.

tobacco used in pipes and cigars, with a relatively high nicotine content. At around the same time, two Swedes produced the first modern safety match, which is still in use today.¹⁹

But the third, and perhaps most critical, development happened courtesy of James Bonsack, who invented a mechanical cigarette-rolling machine. Traditionally, cigarettes were hand-rolled. This was slow, labour-intensive, and often produced products of irregular shape that were loosely filled. A teenage inventor, Bonsack had been trying for years to solve the problem. In 1880, still only aged 21, he applied for the patent for a mechanical rolling machine. Weighing a tonne, it could turn out 70,000 cigarettes each ten-hour day, equalling the output of 40 or 50 workers.²⁰



Photograph of cigarette rolling machine, possibly designed by Bonsack
Source: Bonsack Machine Company Papers, North Carolina State Archives.

This caused an over-supply of a product which still only captured a small percentage of the tobacco market. But change was on the way. The late 19th century heralded the era of urbanisation and industrialisation in America, marked by a significant influx of immigrants from European countries who mainly smoked cigarettes. A new mass market for cigarettes flooded through the Port of New York.

A confluence of circumstance

Economists talk about creative innovation and creative destruction. The first is the development of an existing product or technology, like the safety match or flue-cured tobacco. The Bonsack machine was an example of creative destruction; it both destroyed the hand-rolling business and made the cigarette the premier way of consuming nicotine.

Other societal disruptions were also required to achieve cigarette supremacy. The tabloid press had been born in the USA on the proceeds of advertising revenue from the patent medicine industry. Pharmaceutical-grade cocaine and morphine were sold in over-the-counter preparations to deal with the most distressing symptoms of illness,

The Bonsack machine [...] destroyed the hand-rolling business and made the cigarette the premier way of consuming nicotine

¹⁹ *The history of matches—Swedish Match Industries AB.* (n.d.). Swedish Match Industries AB. Retrieved 26 September 2022, from <https://www.swedishmatchindustries.com/en/the-fire-academy/the-history-of-matches/>.

²⁰ Kluger, 1997, p. 20.

it was the First World War that gave the biggest boost to the cigarette

mainly pain. The early cigarette manufacturers quickly realised they too needed to advertise to build market share. The tabloid press became a national institution delivered to towns and cities not by stagecoach, but by the coming of the railways, which literally spread the news – and the adverts – across the nation.

As the cities grew, now teeming with people, the ease of using cigarettes and the speed of their consumption – compared with leisurely pipe smoking – became symbolic of the quickening pace of urban life. But it was the First World War that gave the biggest boost to the cigarette. By 1917, the joint profits of the two biggest companies, American Tobacco and Reynolds, approached \$25m (about \$600m in 2022).



Poster calling for donations to fund cigarettes for Canadian soldiers.
Source: Charters Towers Historical Photos Club, WW1.

Even so, the tobacco companies were still aware of unmet market potential. Most ordinary American families on modest incomes tended to buy only what they needed, not what they wanted. It was Sigmund Freud's nephew Edward Bernays who saw that the power of propaganda during wartime could also be harnessed in peacetime. He coined the less pejorative expression 'public relations'.

Bernays proposed to link mundane products with people's deepest desires and aspirations

Reading his uncle's work on the subconscious, Bernays proposed to link mundane products with people's deepest desires and aspirations. Cigarette advertising was among the earliest examples of this form of propaganda in peacetime, in particular through advertising aimed at women. In the 1920s, it was still something of a taboo for women to be seen smoking in public. For the companies, this represented a huge untapped market. At the end of the war, the suffragette movement was gaining momentum. Bernays organised a stunt involving a group of debutantes lighting up during the 1929 New York Easter Sunday parade under the banner 'Torches of Freedom'. Naturally, this made all the front pages across the country. The sight of women smoking became symbolic of their right to freedoms previously denied. So successful was this approach that in future cigarettes were promoted as the gateway to all aspects of the American Dream, including material acquisitions, success in love and sex, and the right of rugged men to roam the open plains.²¹

cigarettes were promoted as the gateway to all aspects of the American Dream

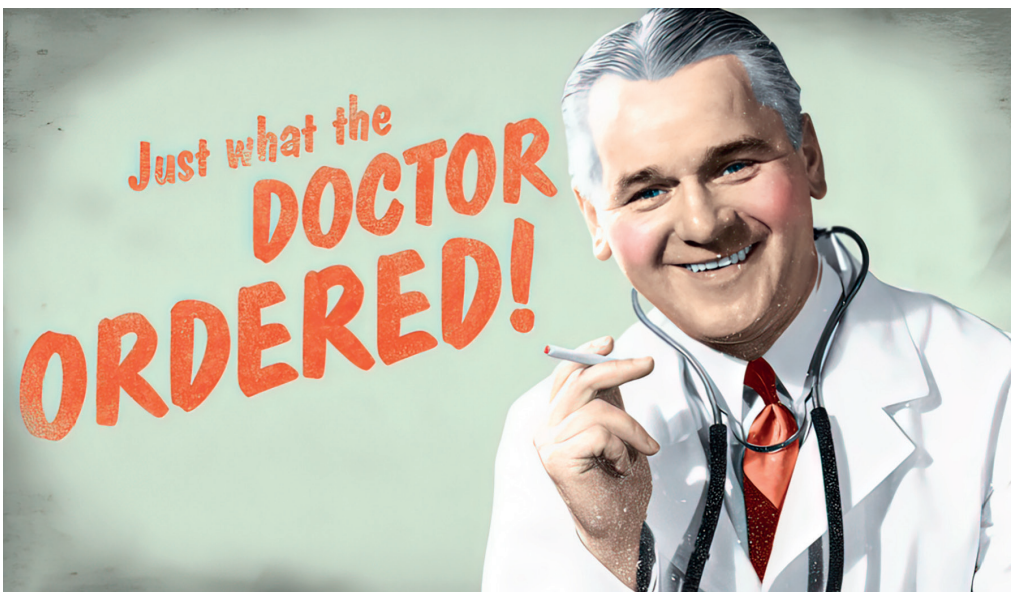
²¹ Bernays featured heavily in Curtis, A. (Director). (2002, March). The Century of the Self, Happiness Machines (No. 1) [BBC documentary Century of the Self]. In BBC. <https://www.bbc.co.uk/programmes/p0720m7r>.



Women smoking in public remained somewhat taboo in the 1920s.
Source: Wikimedia Commons (Suomen Kuvalehti, 1924).

But there was another card to play. Even before the confirmations of science, the fact that so many people who smoked seemed to cough a lot suggested that maybe smoking was not so harmless after all. Yet many doctors and nurses smoked. Why not put their faces on the ads? After all, “if my doctor smokes, it must be OK”.

“many doctors and nurses smoked. Why not put their faces on the ads?”



The tobacco industry used images of medical professionals smoking to try to allay fears about cigarettes' safety.
Source: Healthcare Usability.

The Second World War saw further surges in cigarette sales. Tobacco farmers in the US were bailed out by the government because Britain (US tobacco's major export market) had banned US tobacco imports to save foreign reserves. US tobacco companies were producing the cigarettes sent to the front. Tobacco farmers were seen as an essential part of the war effort, so much so that smoking was presented as virtually a patriotic act.²² By the end of the war, nearly 50% of Americans aged 18 and over (half of men and a third of women) were smoking at least a pack a day.²³

“Tobacco farmers were seen as an essential part of the war effort”

²² Milov, S. (2019). *The Cigarette: A Political History* (Illustrated edition). Harvard University Press, pp. 75, 79.

²³ Kluger, 1997, p. 132.

The truth will out

It was during the 1950s that groundbreaking evidence directly linking smoking to lung cancer began to emerge. In the pre-war period, doctors hardly saw any cases of lung cancer. It was so rare in England that if a case was identified at autopsy, medical students would crowd round out of curiosity. In 1920, there were fewer than 250 lung cancer deaths in England and Wales; by 1960 that figure had risen to over 10,000. Over a similar period in the USA, deaths rose from 3,000 to 41,000.²⁴

The Frank Statement was published in 1954, claiming the industry had the consumers' best interests at heart and would not dream of selling a product that made people ill

The industry's initial response was again to try and forge an emotional link between the consumer and the companies. The Frank Statement was published in 1954, claiming the industry had the consumers' best interests at heart and would not dream of selling a product that made people ill. The industry then came up with a plan to manufacture a smoking 'controversy' to spread doubt and confusion about the association between smoking and cancer. They achieved this by establishing the Tobacco Industry Research Committee, which challenged studies showing links between smoking and lung cancer through papers placed in peer-reviewed journals, newspaper and magazine articles, and media interviews.

The evidence showed that smoking caused cancer

Ultimately the evidence on smoking's effects on human health became undeniable. The signal reports of the UK Royal College of Physicians, *Smoking and Health* (1962), and the US Surgeon General's report, also called *Smoking and Health* (1964), were unequivocal. The evidence showed that smoking caused cancer.^{25 26}

Throughout the following decades, an alliance of politicians and newly founded anti-smoking consumer rights organisations in America collaborated to try and challenge the tobacco industry. Attempts by individuals to sue the industry for the damage caused by smoking failed. The companies contended they produced a legal product which the government advised people not to use – therefore arguing that smokers knew the risk.

in 1998 the top companies agreed on a one-off states-wide multi-billion-dollar settlement, called the Master Settlement Agreement

Next, a flurry of litigation hit the industry, seeking to recoup the cost of healthcare for the many Americans affected by smoking-related diseases. Rather than facing replicated and costly courtroom battles in every states, in 1998 the top companies agreed on a one-off states-wide multi-billion-dollar settlement, called the Master Settlement Agreement.

Much has been written about the Master Settlement Agreement suggesting that it was not the critical blow to Big Tobacco that campaigners claimed. Tobacco companies that signed up found their markets protected, with their financial liability covered by cigarette price increases.

the Master Settlement Agreement [...] was not the critical blow to Big Tobacco that campaigners claimed

More significant for this report, however, were two specific stipulations. The companies were ordered to stop creating and funding research organisations that worked to show tobacco in a favourable light. At the same time, they were obligated to fund the creation of an organisation dedicated to anti-smoking research. Master Settlement Agreement money was poured into the establishment of the American Legacy Foundation in 1999, the "first national public health organisation dedicated to ending tobacco use among youth and young adults".²⁷ In 2015, the American Legacy Foundation was renamed The Truth Initiative – a name which many within the tobacco harm reduction field now view with some considerable cynicism.

²⁴ Taylor, P. (1984). *Smoke Ring: Politics of Tobacco* (First Edition). The Bodley Head Ltd, p. 3.

²⁵ *Smoking and health: A report of the Royal College of Physicians on smoking in relation to cancer of the lung and other diseases.* (1962). Royal College of Physicians. <https://www.rcplondon.ac.uk/projects/outputs/smoking-and-health-1962>.

²⁶ *Smoking and Health.* (1964). [Report of the advisory committee to the Surgeon General of the Public Health Service, Department of Health, Education and Welfare]. Public Health Service. Office of the Surgeon General. <https://profiles.nlm.nih.gov/spotlight/nn/catalog/nlm:nlmuid-101584932X202-doc>.

²⁷ *Our History.* (2021). The Truth Initiative. <https://truthinitiative.org/who-we-are/our-history>.

An industry starting to globalise – and a global response

During the late 1960s, and for the following three decades, many countries introduced demand-reduction tobacco control measures on a domestic level, including warning labels, restrictions on public smoking and advertising, and higher taxation.

Rather than simply exporting cigarettes globally, and with low- and middle-income countries in their sights, major American tobacco companies began to install themselves abroad. As the US-based tobacco industry started buying shares in domestic tobacco companies around the world, a transnational tobacco industry was developing. In response to these commercial developments, the World Health Assembly, the governing body of the WHO, passed 17 resolutions on different aspects of tobacco control between 1971 and 1998.²⁸

In the early 1990s, Ruth Roemer – a public health lawyer based at the University of California – was commissioned to write a second edition of her book *Legislative action to tackle the world tobacco epidemic*, first published by the WHO in 1982.²⁹ The book explored the use of domestic legislation to tackle the smoking epidemic, and soon Roemer teamed up with a Columbia University law student, Allyn Taylor, who had written an article advocating for the WHO to utilise its neglected constitutional powers to develop a legal framework to advance global public health. Together, Roemer and Taylor began advocating for an international convention on tobacco control.³⁰

Their efforts were successful as in 1996, under a mandate from the World Health Assembly, the incoming Director General of the WHO, Dr Gro Brundtland, initiated the process that eventually culminated in the adoption of the Framework Convention on Tobacco Control in 2003.

As the US-based tobacco industry started buying shares in domestic tobacco companies around the world, a transnational tobacco industry was developing

Roemer and Taylor began advocating for an international convention on tobacco control



Dr. Gro Brundtland speaking in Davos at the World Economic Forum in 1989. Source: Copyright World Economic Forum. Wikimedia Commons, licensed under Creative Commons Attribution-Share Alike 2.0 Generic.

²⁸ Wipfli, H. (2015). *The Global War on Tobacco: Mapping the World's First Public Health Treaty*. Johns Hopkins University Press. <https://books.google.pl/books?id=fwPHCQAAQBAJ>, p. 24.

²⁹ Roemer, R. & World Health Organization. (1993). Legislative action to combat the world tobacco epidemic. *L' action législative contre l' épidémie mondiale de tabagisme*. WHO IRIS. <https://apps.who.int/iris/handle/10665/37823>.

³⁰ Wipfli, 2015, p. 25.

the presentations given to the Committee by the tobacco industry were [...] *“sloppy and insubstantial, most if not entirely spin”*

Today, Dr Brundtland says she never saw the tobacco industry as part of the solution to the health crisis caused by smoking. Yet during the public consultation period before convention negotiations got under way, Dr Brundtland and her team – which included Derek Yach, who was soon to be appointed head of the WHO Tobacco Free Initiative – sat down to hear what the industry had to say.

As she said at the time: “Despite our concerns about these clear differences in position, we are committed to hearing how the tobacco companies do propose to reduce the harm that their products cause. Our Advisory Committee is charged with proposing appropriate national and international tobacco product regulatory frameworks. We have invited tobacco company scientists to provide their views on product modification to this Committee.”³¹ But the presentations given to the Committee by the tobacco industry were, in Derek Yach’s words, “sloppy and insubstantial, most if not entirely spin”.

However, because the WHO had already accepted the idea of drugs and HIV harm reduction in its public health vision, it decided that the phrase ‘harm reduction’ should be included in the wording of the definition of tobacco control, alongside demand and supply reduction in Article 1d. Furthermore, in case more demonstrably innovative progress was made towards the development of safer products, Parties to the Convention were mandated to consider the Convention in the light of new scientific, clinical, and technological evidence. When the Convention was signed in 2003, there were no serious THR product contenders on the market that would likely gain general acceptance among smokers.

What is clear, however, is that since the health risks of smoking had become public knowledge in the 1950s, the possibility of trying to produce a ‘safer’ cigarette was under consideration. And not only by the tobacco industry, but also by some in the scientific community.

³¹ WHO. Director-General’s response to the tobacco hearings. 13 October 2000. Cited in Yach, D. (2018). *Project Unthinkable: A Doctor’s Gamble to Save Millions of Lives*. Barlow Publishing.

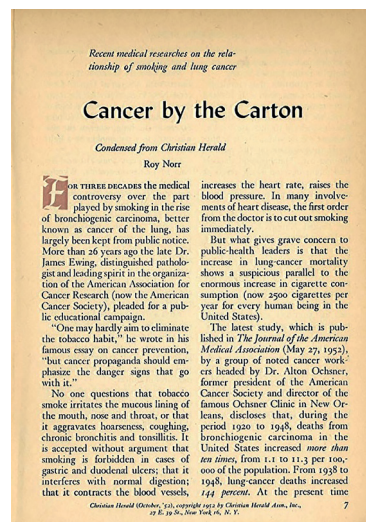
Chapter 2: The genesis of tobacco harm reduction

False starts... and falsehoods

Tobacco harm reduction is most closely associated with the switch from smoking or risky tobacco use to products such as vapes, heated tobacco products, or snus-style oral products, as the independent evidence overwhelmingly supports the premise that these products are significantly less harmful to health. This suite of nicotine delivery systems has become a potentially life-saving alternative for people who want to quit smoking and other forms of dangerous tobacco consumption, while continuing to use nicotine.

Back in the 1950s, of course, no one was talking about harm reduction, let alone tobacco harm reduction. The dangers of smoking had only been flagged up in medical circles. But that changed, at least in the US, in 1952. *Readers Digest* was one of the few mainstream publications to refuse tobacco company advertising money. Its December 1952 edition ran an article titled ‘*Cancer by the Carton*’, which – for the first time – brought the reality of the link between smoking and lung cancer to the wider public gaze, and accused the companies of a cover-up.³² The article sparked increased awareness of the issue and rising public concern prompted tobacco companies to think about making ‘safer cigarettes’.

rising public concern prompted tobacco companies to think about making ‘safer cigarettes’



First page of ‘Cancer by the Carton’, *Readers Digest*, December 1952.

Source: The Center for the Study of Tobacco and Society, University of Alabama. For full details, see ref. 32.

The task was not easy. As Richard Kruger has observed in his book *Ashes to Ashes*: “For a product as simple as a cigarette, no more than a short stick of cured, shredded, flavoured and paper-wrapped leaf, devising a true filter to reduce intake of its combustible by-product was a surprising technological challenge.”³³

³² Norr, R. (1952). Cancer by the Carton. *Reader's Digest*. Archive copy hosted on the website of The Center for the Study of Tobacco and Society, College of Community Health Sciences, University of Alabama. <https://csts.ua.edu/files/2019/01/1952-12-Readers-Digest-Cancer-by-the-Carton.pdf>.

³³ Kluger, 1997, p. 149.

Tobacco smoke contains thousands of chemicals. But back then, what was in tobacco smoke was relatively unknown, let alone which elements would need to be filtered out. The companies had the problem of devising a filter that would not reduce the flavour or the tobacco 'hit'. There was also the question of what material to use. The process of cigarette manufacture was wholly mechanised; a single machine could now turn out 15,000 cigarettes a minute. Natural fibres like cotton or wool did not have the uniform structure that would make them suitable for such a highly automated process. This led the companies to turn to top chemical engineering companies, such as Dow Chemical and Dupont, who were at the forefront of synthetic fibre development, as well as filter development specialists like Eastman Kodak and the Celanese Corporation.

Brown & Williamson had launched the first filter cigarette, Viceroy, as early as 1936. In 1952, the company launched their new 'Health-Guard' filter for the Viceroy brand, made of cellulose acetate. Brown & Williamson went head-to-head with Lorillard and its Kent brand, which used their new Micronite filters. Micronite filters were made of crocidolite asbestos, now considered one of the most toxic types of the mineral. Ultimately, however, Kent failed because smokers complained the cigarette was too bland and hard to draw; the brand was withdrawn from the market four years later in 1956.



1959 Kent filter cigarettes magazine ad.
Source: Ebay listing of original advert.

all the major tobacco companies promoted filter cigarettes as the 'safer' option

For the rest of the 1950s and into the 1960s, all the major tobacco companies promoted filter cigarettes as the 'safer' option. There was no evidence of relative safety; the advertising for filter cigarettes traded on the (correct) assumption that in the public mind the word implied some element of safety. Experiments with smoking machines, intended to replicate how a person smokes, failed to do so. The industry was trying to prove filtered cigarettes were safer based on experiments in the laboratory that did not reflect real-world use of their products. The effective filter was a chimera.

Company lawyers were starting to get worried about the implications for their ordinary brands, if new products were being promoted as 'safer'

It was not simply a technological issue, however. Company lawyers were starting to get worried about the implications for their ordinary brands, if new products were being promoted as 'safer'.

Meanwhile, some industry scientists began to consider if there were options beyond the use of filters to reduce the amount of dangerous toxins people ingested as they smoked, while leaving the chemical make-up of the cigarette unchanged. James Mold, the chief scientist at Liggett, believed he could achieve a reduction in toxic yields by using a metal called palladium, the same substance used in catalytic converters to reduce harmful gas emissions from vehicles.

the lawyers and executives feared that a 'safer cigarette' would not only undermine Liggett's cigarette sales but the whole industry

Mold spent 12 years working in secret on prototypes variously called Project XA, Tame, and finally Eclipse. In 1978, the idea was presented to the Liggett Board. The Board could not believe that millions of company dollars had been spent without their knowledge. In the laboratory at least, Mold could prove substantial reductions in toxicity. But claims that this would lead to better health outcomes for people who smoked could not be substantiated in the real world. Finally, Eclipse failed because people reported that the products tasted awful – while in the background, the lawyers and executives feared that a 'safer cigarette' would not only undermine Liggett's cigarette sales but the whole industry.

Industry efforts to find – or perhaps, more accurately, to promote – 'safer cigarettes' continued well into the 1980s. At the start of the decade, Brown & Williamson announced the launch of the Barclay cigarette, which the company claimed was 99% tar-free thanks to its new filter design. Rival manufacturer Reynolds complained to the Federal Trade Commission. Reynolds revealed that the way the cigarette was produced enabled it to give an exceptionally low tar rating according to the FTC testing regime – in effect, that it had been designed in order to circumvent the test machines. According to documentation supplied by Reynolds to the FTC, "this generation of [Barclay-type] products, or the next, could easily be products which will deliver NO 'tar' or nicotine when smoked by the FTC method, and yet when smoked by humans essentially be unfiltered cigarettes".³⁴

After spending millions of dollars on development, in 1989 Phillip Morris launched its very low nicotine cigarette called Next. Next was criticised for a higher tar content than other brands, meaning it was probably more dangerous because smokers would smoke more to get at the reduced level of nicotine. Conversely, because Next was promoted as a novel way for smokers to consume nicotine, the FDA came under pressure to class Next as a drug delivery system. The brand was trialled in some local US regions, but gained only 0.2% market share and quickly disappeared.³⁵ In another example of not learning from history, the current enthusiasm among some regulators for low nicotine cigarettes will also likely disappoint.³⁶

It is important to note that during the mid to late 20th century, alterations in the manufacturing process applied to a selection of combustible products did make some cigarettes safer than they had been previously. While by no means safe, filtered cigarettes were an improvement on their unfiltered predecessors; they were less likely to give users lung cancer, although the overall risk remained extremely high. And while 'light cigarettes' are often described as just another tobacco industry ploy, there is evidence that these products, which have lower tar content than others, or adaptations such as additional ventilation holes, do offer some reduction in risk. This evidence emerged as early as 1976, and it came from two major studies undertaken by the American Cancer Society (ACS).³⁷

In 1959–60, over a million smokers were enrolled by the ACS into an epidemiological study of cancer risk factors. Smokers were classified according to the nicotine-tar content of the products they used. The results, backed up by a further ACS study in 1979, did show modest positive results for those who smoked 'light' cigarettes over

³⁴ *Barclay cigarette*. (2019). SourceWatch. https://www.sourcewatch.org/index.php/Barclay_cigarette.

³⁵ Dunsby, J., & Bero, L. (2004). A nicotine delivery device without the nicotine? Tobacco industry development of low nicotine cigarettes. *Tobacco Control*, 13(4), 362–369. <https://doi.org/10.1136/tc.2004.007914>.

³⁶ Abrams, D. B., & Notley, C. (2020). Is Nicotine Reduction in Cigarettes Enough? *JAMA Network Open*, 3(10), e2019367. <https://doi.org/10.1001/jamanetworkopen.2020.19367>.

³⁷ Rodu, B. (2010, July 14). Tobacco Truth: Who Said Light Cigarettes Are Safer? The American Cancer Society. *Tobacco Truth*. <https://rodutobaccotruth.blogspot.com/2010/07/who-said-light-cigarettes-are-safer.html>. Reference cites original source: Hammond, E. C., Garfinkel, L., Seidman, H., & Lew, E. A. (1976). 'Tar' and nicotine content of cigarette smoke in relation to death rates. *Environmental Research*, 12(3), 263–274. [https://doi.org/10.1016/0013-9351\(76\)90036-0](https://doi.org/10.1016/0013-9351(76)90036-0).

other products; a 16% lower death rate from all causes, a 14% lower death rate from heart disease, and a 26% lower death rate from lung cancer.³⁸

Of course, this was by no means a major breakthrough in terms of overall health. But it is an example of sources outside of the tobacco industry highlighting the potential gains of encouraging changes in the products themselves in order to reduce the level of risk they posed to consumers. However, these studies, and the evidence they provided, do not neatly match the prevailing narrative. As such, despite their scale, their findings have often been ignored.

Beginning to take note of nicotine without smoke

the idea of creating a 'safer cigarette' was not confined to tobacco company boardrooms and laboratories

"it should not be beyond the wit of man to separate nicotine addiction from carcinogenesis"

To grasp the history of tobacco harm reduction, it is essential to understand that the idea of creating a 'safer cigarette' was not confined to tobacco company boardrooms and laboratories. Many people working in science, research, and policy were also considering how these deadly but legal – and hugely popular – consumer products could be made safer for the millions of people who continued to use them. Their focus was public health, rather than commercial expediency.

In October 1970, a Welsh pharmacologist, Professor J.D.P. Graham, wrote to the *British Medical Journal*. Graham's letter explains that he had attended a regional symposium on addictions, during which he had learned that the harms of smoking are almost entirely resident in the smoke, while nicotine is relatively harmless. Therefore, he suggested, "it should not be beyond the wit of man to separate nicotine addiction from carcinogenesis. Let us devise a cigarette of acceptable shape, size and consistency which contains an aerosol device instead of the lethal weed". He suggested the tobacco companies should be allowed to advertise this safer product as much as they wanted, so long as they shouldered the development costs. For its part, the government could allow a tax-free period. Cigarette taxes would continue to increase, as the companies and the government came to an agreement on a reasonable tax regime for the new product.³⁹

In 1972, the year following Richard Nixon's declaration of a war on drugs, the US Consumers Union published a very balanced report titled *Licit and Illicit Drugs*. It devoted a section to nicotine, including a chapter entitled 'Program for the future', which stated that "first, efforts should be made to popularize ways of delivering frequent doses of nicotine to addicts without filling their lungs with smoke". One of their strategies for achieving this was to "develop smoke-free ways of delivering nicotine to the lungs for example, nicotine inhalers". Another was to "popularise chewing tobacco and snuff". And they also raised the idea of nicotine chewing gum, saying the American Cancer Society was funding research into this idea, while in Sweden, nicotine gum was undergoing trials.⁴⁰

In 1973, the UK's Independent Scientific Committee on Smoking and Health (the Hunter Committee) discussed the development of so-called New Smoking Materials (NSM). Imperial Tobacco was conducting research in the UK in competition with Gallaghers, who were working with chemical company Celanese and their synthetic tobacco-substitute, Cytrel. Research had been underway in the UK since the 1960s,

³⁸ Ibid.

³⁹ Graham, J. D. P. (1970). Nicotine and Smoking. *British Medical Journal*, 4(5729), 244.

⁴⁰ Edward M. Brecher and the Editors of Consumer Reports Magazine. (1972). *Consumers Union Report on Licit and Illicit Drugs. Part III – Nicotine, Chapters 23 – 27*. Archive copy hosted by the Schaffer Library of Drug Policy. <https://www.druglibrary.org/schaffer/library/studies/cu/cumenu.htm>.

when the government had indicated it would endorse such products, although later administrations dropped the support for NSM.

In an echo of the current problems over taxing safer nicotine products, officials within HM Customs and Excise were concerned at the potential loss of tax revenue should NSM products take off. They need not have worried. Firstly, Imperial tested NSM on beagles, which led to a storm of negative publicity and physical attacks from animal rights groups. Ultimately, though, the products which did come to market failed the consumer test. People who smoked did not like the taste.

During the late 1970s, even the WHO bought into the idea of a 'safer cigarette'. An expert committee report published in 1979 asserted: "The evidence that cigarette smoking greatly increases the incidence of lung cancer is now irrefutable. It can therefore be forecast that, if cigarette smoking were to stop or *if cigarettes free from the risk of cancer can be produced* the worldwide epidemic of a disease that at present kills hundreds of thousands of smokers every year would be arrested and begin to recede" [emphasis added].⁴¹ And the truth was that the genie was out of the bottle: cigarette smoking was not going to simply stop.

Michael Russell was a psychiatrist at the Addiction Research Unit based at the Maudsley Hospital in south London. Since the 1960s, Russell had been conducting pioneering work to try to understand the answer to the question nobody had been asking: why do people smoke? Based on his review of what was then fragmentary research literature, he concluded in a 1971 paper that nicotine was the motivating force underlying smoking behaviour. He said: "If it were not for the nicotine in tobacco smoke people would be little more inclined to smoke cigarettes than they are to blow bubbles or light sparklers".⁴²



Psychiatrist Professor Michael Russell answered the question: why do people smoke?
Source: The Global Forum on Nicotine.

In a 1976 British Medical Journal paper on low-tar cigarettes, Russell acknowledged that simply asking people to stop smoking or smoke fewer cigarettes would not work. Neither would reducing nicotine levels below the satisfaction levels for smokers. At that time, therefore, he concluded that the only option available was to reduce the tar while maintaining the nicotine levels.⁴³

But in a paper commenting on the Hunter Committee deliberations, Michael Russell and colleague Martin Jarvis concluded that "an approach aimed simply at further

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simply asking people to stop smoking or smoke fewer cigarettes would not work. Neither would reducing nicotine levels below the satisfaction levels for smokers

⁴¹ WHO Expert Committee on Smoking and its Effects on Health & World Health Organization. (1975). *Smoking and its effects on health: Report of a WHO expert committee* (No. 568; WHO Technical Report Series). World Health Organization. <https://apps.who.int/iris/handle/10665/41157>, p. 50. Cited in Taylor, 1984, p. xvi.

⁴² Russell, M. a. H. (1971). Cigarette smoking: Natural history of a dependence disorder. *British Journal of Medical Psychology*, 44(1), 1–16. <https://doi.org/10.1111/j.2044-8341.1971.tb02141.x>.

⁴³ Russell, M. A. (1976). Low-tar medium-nicotine cigarettes: A new approach to safer smoking. *British Medical Journal*, 1(6023), 1430–1433.

“The production of a combustible cigarette that was both safe enough and acceptable enough to seriously dent the statistics on death and disease was an illusion

reductions in tar and nicotine deliveries will do little to reduce the dangers of smoking. This is not only because smokers compensate by increasing inhalation leaving their smoke intake relatively unchanged, but also because a point is reached where reduced nicotine delivery meets with reduced consumer acceptance”.⁴⁴

While sales of filter cigarettes continued to boom, Russell and Jarvis were expressing what was clear to most tobacco researchers. The production of a combustible cigarette that was both safe enough and acceptable enough to seriously dent the statistics on death and disease was an illusion. Instead, Russell, Jarvis and increasing numbers of other tobacco researchers turned their attention to other tobacco products that had been used for decades or even centuries.

Looking beyond combustibles

In 1980, Russell and Jarvis published a paper in *The Lancet* titled ‘*A New Age of Snuff?*’.⁴⁵ This was one of the earliest papers which put forward the idea of non-combustible nicotine consumption as a safer alternative to smoking cigarettes.

Russell and Jarvis determined that people who smoke may find it acceptable to switch to snuff as “the rate of nicotine absorption from snuff is very rapid”, reporting their findings that “the blood-nicotine level [...] matches the peak levels found in heavy cigarette smokers”. Furthermore, they posited that “snuff could provide many other components of the smoking habit”, including “intricate sensorimotor rituals which add to the pleasure and social aspects” of cigarette use. They continue, introducing the concept of “switching”:

*“Switching from cigarettes to snuff could have enormous health benefits. Although some problems could arise from continued absorption of nicotine and local nasal irritation in heavy users, the absence of tar and gases such as carbon monoxide, oxides of nitrogen, and many other toxic combustion products, would virtually eliminate smoking-related cancer, bronchitis, and possibly heart disease. Also, snuff does not contaminate the atmosphere for non-users.”*⁴⁶

“Russell and Jarvis concluded that “snuff could save more lives and avoid more ill-health than any other preventive measure likely to be available to developed nations well into the 21st century”.

Russell and Jarvis concluded that “snuff could save more lives and avoid more ill-health than any other preventive measure likely to be available to developed nations well into the 21st century”.⁴⁷

Before 1981 in the US, smokeless tobacco (SLT) carried no warnings, was not thought to be associated with any disease, and its use was in decline. The 1964 Surgeon General report found, “no useful mortality statistics in those who chew, snuff or ‘dip’ tobacco”. The 1979 report came to the same conclusion: “snuff and chewing tobacco have not been found to increase mortality (either overall or cause-specific) in the United States”.

Then, in 1981, a study of female smokeless tobacco users published in the prestigious *New England Journal of Medicine* concluded that there was a link between SLT and oral cancer.⁴⁸ The study was quoted by the 2001 Institute of Medicine report *Clearing the smoke: assessing the science base for tobacco harm reduction*. The deliberating

⁴⁴ Jarvis, M. J., & Russell, M. A. (1980). Comment on the Hunter Committee's second report. *British Medical Journal*, 280(6219), 994–995. <https://doi.org/10.1136/bmj.280.6219.994>.

⁴⁵ Russell, M. A., Jarvis, M. J., & Feyerabend, C. (1980). A new age for snuff? *Lancet (London, England)*, 1(8166), 474–475. [https://doi.org/10.1016/s0140-6736\(80\)91010-7](https://doi.org/10.1016/s0140-6736(80)91010-7).

⁴⁶ Ibid.

⁴⁷ Ibid.

⁴⁸ Winn, D. M., Blot, W. J., Shy, C. M., Pickle, L. W., Toledo, A., & Fraumeni, J. F. (1981). Snuff dipping and oral cancer among women in the southern United States. *The New England Journal of Medicine*, 304(13), 745–749. <https://doi.org/10.1056/NEJM198103263041301>.

committee used this example (among others) to suggest that the evidence for the relative safety of smokeless was contradictory.⁴⁹ However, according to tobacco researcher Brad Rodu, the author of the 1981 study never made it clear that the cohort had been using dry rather than moist snuff. In 2004, Rodu co-authored a paper which determined that the dangerous tobacco-specific nitrosamine levels in some dry snuff brands were 100 times greater than in moist varieties such as Skoal Bandits, a product like Swedish snus.⁵⁰

When United States Tobacco (UST) launched Skoal Bandits in 1983 under the slogan “Take a pouch instead of a puff”, the perceived threat to cigarette sales was sufficient to prompt the President of Lorillard to write to the Chairman of UST politely suggesting that he might consider promoting his brand while not at the same time denigrating cigarettes.



1983 Skoal Bandits ad.
Source: Ebay listing of vintage print ad.

The implication of the advertising was that SLT was ‘safe’ as opposed to ‘safer than cigarettes’. States-wide and Congressional pressures forced the introduction of warning labels in the 1980s, although the company staved off warnings of ‘addiction’ by saying that the product was not a safer alternative to smoking – even though subsequent research demonstrated it was. The official line was that all forms of tobacco were equally dangerous. In response, Brad Rodu demonstrated the relative safety of the moist type of American SLT, and Lynn Kozlowski highlighted the extent to which American smokers were misled over the dangers from the 1980s onwards.⁵¹

The potential for American SLT to be the proof of concept for THR was never realised. But one smokeless product – Swedish-style snus – does provide significant evidence in favour of a THR approach.

The Swedes started to use tobacco in a form which later became known as ‘snus’ in the 18th century. This oral product remained the primary mode of tobacco consumption in the country until the 1930s, when it was overtaken by cigarettes. Partly due to the

“The official line was that all forms of tobacco were equally dangerous

“Swedish-style snus [provides] significant evidence in favour of a THR approach

⁴⁹ Institute of Medicine (US) Committee to Assess the Science Base for Tobacco Harm Reduction. (2001). *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* (K. Stratton, P. Shetty, R. Wallace, & S. Bondurant, Eds.). National Academies Press (US). <http://www.ncbi.nlm.nih.gov/books/NBK222375/>, p. 301.

⁵⁰ Rodu, B., & Jansson, C. (2004). Smokeless tobacco and oral cancer: A review of the risks and determinants. *Critical Reviews in Oral Biology and Medicine: An Official Publication of the American Association of Oral Biologists*, 15(5), 252–263. <https://doi.org/10.1177/154411130401500502>.

⁵¹ Kozlowski, L. T. (2018). Origins in the USA in the 1980s of the warning that smokeless tobacco is not a safe alternative to cigarettes: A historical, documents-based assessment with implications for comparative warnings on less harmful tobacco/nicotine products. *Harm Reduction Journal*, 15(1), 21. <https://doi.org/10.1186/s12954-018-0228-8>; Rodu, B., & Godshall, W. T. (2006). Tobacco harm reduction: An alternative cessation strategy for inveterate smokers. *Harm Reduction Journal*, 3(1), 37. <https://doi.org/10.1186/1477-7517-3-37>.

By the 1980s, snus use had overtaken smoking in adult men in Sweden

two well-publicised UK and US medical reports on the dangers of smoking in the early 1960s, cigarette use in Sweden declined in the latter part of that decade. At the same time, snus use rose. This appears to have happened spontaneously, in the absence of publicity about relative safety.

While snus was often cited in population studies as a route out of smoking in Sweden, it was never advertised for this purpose. Other reasons that have been suggested for the rise in snus use were government warnings which focused on the dangers of smoking, rather than all forms of tobacco. By the 1980s, snus use had overtaken smoking in adult men in Sweden.

The Swedish market in cigarettes and snus was dominated by one company – Swedish Match. The company noted that snus use was changing from being predominantly used by older working-class men to becoming a mainstream product. The company responded by making the product more attractive to broader consumer groups. These initiatives included changing the packaging, introducing the pouch concept, and adding new brands with different flavours. In 2000, Swedish Match further consolidated the snus market in Sweden by selling its cigarette operations to the Austrian company Tabak. Over the years, it divested itself of pipe tobacco and cigar manufacturing as well.

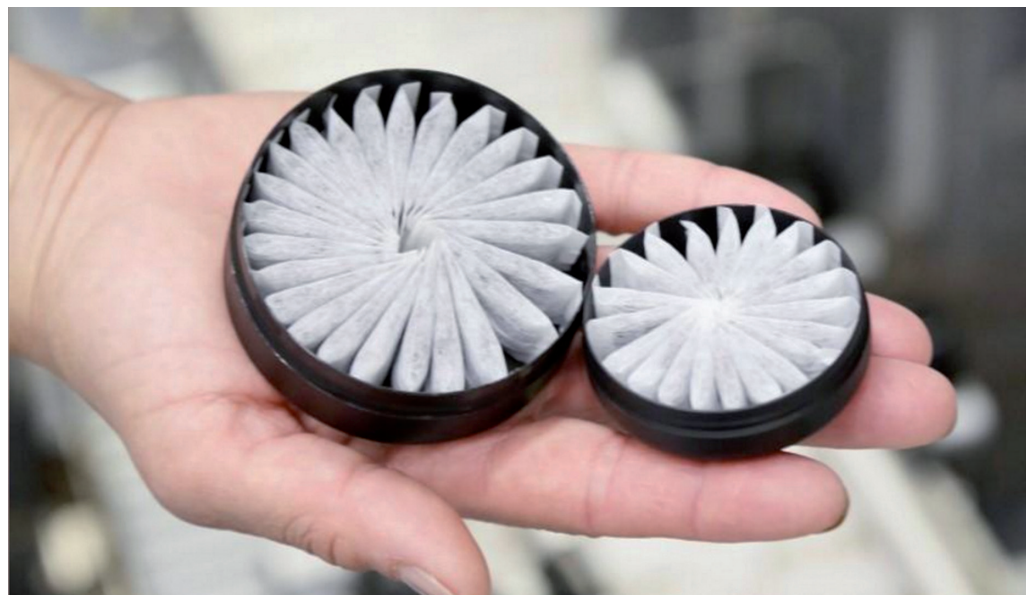


Image: Swedish Match file photo

Naturally, the product piqued the interest of tobacco researchers, who were able to conclude that snus was relatively safer than smoking based on the production process. The process for manufacturing Swedish-style snus was superior to that of dry smokeless tobacco in America and many of the oral tobacco forms found in Asia. The basic process had remained unchanged until the early 1970s, when manufacture came under the control of the Swedish Food Act. The then-state-owned company modernised the process and introduced new quality control measures. The Gothiatek® standard sets out the maximum levels for certain harmful (but naturally occurring) substances, including metals, nitrite, tobacco-specific nitrosamines, agrochemicals, mycotoxins and aldehydes.⁵²

⁵² Full details of the Gothiatek® standard can be accessed on the Swedish Match website *Gothiatek standard: B(a)P*. (2016, March 7). Swedish Match. <https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard/BaP/>.

The Scandinavian experience with snus as a proof of concept for THR is supported by epidemiological data showing that in both Sweden and its neighbour Norway, high levels of snus use are associated with very low levels of smoking and smoking-related disease.

Swedish men have switched from smoking to using snus in large numbers, with 22% using it daily.⁵³ Sweden has by far the lowest rate of smoking in Europe and is the only EU state to have reached ‘smoke-free status’, classically defined as less than 5% adult smoking prevalence, in the adult population aged between 15 and 54. The average EU smoking rate for this population is 26%.⁵⁴ Norway also has very low rates of smoking – 8% of Norwegian adults smoke daily – and increasing uptake of snus use among the young. Just 1% of women aged 16-24 smoke, while some 12% use snus daily.⁵⁵

As well as corresponding to lower smoking prevalence, uptake of snus correlates with lower tobacco-related death rates. Swedish men have Europe’s lowest level of tobacco-related mortality, with 152 deaths attributable to smoking per 100,000 compared with the European average of 373 deaths per 100,000.⁵⁶

At the Global Forum on Nicotine 2022, independent tobacco researcher Dr Lars Ramström presented a new study investigating the impact of the WHO’s tobacco control measures on tobacco-related mortality in Europe. For European women, there was no correlation at all between the level of tobacco-related mortality and a country’s level of implementation of tobacco control measures recommended by the WHO. For European men, he could find no strong relationship between the two; the level of tobacco control implementation was responsible for only a low level of variation, estimated to be 11%, in the mortality rates.⁵⁷

Furthermore, Dr Ramström’s research reveals the positive impact of the use of safer nicotine products, specifically snus, on tobacco-related mortality. The two countries in Europe with the lowest tobacco-related mortality for men were Sweden and Norway. Sweden’s implementation of tobacco control policies is below the European average and yet it has achieved a lower rate of tobacco-related mortality than all the countries that have higher levels of MPOWER implementation except Norway, where snus is also popular.⁵⁸

Despite evidence of its success as a harm reduction intervention at a population level, access to snus remains severely restricted in many countries, with 38 having enacted bans. This includes countries in the EU, with the notable exception of Sweden. In most EU countries, it is illegal to sell snus online or import the product for trade purposes, although import for personal use

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Dr Ramström’s research reveals the positive impact of use of safer nicotine products, specifically snus, on tobacco-related mortality

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⁵³ Statistics Sweden. (n.d.). *Tobacco habits by indicator, study domain and sex. Percentage and estimated numbers in thousands. Year 2008-2009–2021-2021*. Statistikdatabasen. Retrieved 27 September 2022, from http://www.statistikdatabasen.scb.se/pxweb/en/ssd/START__LE__LE0101__LE0101H/LE01012021H06/.

⁵⁴ European Commission. (2021). *Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes (S2240_506_ENG)*. European Commission. http://data.europa.eu/88u/dataset/S2240_506_ENG. Sweden country factsheet accessible at: <https://europa.eu/eurobarometer/surveys/detail/2240>

⁵⁵ Statistics Norway. (2022, January 18). *Tobacco, alcohol and other drugs*. SSB. <https://www.ssb.no/en/helse/helseforhold-og-levevaner/statistikk/royk-alkohol-og-andre-rusmidler>.

⁵⁶ Data presented by Peter Lee, epidemiologist and medical statistician, and tobacco researcher Dr Lars Ramström, at the Global Forum on Nicotine 2017. Reported as *New data reveals potential of snus in reducing impact of tobacco-related diseases* in News Medical (June 16 2017). [Accessed August 2022]. <https://www.news-medical.net/news/20170616/New-data-reveals-potential-of-snus-in-reducing-impact-of-tobacco-related-diseases.aspx>

⁵⁷ *National availability of snus is clearly associated with lower rates of mortality attributable to tobacco – while country-level implementation of WHO tobacco control measures is not*. Research presented by Dr Lars Ramström of the Institute for Tobacco Studies (Sweden) at the Global Forum on Nicotine 2022. <https://gfn.events/new-research>

⁵⁸ Ibid.

is permitted. On joining the EU in 1995, Sweden negotiated a ‘derogation’ (exemption) to the restrictions on snus.

For more information, access the GSTHR Briefing Paper on snus at <https://gsth.org/briefing-papers/an-introduction-to-snus/>

By 2009, the WHO Tobacco Regulatory Committee could conclude that “among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes”.⁵⁹

The term ‘harm reduction’ as applied to tobacco products such as snus began to emerge in tobacco research literature from the late 1990s. One of the earliest references was a paper published in 1997 by Kenneth Warner and colleagues, titled ‘*The emerging market for long-term nicotine maintenance*’.⁶⁰ But where had the phrase ‘harm reduction’ come from? Was it a materially different concept from a purely public health or even a ‘health and safety’ notion of ‘less risky’?

Drugs, HIV and the birth of harm reduction

What we now call ‘harm reduction’ acknowledges that protecting an individual’s health takes precedence over trying to coerce them into stopping behaviours that are often considered problematic by society. Consequently, harm reduction policies and practices also encompass human rights and social justice issues, in tandem with mainstream public health concerns.

However, well before the 1980s, antecedents of a harm reduction approach were already being practised in all but name. For example, in the UK, it was considered legitimate practice for doctors to prescribe medical grade heroin (diamorphine) or cocaine to people dependent on those substances as a measure of last resort. The so-called ‘British system’ remained in place until 1968. The doctors who followed this treatment path would not have called it ‘harm reduction’. Today, ‘safe supply’ and substitute prescribing, with opioid medications developed for heroin dependency, are recognised harm reduction interventions for people who use drugs.

But as the 1980s dawned, while tobacco researchers were contemplating ways to reduce the death and disease due to smoking for those who could not quit, another lethal disease emerged. On 5th June 1981, the U.S. Centers for Disease Control and Prevention (CDC) issued findings in its *Morbidity and Mortality Weekly Report* newsletter of unusual clusters of a type of lung infection found in five gay men in the Los Angeles area. The findings featured in the *San Francisco Chronicle* and the *Los Angeles Times*. News of the disease was picked up in New York, and the city’s first AIDS patient was soon identified. By August 1981, the CDC reported over 100 cases across America.⁶¹

As soon as research revealed that HIV was being spread through sexual contact, community activists began promoting the use of condoms among their peers. A group

⁵⁹ WHO Study Group on Tobacco Product Regulation. *Report on the scientific basis of tobacco product regulation: Seventh report of a WHO study group*. (No. 1015; WHO Technical Report Series). (2019). World Health Organization. <https://apps.who.int/iris/bitstream/handle/10665/329445/9789241210249-eng.pdf>.

See also: Eliasson, M., Lundblad, D., & Hägg, E. (1991). Cardiovascular risk factors in young snuff-users and cigarette smokers. *Journal of Internal Medicine*, 230(1), 17–22. <https://doi.org/10.1111/j.1365-2796.1991.tb00401.x>; Henningfield, J. E., & Fagerstrom, K. O. (2001). Swedish Match Company, Swedish snus and public health: A harm reduction experiment in progress? *Tobacco Control*, 10(3), 253–257. <https://doi.org/10.1136/tc.10.3.253>.

⁶⁰ Warner, K. E., Slade, J., & Sweanor, D. T. (1997). The Emerging Market for Long-term Nicotine Maintenance. *JAMA*, 278(13), 1087–1092. <https://doi.org/10.1001/jama.1997.03550130061038>.

⁶¹ National Institutes of Health. (2016). *In Their Own Words. NIH researchers recall the early years of AIDS*. Office of NIH History and Stetten Museum. <https://history.nih.gov/display/history/In+Their+Own+Words>.

the term ‘harm reduction’ [...] began to emerge in the tobacco research literature from the late 1990s

harm reduction policies and practices also encompass human rights and social justice issues

of New Yorkers established the organisation Gay Men's Health Crisis (GMHC), which is still operating today. An answering machine in the home of a GMHC volunteer became the world's first AIDS hotline and received over 100 calls in its first night of operation.⁶² Similar grassroots action started up in San Francisco. People were coming together to try and come to terms with a disease with no cure that only seemed to affect members of their community. These citizens were already the subject of discrimination and abuse. And they now found themselves further condemned as spreaders of what some termed a 'gay plague'.



Since the crisis emerged in the 1980s, people affected by or at risk of HIV/AIDS have been stigmatised in the media. Source: RapidEye on iStockphoto.

Soon, research also revealed that HIV could be passed between people who shared needles and syringes while injecting drugs. In the Netherlands, a group of people who used drugs had already banded together to provide clean injecting equipment to deal with an outbreak of hepatitis. In the UK, a coalition of drug users, community workers, and enlightened local public health officials began distributing sterile injecting equipment from sites around the country. Following the recommendation of experts, the UK drug treatment system responded by introducing a regime of opiate substitution therapy to bring people into treatment and reduce equipment sharing.

The earliest article to coin the phrase 'harm reduction' was published in 1987 in *Druglink*, the magazine of the Institute for the Study of Drug Dependence, an NGO focused on the provision of non-judgemental, topical, and evidence-based drug information. Written by Dr Russell Newcombe, an independent drug researcher, the piece covered a range of potential drug harm reduction interventions. But the focus was on the needs of heroin injectors for realistic information to reduce harm: essentially, stop if you can; if you can't, smoke or sniff heroin rather than inject it; if you can't stop injecting, don't share needles with others.⁶³

Suffice to say, especially in relation to the supply of sterile injecting equipment, there were many political, medical, and public health splits in opinion. The two main arguments posed against drug harm reduction were that it encouraged illicit and unhealthy behaviours and that it was a 'back door' to drug legalisation. Many of these challenges remain today. For example, in contrast to the WHO, UNAIDS and other UN

the focus was on the needs of heroin injectors for realistic information to reduce harm

⁶² Gay Men's Health Crisis. (2020, October 9). *History—GMHC*. <https://www.gmhc.org/history/>.

⁶³ Newcombe, R. (1987). High Time For Harm Reduction. *Druglink*, 2, pp. 10–11.



The importance of avoiding shared injecting equipment is core harm reduction advice for people who inject drugs. Source: Vladans on iStockphoto.

bodies, the UN Committee on Narcotic Drugs (roughly equivalent to the Conference of the Parties to the Framework Convention on Tobacco Control) still resolutely fails to mention harm reduction in any consensus-based documents in 2022.⁶⁴

However, in the 21st century, many countries accept the need for harm reduction to prevent the spread of HIV/AIDS, though the provision of drug harm reduction interventions is still contentious. It is therefore unsurprising that the relatively new approach of harm reduction for tobacco as a public health intervention is resisted by many in the global health community and among politicians and legislators.

Harm reduction, human rights and leaving no one behind

“harm reduction intersects with human rights

It has been argued that harm reduction intersects with human rights. The right for every citizen to enjoy the highest attainable standard of physical and mental health and the freedom to take control of their own health is enshrined in several international health treaties and statements going back to the formation of the UN in 1948.

From the early 2000s human rights organisations, including Human Rights Watch and the International Harm Reduction Association (now Harm Reduction International), campaigned to establish that harm reduction was a fundamental aspect of the right to health, a view that was eventually accepted within the UN system.

“it has recently also been argued that the right to health supports the right to tobacco harm reduction

That campaign was primarily concerned with achieving the right to harm reduction for people who use drugs. But it has recently also been argued that the right to health supports the right to tobacco harm reduction. In a GSTHR Briefing Paper published in June 2022 (<https://gsth.org/briefing-papers/the-right-to-health-and-the-right-to-tobacco-harm-reduction/>), Professor Gerry Stimson argues that “just as for people who use drugs, the enjoyment of the right to health of all people who use tobacco and nicotine is applicable, irrespective of the fact of their tobacco and nicotine use. The availability of, and access to, safer nicotine products – or tobacco harm reduction – is fundamentally important for protecting the health of tobacco and nicotine users.”⁶⁵

⁶⁴ Bridge, J., Hallam, C., Nougier, M., Cangas, M. H., Jelsma, M., Blickman, T., Bewley-Taylor, D., & Bowdery, D. (2021). *Edging forward: How the UN's language on drugs has advanced since 1990 (Version 2)*. International Drug Policy Consortium. <https://idpc.net/publications/2021/04/edging-forward-how-the-un-s-language-on-drugs-has-advanced-since-1990-version-2>.

⁶⁵ Global State of Tobacco Harm Reduction. (2022b). *The right to health and the right to tobacco harm reduction* (Briefing Papers). <https://gsth.org/briefing-papers/the-right-to-health-and-the-right-to-tobacco-harm-reduction/>.

The right to health for all, with no one left behind, is a pertinent concept in tobacco harm reduction, particularly in light of the significant health inequalities associated with smoking worldwide. While overall smoking rates have been falling in higher income countries for some time, the global number of smokers has remained unchanged at 1.1 billion for over two decades, in some low- and middle-income countries (LMIC), population growth means that even if smoking rates are slowing or plateauing, the actual number of people who smoke continues to grow. The WHO estimates that more than 80% of the world's tobacco users live in LMIC.⁶⁶

Many of these nations are unable to offer their citizens universally accessible, high-quality smoking cessation support, and also struggle to provide the robust healthcare systems necessary to diagnose and treat smoking-related disease. To date, it is higher income countries that have been the main beneficiaries of THR; many LMIC have been left behind. This is due to a combination of factors, including a proliferation of prohibitionist responses from some LMIC governments, mis- or disinformation on the comparative safety of SNP over continued smoking, a lack of appropriate, culturally or socially acceptable safer products, and high prices for SNP compared to the market-dominant combustibles or traditional risky tobacco products.⁶⁷

In many high-income countries, meanwhile, although overall smoking rates have been falling for some years, high smoking rates now tend to be concentrated among communities experiencing disadvantage or social exclusion. In Europe, for example, inequalities in smoking rates have been observed based on people's level of education, their professional or occupational level, their sex, ethnicity, housing tenure and other measures of socioeconomic status.⁶⁸ People who are homeless, are detained in prison or who live with mental health problems or dependency on other substances are more likely to smoke at significantly higher rates than the national average.⁶⁹

In the US in 2020, the Centers for Disease Control found that “approximately 1 in 4 adults in the USA have some form of mental illness or substance use disorder, and these adults consume almost 40% of all cigarettes smoked by adults”.⁷⁰ A study looking at prison populations worldwide found that smoking rates among incarcerated people in 37 countries exceeded community rates by as much as 63 times.⁷¹ Smoking rates also tend to be significantly above the national average among members of LGBTQ+ communities and among indigenous or First Nation peoples.⁷²

High smoking rates among disadvantaged communities directly contribute to the health inequalities that they experience. Data analysis from Cancer Research UK showed that in England, smoking is responsible for nearly twice as many cancer cases in lower income groups compared to higher income groups.⁷³ A landmark review of

The WHO estimates that more than 80% of the world's tobacco users live in LMIC

In many high-income countries [...] high smoking rates now tend to be concentrated among communities experiencing disadvantage or social exclusion

A study looking at prison populations worldwide found that smoking rates among incarcerated people in 37 countries exceeded community rates by as much as 63 times

⁶⁶ WHO, 2022.

⁶⁷ Shapiro, H. (2020). *Burning Issues: Global State of Tobacco Harm Reduction 2020*. Knowledge-Action-Change. <https://gsth.org/resources/item/burning-issues-global-state-tobacco-harm-reduction-2020>, p. 14.

⁶⁸ Loring, B. (2014). *Tobacco and inequities: Guidance for addressing inequities in tobacco-related harm*. World Health Organization. Regional Office for Europe; WHO IRIS. <https://apps.who.int/iris/handle/10665/344628>.

⁶⁹ McNeill, A., Amos, A., McEwen, A., Ferguson, J., & Croghan, E. (2012). Developing the evidence base for addressing inequalities and smoking in the United Kingdom. *Addiction (Abingdon, England)*, 107 Suppl 2, 1–7. <https://doi.org/10.1111/j.1360-0443.2012.04080.x>.

⁷⁰ CDC's Office on Smoking and Health. (2020). *Tobacco-Related Disparities; Tobacco Use Among Adults with Mental Illness and Substance Use Disorders*. Smoking and Tobacco Use. http://www.cdc.gov/tobacco/basic_information/health_disparities/mental-illness-substance-use/.

⁷¹ Spaulding, A. C., Eldridge, G. D., Chico, C. E., Morisseau, N., Drobeniuc, A., Fils-Aime, R., Day, C., Hopkins, R., Jin, X., Chen, J., & Dolan, K. A. (2018). Smoking in Correctional Settings Worldwide: Prevalence, Bans, and Interventions. *Epidemiologic Reviews*, 40(1), 82–95. <https://doi.org/10.1093/epirev/mxy005>.

⁷² Glover, M., Patwardhan, P., & Selket, K. (2020). Tobacco smoking in three “left behind” subgroups: Indigenous, the rainbow community and people with mental health conditions. *Drugs and Alcohol Today*, 20(3), 263–281. <https://doi.org/10.1108/DAT-02-2020-0004>.

⁷³ England: Smoking responsible for twice as many cancers in lower income groups. (2021, August 2). Cancer Research UK – Cancer News. <https://news.cancerresearchuk.org/2021/08/03/england-smoking-responsible-for-twice-as-many-cancers-in-most-deprived-groups/>.

A landmark review of health inequity in England found that smoking is responsible for half the difference in life expectancy between the richest and poorest

health inequity in England found that smoking is responsible for half the difference in life expectancy between the richest and poorest.⁷⁴



A health promotion ad from the US Centers for Disease Control and Prevention highlights the impact of smoking on Brian, who is living with HIV. Source: Pinterest, CDC, US.

people who smoke have been increasingly regarded as undeserving social pariahs

Through the decades, the health messaging warning people of the dangers of smoking has become more and more explicit. The issue of secondary smoke has risen up the agenda, too, and public smoking bans have come into force. The result is that people who smoke have been increasingly regarded as undeserving social pariahs. This is further compounded by the fact that – particularly in high-income countries – smoking is disproportionately concentrated in the marginalised groups outlined above, many of whom are already subject to social stigma.

Harm reduction and the search for a 'safer cigarette'

Ultimately, the tobacco industry's quest for a 'safer cigarette' was a dismal failure

Tobacco harm reduction cannot be implemented unless there are appropriate, acceptable, and affordable products that offer significant reductions in risk when compared to continued use of the combustible cigarette. This chapter has shown that throughout much of the 20th century, the search for suitable and genuinely less harmful alternatives was elusive. Ultimately, the tobacco industry's quest for a 'safer cigarette' was a dismal failure. Either the products offered little or no protection from dangerous chemicals, or they were rejected by consumers, the ultimate arbiters of product success.

There began to be glimmers of hope when health researchers correctly identified that people were continuing to smoke in order to use nicotine – but that nicotine was not the cause of smoking-related death and disease. It became clear that if people could continue using the substance in isolation from the dangers of smoke inhalation, they could do so without coming to significant harm. Therefore, people who could not or did not want to stop using nicotine needed a safer delivery route than that offered by the combustible cigarette.

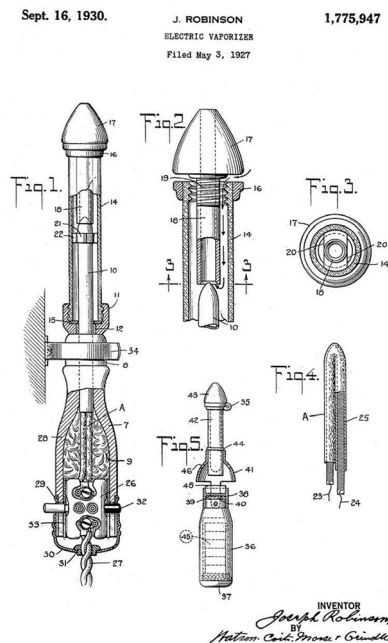
But was it even possible to develop a product that would be far safer than any version of a cigarette – while at the same time appealing to people who smoke?

⁷⁴ Marmot, M. (2020). Health equity in England: The Marmot review 10 years on. *BMJ (Clinical Research Ed.)*, 368, m693. <https://doi.org/10.1136/bmj.m693>.

Chapter 3: A stuttering evolution towards the quiet revolution

Efforts to perfect technological innovations that – intentionally or unintentionally – could be used to make nicotine consumption safer began earlier than many may imagine. On 25th May 1927, Joseph Robinson filed a patent in New York that was granted four years later. His ‘Electrical Vapourizer’ comprised an electrical element contained in a cylinder. This would be heated to vaporise a compound, which would then pass through a mouthpiece. Robinson did not clearly set out the intended use for his invention in the patent application, but it was likely intended for inhaling medicinal products. It does not appear to have gone into production.⁷⁵

“Efforts to perfect technological innovations that [...] could be used to make nicotine consumption safer began earlier than many may imagine



Robinson's 'Electrical Vapourizer'. Patent filed on May 3 1927. Image dated 16 September 1930. Source: Google Patents, No. US1,775,947.

On 27th February 1932, Joseph Z. Dalinda filed a patent for a ‘Method and Apparatus for Smoking’. He wrote in his application: “It is well known that in the burning of tobacco in smoking, ...many products or compounds are formed, which have a harmful or irritating effect upon the human organs [...]. All of the usual disadvantageous characteristics of smoking have been eliminated by my method of smoking. It is not necessary for the user to carry on any combustion whatsoever.”⁷⁶ Despite these insights, there is no evidence the device was developed beyond the patent stage.

Two decades later, and the early 1950s heralded the publication of two landmark scientific studies that revealed the dangers of smoking (see Chapter 1). These reports, and the headlines they generated, forced the tobacco industry to respond. The

“All of the usual disadvantageous characteristics of smoking have been eliminated by my method of smoking. It is not necessary for the user to carry on any combustion whatsoever”

⁷⁵ Robinson, J. (1931). *Electrical vaporizer* (United States Patent No. US1806646A). <https://patents.google.com/patent/US1806646/en>.

⁷⁶ Dalinda, J. Z. (1936). *Method and apparatus for smoking* (United States Patent No. US2051030A). <https://patents.google.com/patent/US2051030A/en?q=US2051030>.

both inside and outside of the tobacco industry, there were faltering steps towards a different and radical path away from combustible cigarettes

Ellis and his team of researchers [...] aimed to understand why smokers smoked

Ellis [...] knew that the nicotine needed to be palatable to the consumer

Tobacco executives felt they could breathe easier – even if their customers could not

There are those [...] who believe an American named Herbert Gilbert [...] to be the ‘godfather’ of the modern electronic cigarette

industry did so with public misinformation and denial, and attempted to assuage smokers’ concerns by developing filter cigarettes. Behind the scenes, though, both inside and outside of the tobacco industry, there were faltering steps towards a different and radical path away from combustible cigarettes.

The nucleus of an idea

Sir Charles Ellis was a renowned British nuclear physicist who had worked on fission as part of the investigation into the feasibility of nuclear weapons. Knighted in 1946, he was a scientific adviser for the UK National Coal Board until 1955, when he was recruited by British American Tobacco (BAT) as their scientific adviser. Ellis and his team of researchers conducted two studies, codenamed ‘Mad Hatter’ and ‘Hippo’. The research aimed to understand why smokers smoked.

Ellis’ research confirmed to his satisfaction that it was all about the nicotine. He wrote a proposal for the BAT board to develop “a new smoking device that by administration of nicotine in a suitable form should give full satisfaction to smokers while at the same time avoiding the well-known disadvantages inherent in actual smoking”.⁷⁷

Despite internal opposition, Ellis was allowed to pursue the idea. He knew that the nicotine needed to be palatable to the consumer. The design recognised that combustible cigarettes burn at 700°C to 800°C, which is a much higher temperature than is required to release nicotine from tobacco, which occurs at around 250°C to 300°C. Thus the team aimed to create a “two-tiered device in which the outer part would provide the heat to liberate the nicotine from the inner part”. Tobacco would be burned on the outer layer, while a nicotine extract would be placed into an inner tube.⁷⁸ It was “essentially a cigarette within a cigarette separated by a tube of aluminium”.⁷⁹

Ellis named the resulting device Aerial, after the first British satellite in space. While initial testing was not very encouraging, the proof of concept was sufficient for BAT to lodge numerous patents to shut down any potential competition. Ellis had documentary evidence that BAT’s US subsidiary Brown & Williamson was thinking along similar lines, and it is possible that Reynolds and Philip Morris were as well.

In time, Ellis was replaced as project leader; Aerial limped on with no sign of a commercial product until it was eventually abandoned altogether in 1969. The reasons for this are unclear. BAT may have lost interest because the expected regulatory fall-out following the high-profile UK and US medical reports on smoking had not materialised. Tobacco executives felt they could breathe easier – even if their customers could not.

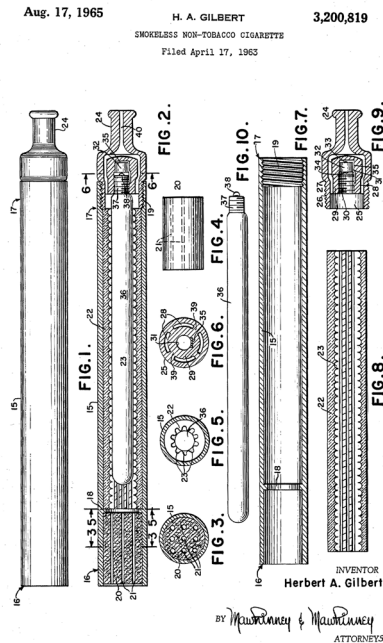
There are those within today’s vaping sector who believe an American named Herbert Gilbert, a business studies graduate and former serviceman, to be the ‘godfather’ of the modern electronic cigarette. Then a 40-a-day smoker living in Pennsylvania, it was Gilbert who filed a patent application for a ‘Smokeless Non-Tobacco Cigarette’ back in 1963. When interviewed by James Dunworth in 2013, Gilbert said he had experienced a eureka moment; “the problem, as I concluded, was that when you burned leaves and wood, even if you did it in your back yard, it yielded a result that no one wanted to take into their lungs”.⁸⁰

⁷⁷ Risi, S. (2017). On the Origins of the Electronic Cigarette: British American Tobacco’s Project Ariel (1962-1967). *American Journal of Public Health*, 107(7), 1060–1067. <https://doi.org/10.2105/AJPH.2017.303806>.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Dunworth, J. (2013, October 2). An Interview with The Inventor of the Electronic Cigarette. *Ashtray Blog*. <https://www.ecigarettedirect.co.uk/ashtray-blog/2013/10/interview-inventor-e-cigarette-herbert-a-gilbert.html>.



Gilbert's 'Smokeless Non-Tobacco Cigarette'.
Source: Google Patents, No. 3,200,819A.

While Charles Ellis' Aerial was a cigarette inside a cigarette, Gilbert's device was more like the basic modern-day e-cigarette; a long, cylindrical body, a battery, a heat source, and a flavour cartridge. The description from the patent office describes it as "a battery-powered 'cigarette' [which] uses no tobacco and produces no smoke". The crucial difference between Gilbert's device and Aerial, however, was that Gilbert's proposed product was nicotine-free. The device never made it to market, and existing prototypes perished in a warehouse fire.

In all likelihood, if Gilbert's invention had gone into production, the fact that it did not deliver nicotine would have led to failure. But speaking in 2013 when in his 80s, it was clear that Gilbert believed other forces were at work. He explained to Dunworth that he showed it to "chemical companies, pharmaceutical companies and tobacco companies" who could have put it into production – "but they chose to wait for the patent to expire and then file their own versions".⁸¹

Tobacco industry scientists continued to pursue filters and reducing the tar content of combustible cigarettes to produce 'light' and 'ultralight' products. Meanwhile, lone inventors with no connection to the industry, but who were interested in looking for a safer option to consume nicotine, continued to experiment.

Into the space age?

In 2014, James Dunworth's Ashtray Blog published an interview with Dr Norman Jacobson. Jacobson was a physician; one of his patients was a man named Phil Ray, a space engineer at NASA who had managed the Apollo programme and is credited with pioneering the microprocessor.⁸² Ray was a smoker. He did not want to give up nicotine, and wondered if he could reduce the harm by simply inhaling nicotine without the smoke. In the late 1970s, he discussed his idea with Jacobson, who conducted a small clinical trial with eight current smokers to see what would happen.

⁸¹ Ibid.

⁸² Dunworth, J. (2014, June 23). An Interview With A 1970's Vaping Pioneer. *Ashtray Blog*. <https://www.ecigarettedirect.co.uk/ashtray-blog/2014/06/favor-cigarette-interview-dr-norman-jacobson.html>.

While Charles Ellis' Aerial was a cigarette inside a cigarette, Gilbert's device was more like the basic modern-day e-cigarette

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the trials conducted by Jacobson using Ray's idea provided further proof that the idea of nicotine without smoke could work

Jacobson cannot recall who on the team coined the term, but this was the group who first used the word 'vaping'

The plastic device that they designed was shaped like a cigarette and contained paper soaked in nicotine. Because of nicotine's low volatility, the user simply had to inhale from one end to draw out the nicotine: there was no combustion or heating at all. In that sense, it was more like a nicotine inhaler than a modern vaping device. But the trials conducted by Jacobson using Ray's idea provided further proof that the idea of nicotine without smoke could work. The levels of carbon monoxide in the trial subjects' blood were dramatically reduced, matching levels seen in non-smokers. Subjects inhaled less nicotine than they would from using a combustible cigarette. Follow up reports found that they either smoked less or quit for up to two years after the trial.

As part of their research, Jacobson and a colleague came to England to meet with Michael Russell. And, in 1979, Jacobson delivered the preliminary results of the trials to a meeting of the American College of Chest Physicians in Houston, under the title, '*Nicotine inhalation or vaping*'. Jacobson cannot recall who on the team coined the term, but this was the group who first used the word 'vaping'. In the early 1980s, the men established Advance Tobacco Products Inc to commercialise the product. After a false start with the original managerial team, Jacobson entered the company as CEO. In 1985 the product launched under the trade name Favor, with the tagline 'Do yourself a favor'.

Unfortunately, Favor failed on three counts. Firstly, nicotine evaporates very quickly. The shelf-life of the cartridges was too short to be a practical alternative to smoking. Secondly, when it does degrade, nicotine converts into the metabolite cotinine, which has a bitter taste. Refrigeration was the only option to prevent this happening to the nicotine-soaked paper that was key to Favor, but this increased the complexity of marketing the product. Finally, in February 1987, the US Food and Drug Administration (FDA) banned it outright, deeming it to be a new drug (nicotine removed from tobacco) delivered by an unproven drug delivery system.⁸³ Eventually the patent for Favor was sold to a Swedish company, which converted the device to a nasal spray.

Patents proliferate

Through the 1980s and 1990s, numerous patents for similar devices were lodged in the US by Philip Morris and Reynolds. They often cited Herbert Gilbert's original invention – as did several pharmaceutical companies, which lodged patents based on the same technology in efforts to create devices that would deliver medicines via inhalation.⁸⁴ In the tobacco industry, however, it was Reynolds that picked up where BAT and Aerial left off, with the arrival of 'Premier' in 1987.

The research that led to Premier began back in 1981. It remained hidden from the Reynolds board – just as James Mold's Eclipse had been concealed from the board at Liggett (see Chapter 2). In July 1986, Reynolds' board members were stunned to receive a presentation about a project they had known nothing about. The new product resembled a normal cigarette, and inside was a tiny amount of tobacco. But to use Premier, the smoker lit a carbon tip at the end, which heated rather than burned the tobacco inside, producing no smoke and very low levels of tar.

Board members were furious at being kept in the dark. However, as \$68m had already been spent in research and development costs, they allowed the project to proceed.

⁸³ Michels, D. L. (1987, February 9). *Regulatory Letter*. Truth Tobacco Industry Documents. <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=xggy0038>.

⁸⁴ Duffon, E. (2015, January 22). *The Strange and Complicated History of Patenting the E-Cigarette*. Points: Short & Insightful Writing about the Long & Complex History of Drugs & Alcohol. <https://pointshistory.com/2015/01/22/the-strange-and-complicated-history-of-patenting-the-e-cigarette/>.

The final bill Reynolds footed for the development of Premier is estimated to be in the region of \$300 million.

In September 1986, Premier was announced at a press conference, with test market launches coming a year later. Those in charge of the project knew it was not ready. Unfortunately, their fears were confirmed; while being tested in the US, only 5% of smokers liked it. The response from Japanese test smokers? Allegedly, respondents said “it tastes like shit” and reported that it smelt even worse, as sulphur from the match head reacted badly with the carbon tip. Inside the company, the joke was you could get a hernia just trying to draw on it.⁸⁵



The Premier cigarette went up in smoke - taking hundreds of millions of dollars of Reynolds' money with it. Source: Mikael Seegan on Unsplash.

A changing nicotine landscape

Despite the failure of Premier, it got the attention of other companies, especially Philip Morris. They immediately began a series of experiments, labelled Beta, Delta and Sigma, collectively known as ‘The Greeks’, to try and swerve around the combustion problem using different heat sources including battery technology, while ‘Project Leap’ briefly took Philip Morris down the nicotine inhaler route.

In May 1992, an internal document, *Products of the Future*, stated in no uncertain terms the reason for this experimentation. “Premier probably changed the cigarette business forever.”⁸⁶ It is interesting to note that in the race to develop an acceptable, non-combustible device for nicotine delivery, this document reveals Philip Morris was as worried about competition from the pharmaceutical industry as its rivals in the tobacco sector.

By the early 1990s, the pharmaceutical sector was making good money from nicotine products; nicotine within a medical context, as nicotine replacement therapy or NRT, was now acceptable. Some at Philip Morris had obviously begun to wonder how long

“Despite the failure of Premier, it got the attention of other companies, especially Philip Morris

“Premier probably changed the cigarette business forever.”

⁸⁵ Etter, L. (2021). *The Devil's Playbook: Big Tobacco, Juul, and the Addiction of a New Generation*. Crown, New York, p. 42.

⁸⁶ *Product Of The Future—White Paper*. (1992). Truth Tobacco Industry Documents. <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=ftkw0128>.

it would be before pharmaceutical companies would create an acceptable device that could be used for the ‘recreational’ use of nicotine. Of course, such a device may not have been a natural fit within the pharmaceutical portfolio. Nevertheless, this certainly represents a ‘what if’ moment in the development of safer nicotine products.

Philip Morris’ other concern was product development. The company knew nothing about battery technology, electronics or any of the research, development and logistics that could pull them into the 21st century. Ironically, to address this deficit, Eastman Kodak was listed among possible partners. Kodak is a company that ultimately fell victim to disruptive technology; while it developed digital camera technology, the company never imagined it would supplant physical film. This allowed competitors to steal a march and, eventually, to put an end to the whole business.

In 1995, another ‘blue sky’ document called *Project Table* did the rounds inside Philip Morris, which again tried to set out the competition in the nicotine delivery landscape. It included references to smokeless and nicotine replacement products, and pointed to the number of patent applications for non-combustibles from industry rivals.⁸⁷ But this was a dangerous time for the industry; over nearly 700 pages, the 1988 US Surgeon General’s report set out the evidence that nicotine was an addictive drug. Eventually, this led to an investigation by the Food and Drug Administration (FDA) in the mid-1990s seeking to deem (and then control) any new devices as delivery systems and so subject them to medical regulation.

In the meantime, the avalanche of litigation that was about to bury the industry, and which ultimately led to the Master Settlement Agreement (see Chapter 1), was focussing minds away from new product development. In 1994, a mass of documentation was leaked to the University of California by Merrill Williams Jr., who became known as the ‘Brown & Williamson whistleblower’. It laid bare the deceptions practised by the industry over decades.⁸⁸

The litigation and close scrutiny the industry was rightly placed under probably accounts for the low-key launch of Philip Morris’ heated tobacco product Accord in 1997. Accord failed due to poor sales and low consumer appeal. However, it was the closest the company had come so far to producing a heated tobacco device – something that would eventually achieve a market share under the IQOS brand in the 21st century.

Clearing the smoke: a missed opportunity for THR?

The publication in 2001 of *Clearing the smoke: assessing the science base for tobacco harm reduction*, from the US Institute of Medicine (see Chapter 2), was an important point in the history of tobacco harm reduction, especially in the US. The report, the result of work by a distinguished committee drawn from the Institute’s Board on Health Promotion and Disease Prevention, sparked a national debate about nicotine.

Most importantly, *Clearing the smoke* provided one of the first definitions of THR from an official and highly credible source:

the avalanche of litigation that was about to bury the industry [...] was focussing minds away from new product development

in 1994, a mass of documentation was leaked to the University of California [which] laid bare the deceptions practised by the industry over decades

The publication in 2001 of *Clearing the smoke* [...] was an important point in the history of tobacco harm reduction

⁸⁷ Reuter, B. (1992). *Table*. Truth Tobacco Industry Documents. <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=ppdl0128>.

⁸⁸ For further information, see Lewis, L. (2013, December 4). Whistleblower described as “tobacco industry’s worst nightmare” dies. *Whistleblowing Today*. <http://whistleblowingtoday.org/2013/12/whistleblower-described-as-tobacco-industrys-worst-nightmare-dies/>.

“For the purposes of this report, a product is harm reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants”⁸⁹



Publication of the ‘Clearing the smoke’ report in 2001 was a missed opportunity in the history of THR.
Source: Pascal Meier on Unsplash.

Clearing the smoke also offered an alternative view to those who only saw emerging products as a nefarious scheme by the tobacco industry to condemn more people to tobacco-related death and disease:

“For many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible. Currently available PREPs (Potential Reduced Exposure Products) have been or could be demonstrated to reduce exposure to some of the toxicants in most conventional tobacco products.”⁹⁰

Their principal recommendations are directly quoted below (emphases in original text):

- » “manufacturers have the necessary *incentive* to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease;
- » consumers are fully and accurately *informed* of all of the known, likely, and potential consequences of using these products;
- » promotion, advertising and labelling of these products are firmly *regulated* to prevent false or misleading claims, explicit or implicit;
- » health and behavioural effects of using PREPs are *monitored* on a continuing basis;
- » basic, clinical, and epidemiological *research* is conducted to establish their potential for harm reduction for individuals and populations;
- » harm reduction is implemented as a *component* of a comprehensive national tobacco control programme that emphasises abstinence-oriented prevention and treatment.”⁹¹

Subsequent history tells us that pressured by influential, well-funded lobby groups, the US government has not followed these recommendations, instead doing everything in its power to *disincentivise* manufacturers and ensuring that adults who smoke are exposed to nothing but anti-THR propaganda about safer nicotine products.

However, back in 2001, *Clearing the Smoke* and the associated debate showed the industry that it was worth pursuing what, to date, had been a litany of very expensive dead ends. In 2004, a re-energised Philip Morris, which always liked to position itself

Clearing the smoke provided one of the first definitions of THR from an official and highly credible source

Clearing the smoke also offered an alternative view to those who only saw emerging products as a nefarious scheme by the tobacco industry

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⁸⁹ Stratton, Shetty, Wallace, & Bondurant, 2001, p. 301.

⁹⁰ Ibid.

⁹¹ Ibid.

the most significant development in nicotine consumption since the creation of the cigarette rolling machine was already happening on the other side of the world

Chinese men smoke more than a third of the world's cigarettes, following a large increase first in urban, and then in rural, use of combustible cigarettes

as a primary industry innovator, floated what one writer described as a “Willie Wonka-style” set of product ideas including nicotine pills and popcorn.⁹²

But even as tobacco industry executives were debating the way forward in the early 2000s, the most significant development in nicotine consumption since the creation of the cigarette rolling machine was already happening on the other side of the world.

The modern vaping device is born

China's entrance into the story began inauspiciously. In 1995, an entrepreneur named Pu Danming, operating as General Manager of the China Healthy Cigarette Development Company, marketed a new ‘cigarette’. The device consisted of a perforated plastic tube, a mix of herbs scenting the air being inhaled, a light on the end, and when it was used, it played a patriotic tune, powered by a suction-activated battery.⁹³ The real innovation was a few years off yet.

The need for innovation to reduce smoking-related harms in China, however, could not have been more acute, and it remains so today. In 2015, a study published in the *Lancet* estimated that Chinese men smoke more than a third of the world's cigarettes, following a large increase first in urban, and then in rural, use of combustible cigarettes.⁹⁴ In 2022, China has an estimated 289.6 million smokers, meaning the country is home to one in four of the world's 1.1 billion global smoking population. In China, smoking is mainly concentrated among men; 47.7% of men smoke, compared to 1.8% of women. Each year, there are around two million smoking-related deaths in the country – again, roughly a quarter of the global total.⁹⁵



Hon Lik is the Patron of KAC Communications' Global Forum on Nicotine and spoke at the event in 2017. Source: The Global Forum on Nicotine.

⁹² Etter, 2021, p. 51. See also documents 3008372872; 3116015004; 3009578596 at <https://www.industrydocuments.ucsf.edu/tobacco>

⁹³ Wallace, B. (2013, April 26). *Smoke Without Fire*. New York Magazine. <https://nymag.com/news/features/e-cigarettes-2013-5/>.

⁹⁴ Chen, Z., Peto, R., Zhou, M., Iona, A., Smith, M., Yang, L., Guo, Y., Chen, Y., Bian, Z., Lancaster, G., Sherliker, P., Pang, S., Wang, H., Su, H., Wu, M., Wu, X., Chen, J., Collins, R., Li, L., & China Kadoorie Biobank (CKB) collaborative group. (2015). Contrasting male and female trends in tobacco-attributed mortality in China: Evidence from successive nationwide prospective cohort studies. *Lancet (London, England)*, 386(10002), 1447–1456. [https://doi.org/10.1016/S0140-6736\(15\)00340-2](https://doi.org/10.1016/S0140-6736(15)00340-2).

⁹⁵ *Smoking, vaping, HTP, NRT and snus in China*. (2022). Global State of Tobacco Harm Reduction. <https://gsth.org/countries/profile/chn/>.

Hon Lik was born in northern China in 1951. As a teenager during the Cultural Revolution, he was sent to work on tobacco farms. Later, he graduated from the Liaoning College of Traditional Chinese Medicine as a pharmacist and began a career trying to devise easier ways for people to ingest traditional Chinese herbal remedies like ginseng.

Hon Lik used to be one of the many millions of Chinese men who smoked. He smoked a lot; two or three packs a day. Though he tried to quit using nicotine patches, they had little effect. When he recounts the story, he says that the idea of delivering nicotine in a vapour came to him in a dream; he went to bed one night and forgot to remove his patch. Vivid dreams are a known effect of nicotine patch use during sleep.⁹⁶ That night, Hon Lik dreamed he was drowning in a deep sea, when suddenly the sea vapourised and he found himself floating in a brightly coloured fog.

On reflection, Hon Lik realised that the continuous dose from the nicotine patch had been the cause of his nightmares. He also reasoned that the steady delivery of the substance in the patch was inadequate for him in his efforts to quit. He preferred the stress relief he achieved by the discrete nicotine high of a cigarette, and reckoned that vaporising nicotine – in an echo of the vapourised ocean of his dream – would simulate more of the cigarette experience.⁹⁷ He was right.

Hon Lik's efforts to investigate his theory were further motivated when his father, also a heavy smoker, was diagnosed with lung cancer. "In 2001, I devised a system on a large console, using food additives as solvents. At the time I was working on vaporisation by ultrasound, but the droplets formed were too big to resemble tobacco smoke".⁹⁸ The challenge was radically reducing the size of the mechanism to fit into a hand-held cigarette-sized device, getting the right dose of nicotine in a form that resembled smoke, while also getting the right odours from harmless additives.

In 2003, he came up with the idea of using a high-frequency piezoelectric ultrasound-emitting element to vaporise a pressurised jet of liquid containing nicotine. Piezoelectricity is an electrical charge that accumulates in response to applied mechanical stress in certain solid materials, including crystals and certain ceramics, as well as biological matter such as bone, DNA, and various proteins.

Piezoelectricity has many practical applications, from sonar to ceramic cartridges on vinyl record decks to – ironically – igniting cigarette lighters. But Hon's new electronic cigarette design, with its piezoelectric ultrasound-emitting element, successfully created a smoke-like vapour that delivered nicotine. One crucial additional step forward from previous efforts saw the nicotine protected from vaporisation until it was heated. Here was a stable nicotine delivery system and a smoke-like vapour wrapped in a device that looked like a cigarette.

Hon Lik's first products hit the market

Hon Lik filed the first patent in 2003, with more to follow. The company he worked for, Golden Dragon Holdings, changed its name to Ruyan, meaning 'like smoke'. Beijiing Saybolt Ruyan Technologies was registered on 29th December 2003. By the time Ruyan launched its first products, Hon Lik had refined the design further, and it is this

the idea of delivering nicotine in a vapour came to [Hon Lik] in a dream

[Hon Lik] reckoned that vaporising nicotine – in an echo of the vapourised ocean of his dream – would simulate more of the cigarette experience

Here was a stable nicotine delivery system and a smoke-like vapour wrapped in a device that looked like a cigarette

⁹⁶ Page, F., Coleman, G., & Conduit, R. (2006). The effect of transdermal nicotine patches on sleep and dreams. *Physiology & Behavior*, 88(4–5), 425–432. <https://doi.org/10.1016/j.physbeh.2006.04.009>.

⁹⁷ Geller, M. (2015, June 9). E-cigs a 'consumer-driven' revolution born from a bad dream. *Reuters*. <https://www.reuters.com/article/us-ecigarettes-inventor-idUSKBN0OP1YV20150609>.

⁹⁸ Dave Cross. (2017, August 3). *Hon Lik speak at ISoNTEch*. Planet of the Vapes. https://www.planetofthevapes.co.uk/news/vaping-news/2017-08-03_hon-lik-speak-at-isontech.html.

The first vaping products went on sale in China in 2004

design that forms the basis of modern vaping devices today. In order to shrink the technology (and the device size), he eventually dispensed with piezoelectric ultrasound in favour of a smaller but equally effective heating element to vaporise the liquid containing nicotine.

The first vaping products went on sale in China in 2004; this was the same year Hon Lik's father died of lung cancer.⁹⁹ The initial product came in five different designs: the original descriptions, as translated into English by the company at the time, give a sense of what they were aiming for. The Marquis series was “designed for successful person[s]”; the Earl series, had “many appearances like traditional pipes, elegant, classical types”; the Viscount series, had “neutral design, multi-choice, [to] feel the new conception of cigarette smoking easily”; the Saron series, had “well-rounded appearances, cool sculpt; multi flavour”; and finally Love of Angel, with its “delicate appearances [and] light smoke”, was considered “suitable [for the] female”.¹⁰⁰

[Ruyan's products] were a huge success, earning the company a reported \$13m in 2005 alone

The devices came with cartridges of varying nicotine strengths and flavours like jasmine tea. More the length of a cigar than a cigarette, each had a slim white body, but with an LED at the tip which glowed red when the user inhaled. “A lot of consumers were shocked and surprised,” said Hon Lik. “They could not believe there was something they could put in their pocket and smoke like a cigarette, anytime, anywhere they liked”. Costing the equivalent of \$208, a significant outlay, nevertheless they were a huge success, earning the company a reported \$13m in 2005 alone.¹⁰¹

As previously mentioned, when the Reynold's Premier had been tested in Japan, consumers had complained it tasted like shit. When first presented with Hon Lik's device, a Philip Morris executive apparently asked “what the hell is this shit?”¹⁰² But what was immediately clear was that this was something new and, crucially, something that people liked using. Philip Morris employees in Beijing began buying up the products, taking them apart to see how they worked – and then reporting back to head office.

Significantly, an internal Philip Morris memo reveals that Ruyan's product had been signed off by the Chinese health authorities

Significantly, an internal Philip Morris memo reveals that Ruyan's product had been signed off by the Chinese health authorities. “The China Smoking and Health Association has said that this high tech product eliminates more than 4000 harmful chemical components that exist in a conventional cigarettes. The health experts have said that this electronic cigarette provides smokers with a complete, effective, practical and painless mechanism to quit smoking. The health experts have said that this design can satisfy smokers' addiction to cigarettes; however, with no harm to the smoker's health, due to the fact that the electronic cigarette only contains a small amount of nicotine in the flavor insert, but no tar content”.¹⁰³

Shenzhen enters the story

A new industry based on Hon Lik's invention began to emerge over a thousand miles south of Beijing, where Ruyan Technologies was registered

Once Hon Lik and Ruyan had shown the way, other Chinese companies were quick to follow. A new industry based on Hon Lik's invention began to emerge over a thousand miles south of Beijing, where Ruyan Technologies was registered. A critical time in the history of tobacco harm reduction, this is where the city of Shenzhen enters the tale.

Shenzhen stretches over 80 kilometres along the coast of the South China Sea and lies immediately north of Hong Kong. By the early 2000s, it was well established as

⁹⁹ Geller, 2015.

¹⁰⁰ Roger Slagle. (2004, June 2). *Beijing Saybolt Ruyan Technologies*. Truth Tobacco Industry Documents. <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fzmv0151>.

¹⁰¹ Ducharme, J. (2022). *Big Vape*. Hodder & Stoughton, p. 17.

¹⁰² Etter, 2021, p. 39.

¹⁰³ Roger Slagle, 2004.

an economic powerhouse in China; in 1980, it had been established as the first of the country's 'Special Economic Zones' (SEZ).¹⁰⁴ SEZ were introduced as the government of the late 1970s recognised the need for economic reform if China was to compete against both the industrialised west and those powers on the doorstep whose economies were booming – including, notably, Hong Kong, as well as Japan, Korea, Taiwan and Singapore.



The city of Shenzhen, China.
Source: Robert Bye on Unsplash.

SEZ have been in existence since the 1950s across a number of countries. The basic concept shares several specific characteristics; they are geographically delineated (and possibly physically secured); they have a single administration; they enjoy a favourable geographical location, and they operate a separate customs duty area. SEZ tend to operate under more liberal economic laws than those prevailing in the host country, and that is certainly the case for those in China, where they are granted more flexible government measures and the opportunity to pursue free-market oriented policies, in sharp contrast to the planned economy elsewhere.¹⁰⁵ Their introduction has been credited as playing a key role in the dramatic growth of China's economy over the last few decades, now second only to the US in terms of size.¹⁰⁶

Initially, Shenzhen's coastal location saw it focus on shipping and logistics, which enabled it to become an important manufacturing hub.¹⁰⁷ Later, however, the SEZ began to concentrate on technological innovations, and by 1998 high-tech industries accounted for almost 40% of the zone's industrial output.¹⁰⁸ By the early 2000s, then, Shenzhen was a fertile environment for a new industry to develop around Hon Lik's invention: it boasted a developed industrial chain, well-equipped manufacturing plants for hardware, a highly skilled workforce, and the right geographical position for global export of the finished products. Crucially, once the emerging e-cigarette industry got

Special Economic Zones tend to operate under more liberal economic laws than those prevailing in the host country, and that is certainly the case for those in China

By the early 2000s, Shenzhen was a fertile environment for a new industry to develop around Hon Lik's invention

¹⁰⁴ Fish, I. S. (2010, September 25). *China's Hottest Cities and Kashgar*. Newsweek. <https://www.newsweek.com/chinas-hottest-cities-and-kashgar-72333>.

¹⁰⁵ Zeng, D. Z. (2012). China's special economic zones and industrial clusters: The engines for growth. *Journal of International Commerce, Economics and Policy*, 03(03), 1250016. <https://doi.org/10.1142/S1793993312500160>.

¹⁰⁶ Santosdiaz, R. (2022, February 7). *How a Special Economic Zone can propel economic development*. World Economic Forum. <https://www.weforum.org/agenda/2022/02/special-economic-zones-how-one-city-helped-propel-its-country-s-economic-development/>.

¹⁰⁷ Ibid.

¹⁰⁸ Zeng, 2012.

the new products – while being sold on the Chinese market – also began to travel

its foothold, Shenzhen was home to numerous science and technology industrial parks where research and development could take place. This would firmly secure its ongoing role in innovations – both in the products themselves, and in the various components used in their manufacture.¹⁰⁹

In the early stages of the Shenzhen e-cigarette industry, however, multiple small and specialised e-cigarette companies were established that simply imitated Hon Lik's technology. Numerous entrepreneurs from various industries unrelated to tobacco saw its potential; start-ups proliferated. And the new products – while being sold on the Chinese market – also began to travel.

Products arrive elsewhere – and the tobacco industry is not on board

significant business disruption rarely happens from inside long-established and risk-averse industries

As Calestous Juma points out so cogently in his book *Innovation and its enemies: why people resist new technologies*, significant business disruption rarely happens from inside long-established and risk-averse industries.¹¹⁰ In this, the history of SNP is no different from the story of the laptop computer or the mobile phone.

As we have seen, employees in major tobacco companies were aware of Hon Lik's invention. But in the early 2000s, the big American companies remained committed to developing and producing their own products. Partnering with a new electronics industry in China was far outside their comfort zone. Once again, it fell to a few individuals who could see the potential of the new technology – and the potential to reap financial rewards from it – to make things happen.

it fell to a few individuals who could see the potential of the new technology – and the potential to reap financial rewards from it – to make things happen

In the US, a key role was played by patent attorney Mark Weiss. Mark had followed in his father's footsteps in his choice of career; his father had taught Mark and his two brothers to always be looking out for a good idea. The story changes in the telling, but Weiss either saw Hon Lik's device at a trade show in China, or may have been shown it via a contact at Ruyan Technologies back in the US. Weiss tried but could not reach a deal with Ruyan to bring the products to the American market. It did not take long for other manufacturers to begin making products based on Hon Lik's design, so Weiss went elsewhere – and struck a deal to import e-cigarettes into the USA.¹¹¹

In 2007, Weiss set up a company called Sottera with his brothers Craig and Jeff. Sottera started trading imported vaping devices under the brand NJOY. Their King product was a classic early 'e-cigarette'; disposable with a white paper wrapping, a faux filter, and a red 'ember' which lit up when drawn on.¹¹²

Weiss wanted NJOY to be where people were buying cigarettes – in convenience stores, supermarkets and gas stations

Weiss wanted NJOY to be where people were buying cigarettes – in convenience stores, supermarkets and gas stations. At the time, there were no restrictions on where or how vaping products were advertised as long as no health claims were made.

¹⁰⁹ Xu, Y., Song, X., Li, X., Wang, Z., & Zhang, Y. (2022). Research on the Ecological Deconstruction of E-Cigarette Industrial Clusters in Shenzhen, China, and a Niche Analysis of Related Enterprises. *Sustainability*, 14(9), 5606. <https://doi.org/10.3390/su14095606>.

¹¹⁰ Juma, C. (2019). *Innovation and Its Enemies: Why People Resist New Technologies* (Reprint edition). Oxford University Press.

¹¹¹ Website of the Consumer Advocates for Smoke-free Alternatives Association (CASAA). The History of Vaping. (2020). CASAA. <https://casaa.org/education/vaping/historical-timeline-of-electronic-cigarettes/>. The first import ruling locatable in the US Customs and Border Protection website is dated August 2006. US Customs and Border Protection. *M85579: The tariff classification of a nicotine inhaler and parts from China*. (2006, August 22). Customs Rulings Online Search System (CROSS). <https://rulings.cbp.gov/search?term=m85579&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1>.

¹¹² The NPRO-Mini also resembled an early NJOY product. NJOY Review (NPRO Mini)—As good as people say? (n.d.). Retrieved 27 September 2022, from <http://www.electroniccigarettereview.com/njoy-review-npro-mini/>.



NJOY Kings - image from a later product launch in 2012.
Source: Company-supplied image to PR Newswire.

By 2008, NJOY was doing well, earning around £3 million in sales. Then the FDA stepped in and almost killed the industry before it had really got going. Imports from China that were destined for two companies, NJOY and Smoking Everywhere, were seized. The FDA argued that vaping products were drug delivery devices, and so fell under their jurisdiction. In order to continue selling the products, the companies would need to foot the significant bill for stringent pharmaceutical testing.

Both companies sued the FDA; eventually NJOY took on the case alone and won. At the same time, the FDA finally gained control of tobacco products under the Family Smoking Prevention and Tobacco Control Act 2009. However, this excluded vaping products. It took until 2014 for the FDA to issue a set of regulatory proposals, and a further two years before the final ‘deeming regulations’ were published in May 2016. These gave the FDA the authority to regulate any products made of or derived from tobacco and intended for human consumption (for more on how, see Chapter 6).

Meanwhile in Europe, a British businessman, Greg Carson, is credited with introducing what he called the ‘Electro Fag’ in 2005. Interviewed by *The Daily Mail* in July 2007, Carson said he came across the device on the internet and went to China to investigate. “At first, I was highly sceptical [...]. As a non-smoker it was difficult to form an opinion, but I brought some samples back with me. The reaction has been phenomenal. The product might look simple, but the technology is astonishing”. In England, the indoor smoking ban came into force on 1st July 2007; Carson imported 1,500 of what the *Daily Mail* called ‘fake cigarettes’ to beat the ban.

For a brief period, Ruyan itself had a European arm. Ruyan-Europa had a registered office in the UK. One of the directors was Renuit Derler, who knew Professor Bernd Mayer, a toxicologist at the Karl-Franzens University in Graz, Austria. In 2006, Derler approached Mayer. “He came to my office and showed me a small box lettered in Chinese. It turned out to contain a cigar-type electronic cigarette. He asked me for a written expert opinion on the toxicology and potential usefulness of this device for smoking cessation. At that time, I was a heavy smoker and was enthusiastic after the first draw. No surprise, as I had selected the ‘strong’ variant, which contained 60 mg/ml nicotine. I provided him an overwhelmingly positive report for the Austrian authorities and predicted this device would eradicate smoking within the next 15 years.”¹¹³

in Europe, a British businessman, Greg Carson, is credited with introducing what he called the ‘Electro Fag’ in 2005

“I [...] predicted this device would eradicate smoking within the next 15 years”

¹¹³ Professor Mayer. Personal communication.

The advent of vaping products remained a quiet revolution for some years after the first devices arrived in the US

The advent of vaping products remained a quiet revolution for some years after the first devices arrived in the US. Many smokers were reluctant to try them. Companies were not allowed to advertise any health benefits, so their hands were tied as public health agencies and anti-vaping lobbyists had the media landscape to themselves. Even so, the reprieve offered by NJOY's legal success, and the FDA being refused jurisdiction over the industry, gave the embryonic vaping sector time to grow.

The vape industry went down parallel tracks – in store and online. Some companies aimed for the consumers who might be willing to try the product if it was on sale where they bought their cigarettes. This was NJOY's market; their King brand became a market leader across some 70,000 retail outlets. But they did not have the field to themselves. In May 2009, for example, Australian entrepreneur Jason Healy and eleven other investors launched blu. Blu relied heavily on promotion via social media, giveaways, and events sponsorship to build an online brand, before moving into bricks-and-mortar retail. Vaping, it seemed, was here to stay.

This chapter has described a series of steps forward in technology for the safer delivery of nicotine. Sometimes these steps were isolated from one another; some were built on the back of what had come before. But these steps, faltering as they were to begin with, eventually led to Hon Lik's development of the modern vaping device and the creation of a new industrial centre in China, far from the reaches – and the comfort zone – of the traditional tobacco industry.

Consumers were interested in these products; the quiet revolution had begun

Consumers were interested in these products; the quiet revolution had begun. In our next chapter, we explore how consumer interest grew and evolved. We also consider how the tobacco industry, or elements of it at least, responded to the disruption these new products were evidently set to cause.

Chapter 4: Community innovation – and commercial expansion

The emergence of the active consumer

Right from the earliest days of e-cigarettes hitting the market, a buoyant subculture of people who had switched away from smoking and started vaping began to emerge. Some of these people had tried to quit smoking ‘cold turkey’ or with NRT, and had failed; they tried and found success with these new products. But there were also many who became ‘accidental quitters’. They tried vaping one day, stuck with it, and then realised they were no longer smoking.

This is part of the THR story that defeats public health logic. Many users of SNP did not necessarily see smoking as a problem in their lives: they did not always start vaping with the intention of quitting. But e-cigarettes allowed them to carry on consuming nicotine in a way that – crucially – they found more enjoyable than smoking. It was also significantly safer.

First experiences of vaping came from multiple sources; curiosity after a media mention, spotting one when buying cigarettes, an online post, a try-out from a friend. Some people stuck with store-bought cig-a-likes; often, these did not offer enough to replace the smoking experience, and a return to smoking may have followed.

Others went online. They went looking for tips on how to improve their vaping experience, or where to buy the best devices or liquids. Eventually, the more enterprising and enthusiastic vapers set up online forums dedicated to this kind of information exchange. In time, many of the vaping forums would expand, with some going on to attract thousands of members and hundreds of thousands of posts. These online vaping communities would go on to play a significant role – both in the development of the technology they were using, and also in tobacco harm reduction as a whole.

Many vaping forums are still very much alive and well in 2022. Others, including some which played a pivotal role in the early days, have now closed down. Some consumers have shared their memories of the forums with us. However, we do not pretend that the view we offer here is anything other than partial. The following is focused mainly on English-language forums, which were and are host to active and influential consumer populations in the UK, US and elsewhere. But online vaping communities were present and active in other countries and in other languages around the world. So what follows is just a glimpse into the role consumers played.

Some of the best known and most used UK-based vaping forums were Planet of the Vapes (<https://www.planetofthevapes.co.uk/forums/>) and All About E-Cigarettes (<https://allaboute-cigarettes.proboards.com/>), both of which are still active today. UKVapers.org was another influential platform; established in 2012, it closed permanently in February 2022. Another noteworthy site is the US based E-Cigarette Forum, one of the earliest sites, which began life in 2007.

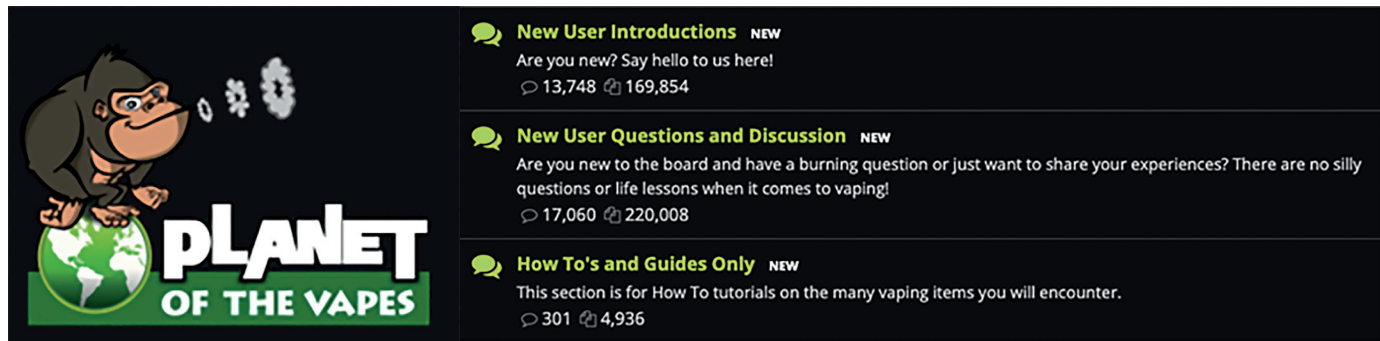
Most forums operate along broadly similar lines; members open threads on a wide variety of vaping-related topics, and receive replies from others, who share their views, experiences, tips, or insights. Some of the most popular and dynamic sections on all

e-cigarettes allowed them to carry on consuming nicotine in a way that – crucially – they found more enjoyable than smoking

These online vaping communities would go on to play a significant role – both in the development of the technology they were using, and also in tobacco harm reduction as a whole

“Since their earliest days, the importance of generous peer-to-peer support has characterised vaping communities

platforms are those aimed at ‘newbies’ – people who have just started vaping and are seeking information and advice. Since their earliest days, the importance of generous peer-to-peer support has characterised vaping communities. This image from Planet of the Vapes gives an insight into the tone of these pages, replicated across all forums, as well as the vast scale of the interactions they invite:



Screenshot from the UK-based Planet of the Vapes vaping forum.

“In the vaping industry’s infancy, only the most agile of manufacturers would survive – competition was fierce, and this made consumers powerful

But these forums did not just host how-to guides for ‘newbie’ vapers, or discussions of the latest products or liquids. Soon, through information posted on various vaping forums, the views, experiences, inventions, and innovations of consumers influenced the products made by the vaping industry itself. In the vaping industry’s infancy, only the most agile of manufacturers would survive – competition was fierce, and this made consumers powerful.

The dawn of the mod

“consumers turned to the forums to find out whether there were ways of modifying products they had already bought

Back when the technology was first available, most vaping devices suffered from a range of shortcomings, including short battery life, weak nicotine delivery, overheating, and leaky cartridges. Some consumers turned to the forums to find out whether there were ways of modifying products they had already bought. And it turned out that there were.

London-based Scott Bonner, who founded E-Cig-Reviews.com, was interviewed for *Engadget* in 2014 about what became known among vapers as ‘modding’. “The very early modders were regular cig-a-like users that were tinkering with their cartridges, experimenting with different wicking materials, removing parts of the atomizer, et cetera, and we would gather on the forum, swap ideas and share our findings”.¹¹⁴

“vapers and manufacturers collectively had an epiphany that would change everything. E-cigarettes don’t need to look like cigarettes”

As described by Mike Huml in *Tobacco Reporter*, soon “vapers and manufacturers collectively had an epiphany that would change everything. E-cigarettes don’t need to look like cigarettes”.¹¹⁵ Innovation was driven by consumer demand – longer-lasting batteries, variable voltage devices, tanks to avoid constant refilling – and also by consumer-led developments. Discussion board members would declare they could build better than what was on offer, and then went away to their sheds or kitchen tables and did it.¹¹⁶

New devices began to appear, soon dubbed ‘mods’. Developed and then sold by their creators, many devices were very sought after. The emergence of the mod was happening not only in the UK and US; other known locations include Italy, France, and the Philippines. Filipino vapers notably produced mods that were of high quality and

¹¹⁴ Grothaus, M. (2014, October 1). *Trading addictions: The inside story of the e-cig modding scene*. Engadget. <https://www.engadget.com/2014-10-01-inside-story-e-cig-modding-uk.html>.

¹¹⁵ Huml, M. (2022). Major milestones. *Tobacco Reporter*, 26–29. <https://tobaccoreporter.com/digital/april22/>.

¹¹⁶ Grothaus, 2014.

that were consequently in high demand. Once the mod took off, the days of the simple cig-a-like were numbered.

Many consider the first true e-cig body mod to be ‘The Screwdriver’, designed by a British father-and-son team, Ted and Matt Rogers, or ‘Trog’ and ‘Mrog’ as they were known online. “We found a really strangely shaped flashlight that might make a good donor for the first Screwdrivers,” said Matt, when interviewed in 2014. “After much tinkering and making of custom parts, the original flashlight housing was turned into an effective e-cig. Physically it rather resembled a screwdriver, and so the name stuck”. The resulting device allowed the user to vape for longer in between charges, as the torch body contained a higher-capacity battery than any cig-a-like then on the market. Once images of the Screwdriver were shared on forums, other vapers wanted them – so the Rogers began making them for sale.¹¹⁷



Still from GrimmGreen's review of the Screwdriver, YouTube, March 2009. Source: <https://www.youtube.com/watch?v=tcukaPFTUKA>



Vaping box mod and tank. DedMityay on Depositphotos

Other shapes and styles of vape began to emerge. For example, one UK-based vaper, Larry Ross, was inspired by the Screwdriver's success to try to increase the length of time between e-liquid refills, by enlarging the tank. He did this by developing a box-shaped device. Ross was not the only one to end up with a boxier design, and soon, ‘box mods’, as they became known, became phenomenally successful among the vaping community, as they allowed for both a longer-lasting battery and a larger tank.¹¹⁸ This type of device remains a popular choice for vapers today.



A Provari vape mod. Source: GSTHR.



A mechanical vape mod. Source: GSTHR.

“Once images of the Screwdriver were shared on forums, other vapers wanted them”

“‘box mods’, as they became known, became phenomenally successful among the vaping community”

¹¹⁷ Ibid.

¹¹⁸ Rising Vapors: The Vape Pen's Incredible Journey from Garden Shed to Fashion Runway. (2016, February 26). *Electric Tobacconist*. <https://www.electrictobacconist.com/blog/2016/02/rising-vapors-the-vape-pens-incredible-journey-from-garden-shed-to-fashion-runway/>.

“**Flavours were and remain a critical part of the vaping experience**”

“**In the developing Shenzhen e-cigarette industry, the efforts of the modders did not go unnoticed**”

“**the community encouraged competition between manufacturers and assured a diversity of supply**”

Numerous other device types and features came about as a result of the work of modders. These include tube mods, such as the Provari and Vamo, and ‘squonkers’, which use a built-in squeeze bottle to feed the e-liquid to the atomiser. *Vaping360* traces the origins of squonking to 2009 and the handmade Juice Box made by E-Cigarette Forum user ‘TheCarlos49’.¹¹⁹

As well as the devices themselves, consumers also experimented with mixing their own e-liquids and creating their own flavours. Flavour experimentation became a cottage industry in its own right. Flavours were and remain a critical part of the vaping experience. Some former smokers wanted the memory of tobacco in the flavours they used, although for others, the liquids on offer did not replicate the taste. Others did not want reminders of cigarettes, but something completely different instead. Many vapers would report that flavours made nicotine use enjoyable – some may see flavours as instrumental in their switch from smoking, and others may simply value the pleasure they gain from using them.

In the developing Shenzhen e-cigarette industry, the efforts of the modders did not go unnoticed. The information that consumers were posting on forums permitted manufacturers to watch what was happening in real time, and to understand where their consumers’ interests lay. There were pages on some websites and dedicated areas on forums that enabled direct interaction between manufacturers, vendors and consumers. This was not simply for the sales and marketing of products, but permitted targeted market research and two-way communication.¹²⁰

Vapers led on some standardisation developments, too. Recognising that a standard way to connect batteries to cartomisers would be beneficial to both the production and use of vaping devices, members of the vaping community adopted a particular (screw) thread size, the 510. This had been in use on a Joyetech cig-a-like since late 2008. By promoting the use of this standard, the community encouraged competition between manufacturers and assured a diversity of supply. Many companies responded by producing battery devices and refillable cartomisers that used the 510 thread.¹²¹



A 510 thread battery.

Source: <https://o2vape.com/product/vape-pen-battery-button/>

¹¹⁹ Best Squonk Mods 2022. What is a squonk mod and what is squonking? (2022, June 8). *Vaping360*. <https://vaping360.com/best-vape-mods/squonk-mods/>.

¹²⁰ For example, *Which cartomisers do you like most?* (2011). All About E-Cigarettes UK. <https://allaboute-cigarettes.proboards.com/thread/9839/which-cartomisers-most>.

¹²¹ Morris, J., & Khan, A. U. (2016). *The Vapour Revolution: How Bottom-Up Innovation Is Saving Lives* [Working Paper]. Reason Foundation. https://reason.org/wp-content/uploads/files/vapour_revolution_working_paper.pdf.

Dr Attila Danko, a leading consumer advocate and one-time president of the New Nicotine Alliance Australia, has no doubt that the role of vapers was crucial:

“From 2012 to 2014 vaping was taking off at an exponential rate worldwide. A community of underground hardware hacking pioneers had already been working for years to improve the early e-cigarettes. Using their distributed intelligence, they connected through Internet forums freely, just like open source software developers, but their work was creating open source, unpatented nicotine delivery systems. They tinkered in their sheds to increase the power, capacity and e-liquid delivery [...] Their inventions were adopted by new nimble Chinese e-cigarette companies who started mass producing the devices and millions of smokers began using them.”¹²²

“they connected through Internet forums freely, just like open source software developers, but their work was creating open source, unpatented nicotine delivery systems”

Communities begin to coalesce

While consumer-led technological developments were being shared online, vapers also began to meet in real life. Small gatherings were held in pubs and cafés; in 2010, both the UK and the US saw the arrival of ‘VapeFest’ events, with other regular large vape meets soon joining the calendar. Numerous annual vaping expos, trade shows and festivals now take place around the world.

While consumer-led technological developments were being shared online, vapers also began to meet in real life

The community element was very important. People had left behind – or were trying to – more than just cigarettes. The social and ritualistic aspects of smoking had gone too. As smokefree workplaces and venues became more common, people who smoked had been left huddled in the wind and rain outside. Now vapers could meet, often indoors, with like-minded people, exchanging information about devices and liquids. Vaping took on a ‘hobbyist’ quality for some.

Online forums continued offering valuable advice, product reviews and news about the wider vaping business. Some also discussed and debated various proposals for regulatory changes which could change or potentially inhibit access to certain products, as well as ways the community felt vaping was misrepresented in media coverage.

In the UK in 2010, the Medicines and Healthcare Products Regulatory Agency (MHRA) opened a consultation on “whether and how to bring unlicensed nicotine containing products, such as electronic cigarettes, within the medicines licensing regime”.¹²³ Many vapers were concerned that the UK government was about to make it difficult for them to access their preferred products, which many saw as essential in helping them remain free of smoking. An All About E-Cigarettes member who went under the name ‘Lolli’ published this poem on the forum in response:

vapers were concerned that the UK government was about to make it difficult for them to access their preferred products, which many saw as essential in helping them remain free of smoking

*Oh PLEASE Mr Government, don't ban our e cigs now
The reasons you are giving are all nonsense anyhow!
We interfere with no one! Want our freedom, just to vape
We're not polluting anywhere! That fact you can't escape!
It's just a little metal tube, with cartridge at the end
The liquid we put into it, we strongly do defend!
It's nicotine, PG, VG and flavouring (a lot!)
They're all in use elsewhere you know! You must've lost the plot!*

¹²² Danko, A. (2018, April 3). How Tobacco Control Saved Big Tobacco. *Vaping360*. <https://vaping360.com/vape-news/64430/attila-danko-tobacco-control/>.

¹²³ *Electronic Cigarettes. Volume 508: Debated on Wednesday 7 April 2010*. (2010, April 7). Hansard – UK Parliament. <https://hansard.parliament.uk/commons/2010-04-07/debates/10040762000014/ElectronicCigarettes>.

*It doesn't give us cancer or any smoke disease
So burdens on your N H S,
it will surely ease?*

*It doesn't give us cancer or any smoke disease
So burdens on your N H S, it will surely ease?
It helps to stop us smoking the tobacco cigarette
Where other stuff has failed us! – like “Inhaler Nicorette”
Tobacco firms have loads of dosh! The Pharm' boys have lots too!
But, putting us at risk for them? – It simply will not do!!!
Four thousand noxious substances in cigarettes on sale!
Fine, for those that choose them, “the tobacco coffin nail”
We live in a Democracy! We want our right to choose!
So, if our e cigs stay on sale, then nobody will lose!
So, PLEASE Mr Government, let our e cigs stay...
ON SALE – or – we'll smoke again! You leave no other way!¹²⁴*

It was becoming clear that vaping communities would mobilise to advocate for their right to continue accessing products that they felt were benefiting them

Encouraged by fellow site members, 'Lolli' submitted the poem to the MHRA's public consultation. It was becoming clear that vaping communities would mobilise to advocate for their right to continue accessing products that they felt were benefiting them. As noted in the Foreword to this report, vaping and wider SNP advocacy would see people banding together to protect their right to use consumer products in the service of public health in ways that may be unprecedented. For more on the development and role of consumer advocacy in THR, see Chapter 7: The right to choose and the right to use.

Eyes off the ball



The tobacco industry was not prepared for the emergence of safer nicotine products.
Source: Edited photo from depositphotos

Until around 2012, the major tobacco companies had no skin in the new products game, nor did they show much interest in entering it

Until around 2012, the major tobacco companies had no skin in the new products game, nor did they show much interest in entering it. Smokeless products held an interest, given their long tradition in US markets; Gallaghers (now JTI) bought the Swedish firm Gustavus, and Reynolds bought Swedish NRT company Nicovum. In 2009, Swedish Match signed a partnership deal with Philip Morris International (PMI) to grow global sales of snus, but sales were slower than anticipated and the joint venture was dissolved in 2015 – although at the time of writing, PMI and Swedish Match are in ongoing merger talks.¹²⁵ And in 2010, BAT set up Nicoventures to develop new

¹²⁴ *Oh Please Mr Government!!!* (2010, March 20). All About E-Cigarettes UK. <https://allaboute-cigarettes.proboards.com/thread/1115/oh-government>.

¹²⁵ Mannes, M., Naidu, R., Mannes, M., & Naidu, R. (2022, September 29). Philip Morris not planning to drop \$16 bln Swedish Match bid—CEO. *Reuters*. <https://www.reuters.com/markets/deals/philip-morris-not-planning-drop-swedish-match-bid-ceo-2022-09-28/>.

products. But in the end, it was one of the oldest US companies, Lorillard, founded in 1760, that made established companies sit up and take new generation products seriously.

Perhaps unsurprisingly, the top brass at Lorillard were traditional in their outlook. There is no evidence that the company had shown any interest in the non-combustible experiments of their rivals. That changed with the appointment of Murray Kessler in 2009. Described as ‘a visionary’ by a former Lorillard staffer, Kessler had been CEO at UST, a leading US smokeless tobacco company. When UST was bought out by Altria in 2009, he moved on to take the position as CEO at Lorillard.

Kessler could see that e-cigarettes had to be part of the tobacco industry’s future, but instead of trying to reinvent the wheel, in 2012 he simply bought out blu for £135m, much to the astonishment of other companies. Of course, the wheels of business never stop turning; Lorillard itself was taken over by Reynolds the following year.

As Reynolds had already developed a vape product, Vuse, it sold the blu brand to Imperial. Imperial established a new company arm, Fontem Ventures, to develop its own next generation products. Not to be left behind, Altria (formerly Philip Morris) brought the MarkTen vape to market in 2013 – the same year that BAT launched Vype.

NJOY, one of the original players on the vape market, now had multiple rivals in the convenience stores. It found it increasingly hard to compete, and suffered for its pioneering role. NJOY’s disposables were more expensive than newer rechargeable devices. The company was too slow to recognise the importance of flavours, and was still saddled with crippling debt due to the successful FDA legal challenge back in 2009. The company tried to revive its fortunes with the King 2.0, but it was not enough, and the company filed for bankruptcy in 2016. But thanks to a significant injection of capital equity from an investment firm specialising in corporate turnarounds, NJOY rose from the ashes in 2017 and is still operating in 2022.¹²⁶

A pinch of salt

Yet even with all the new products available, the industry still had not generated the kind of breakthrough product that could catch the public imagination and take vaping to the next level. Then, out of the San Francisco-based tech scene, a new company entered the market.

JUUL launched in 2015. Suddenly, vaping became big news – and not always for the right reasons. The company offered a single device. Marketed to be discreet, with a sleek design, it was easy to use and delivered sufficient nicotine strength and throat hit for adult smokers, in a variety of flavours in interchangeable, disposable pods.

More has been written about JUUL than any other SNP company. To date, there have been at least two full-length journalistic accounts and many thousands of column inches, news packages and documentaries covering the company’s rise (and fall).¹²⁷ For the purposes of this report, the most interesting thing about JUUL is not necessarily the product’s looks, or its damaging marketing missteps and the associated controversy. It was JUUL’s popularisation of nicotine salts e-liquid.

“the industry still had not generated the kind of breakthrough product that could catch the public imagination

“More has been written about JUUL than any other SNP company

¹²⁶ McDonald, J. (2017, February 27). NJOY is Back From Bankruptcy. *Vaping360*. <https://vaping360.com/vape-news/44289/njoy-back-in-business/>.

¹²⁷ Ducharme, 2022; Etter, 2021.



A JUUL device, with charger and flavour pods.

Source: Wikimedia Commons. Author: FairExpert. Published under the Creative Commons Attribution-Share Alike 4.0 International license https://commons.wikimedia.org/wiki/File:Electronic_cigarette.jpg

By 2015, the founders of JUUL Labs, James Monsees and Adam Bowen, had launched prototype vapes that failed when they entered the market. Their experience taught them that adult smokers who were looking to switch or try out vaping often gave it up. Common reasons included that the nicotine strength could not compete with a cigarette, while the throat hit of conventional e-liquid was too harsh.

Reynolds was already using nicotine salts in its Vuse product. As early as 1978, company scientist Thomas Perfetti had been intrigued that nicotine evaporated quickly, except on the leaves of the tobacco plant itself. Perfetti determined that it was the acids in the plant that stabilized nicotine.¹²⁸ What resulted was freebase nicotine plus acid, or nicotine salts. When used in e-liquids, nicotine salts were more stable and could be kept longer. The salt variety also enhanced the flavours and produced a smoother throat hit. The vaper could inhale more nicotine for a sensation very close to a cigarette. Monsees and Bowen adopted nicotine salts for their new product, and JUUL was born.

JUUL Labs started life in Silicon Valley. Just three years after it launched, JUUL was the dominant player, topping out at over 70% of the \$6.6 billion vaping market in 2018.¹²⁹ And on 19th December 2018, tobacco company Altria offered \$12 billion for a 35% share.¹³⁰ But the company suffered fallout from the spate of THC e-liquid related lung injuries in 2019 and its impact (for more on this, see Chapter 5). JUUL was further dogged by scandal relating to poor marketing decisions early on, which ultimately resulted in the withdrawal of flavours. It has faced a mountain of litigation – much of which is still pending – plus aggressive pricing by Vuse, its nearest competitor. By 2021, the company was in survival mode. Market share had fallen back to 38%, with Vuse only 4% behind.¹³¹ At the time of writing, JUUL has active lawsuits pending against the FDA, following a marketing denial order against JUUL products.^{132 133}

¹²⁸ Ducharme, 2022, p. 43.

¹²⁹ Becker, R. (2018, November 21). *Juul's nicotine salts are dominating the market—And other companies want in*. The Verge. <https://www.theverge.com/2018/11/21/18105969/juul-vaping-nicotine-salts-electronic-cigarettes-myblu-vuse-markten>.

¹³⁰ Levy, D. T., Sweanor, D., Sanchez-Romero, L. M., O'Connor, R., Goniewicz, M. L., & Borland, R. (2020). Altria-Juul Labs deal: Why did it occur and what does it mean for the US nicotine delivery product market. *Tobacco Control*, 29(e1), e171–e174. <https://doi.org/10.1136/tobaccocontrol-2019-055081>.

¹³¹ Vuse Quickly Narrowing Market Share Gap With Juul. (2021, December 16). *Vapor Voice*. <https://vaporvoice.net/2021/12/16/vuse-quickly-narrowing-market-share-gap-with-juul/>.

¹³² Office of the Commissioner. (2022, July 5). *FDA Denies Authorization to Market JUUL Products*. FDA; FDA. <https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products>.

¹³³ Florco, N. (2022, September 29). Juul exec slams FDA over its approach to regulating vaping. *STAT*. <https://www.statnews.com/2022/09/29/juul-exec-slams-fda-over-its-approach-to-regulating-vaping/>.

Shenzhen: always there in the background

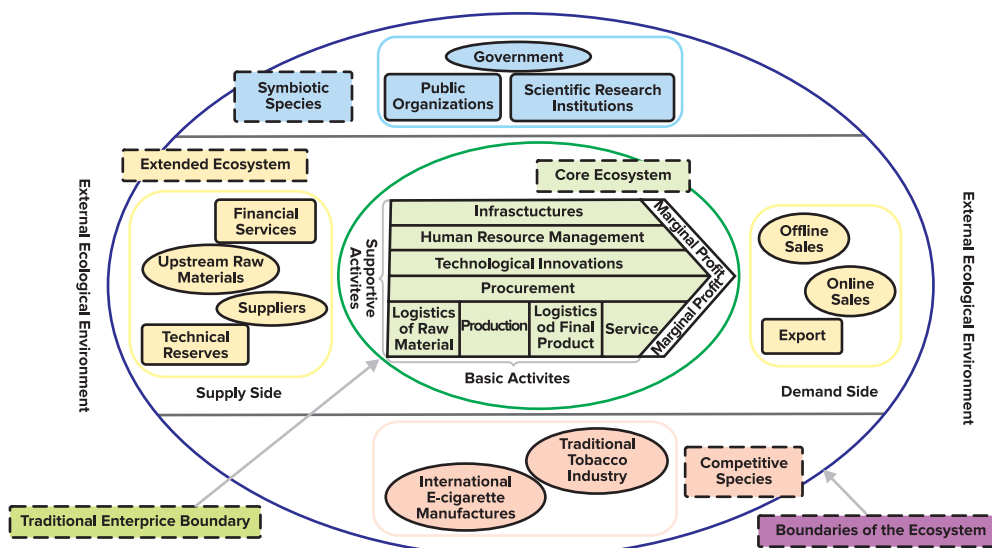
In 2022, most of the major international tobacco company players are, with varying levels of commitment and resources, now in the SNP market. Their involvement has attracted legitimate scrutiny. It has also caused some to dismiss the harm reduction potential offered by SNP. Paradoxically, this does little other than protect the market for combustible tobacco.

While the traditional tobacco industry prevaricated, the vaping industry in Shenzhen was quietly going about its work. China still plays an enormous, if perhaps largely unrecognised, role in the market. While many of the first e-cigarette manufacturing companies did not survive, others have grown to become multimillion dollar corporations as the global vaping consumer base has increased. Today, it is estimated that China's vaping industry accounts for close to 90% of global production.¹³⁴

Today, the number of e-cigarette manufacturing and brand enterprises in China stands at around 1,500. They are estimated to employ 1.5 million people. There are also 100,000 e-cigarette supply chain and merchandise service businesses, employing in the region of 4 million people.¹³⁵ In June 2022, the value of Chinese e-cigarette exports in 2021 was estimated to be CNY138.3 billion (\$19.4 billion). Roughly 60% of exported products are destined for the US, and 25% to the EU and Britain.

While the traditional tobacco industry prevaricated, the vaping industry in Shenzhen was quietly going about its work

it is estimated that China's vaping industry accounts for close to 90% of global production



Research on the Ecological Deconstruction of E-Cigarette Industrial Clusters in Shenzhen, China, and a Niche Analysis of Related Enterprises. Sustainability. 2022, 14, 5606. <https://doi.org/10.3390/su1>

A 2022 study from Yanmei Xu, Xia Song et al at Beijing's University of Chinese Academy of Sciences considers the development and current status of the Shenzhen e-cigarette industry, concluding it is currently in a rapid development phase. The 'business ecosystem' they identify has four components, as identified on the diagram reproduced above. Under this analysis, traditional tobacco companies and international e-cigarette manufacturers are both viewed as 'competitive species':

"Traditional tobacco enterprises have cultivated a large and fixed consumer population after years of tobacco sales. The price advantage, high consumer

traditional tobacco companies and international e-cigarette manufacturers are both viewed as 'competitive species'

¹³⁴ MacKenzie, R., Fang, J., & Smith, J. (2020, May 19). *China's e-cigarette manufacturers facing uncertain future*. Blog - Tobacco Control. <https://blogs.bmj.com/tc/2020/05/19/chinas-e-cigarette-manufacturers-facing-uncertain-future/>.

¹³⁵ China E-Cigarette Exports to Exceed \$27 Billion. (2022, June 16). *Tobacco Reporter*. <https://tobaccoreporter.com/2022/06/16/china-e-cigarette-exports-to-exceed-27-billion/>.

*acceptance, and high market saturation of traditional tobacco products make it difficult for the market entrance and expansion of e-cigarette enterprises. In addition, Philip Morris International, British American Tobacco, Japan Tobacco, Imperial Tobacco, and other multinational tobacco companies have significantly developed in the e-cigarette area, making the international e-cigarette market increasingly competitive”.*¹³⁶

Will the Chinese vaping industry find itself at risk of disruption as major tobacco company players increase their stake in the market?

Will the Chinese vaping industry find itself at risk of disruption as major tobacco company players increase their stake in the market? Only time will tell. It may face disruption at home, as well. In April 2022, the Chinese government announced a significant new regulatory package, set to affect vaping devices sold on the domestic market and those made for export. It remains to be seen what impact the new domestic regulations will have on the industry when they come into force in October 2022.¹³⁷

In this chapter, we have seen how technological advances in the manufacture of vaping products – some of them consumer-led – solved many of the problems that caused initial consumer resistance and poor sales. Fortunes were made, and lost. Meanwhile, communities of vaping consumers were developing, and the quiet revolution was publicly becoming very loud.

where they are available and accessible, the emergence of novel nicotine delivery systems has had a dramatic impact, disrupting combustible cigarette sales and bringing reductions in smoking rates

As we shall see, these innovations in the safer delivery of nicotine have brought profound benefits. Over time, snus use in Sweden and Norway has resulted in some of the lowest smoking prevalence rates in the world. Similarly, where they are available and accessible, the emergence of novel nicotine delivery systems has had a dramatic impact, disrupting combustible cigarette sales and bringing reductions in smoking rates. In Japan, competition from heated tobacco products has seen an accelerated five-fold decline in cigarette sales since 2016.¹³⁸ In the UK, a regulatory and policy environment in favour of vaping for smoking cessation has seen an increase in vaping matched by a continuing major reduction in smoking, with under 15 per cent of the adult population currently using combustible tobacco.¹³⁹ The GSTHR estimates that in 2021 there were 82 million vapers worldwide, with a further 20 million using heated tobacco products and 10 million using snus and other smokeless products – a total of 112 million safer nicotine product users around the world.¹⁴⁰

The next chapter looks at how the evidence base in favour of safer nicotine products developed alongside product innovation. It also considers how tactics that are more commonly associated with the deceptions of Big Tobacco in the 1950s are now being used to undermine that evidence.

¹³⁶ Xu, Song, Li, Wang, & Zhang, 2022.

¹³⁷ Keller and Heckman LLP. (2022, August 23). *A Closer Look at China's New E-Cigarette Regulations*. Lexology. <https://www.lexology.com/library/detail.aspx?g=39bbbb46-de94-4b30-99c5-ce5119665695>.

¹³⁸ Cummings, K. M., Nahhas, G. J., & Sweanor, D. T. (2020). What Is Accounting for the Rapid Decline in Cigarette Sales in Japan? *International Journal of Environmental Research and Public Health*, 17(10), 3570. <https://doi.org/10.3390/ijerph17103570>.

¹³⁹ *The UK and tobacco: Successful elements of a harm reduction strategy and the chance to influence the international response to smoking* (GSTHR Briefing Papers). (2021). Global State of Tobacco Harm Reduction. <https://gsthr.org/briefing-papers/august-2021/>.

¹⁴⁰ Global State of Tobacco Harm Reduction, 2022a.

Chapter 5: ‘Fear, Uncertainty and Doubt’

The phrase ‘fear, uncertainty and doubt’ – often shortened to ‘FUD’ – emerged in the mid-1970s to describe a tactic in marketing, sales, and public relations. It is a strategy that uses the propagation of negative or even false information in order to shape people’s beliefs and to play on their fears.

FUD has been especially prevalent in the tech sector, as companies warn of the dangers of switching to rival (usually newer) products. Companies selling security software often promote dire warnings of malware and viruses, for example, to encourage those who are responsible for essential infrastructures to employ expensive security consultants. One classic example is the millions spent by companies to protect against the so-called ‘Millennium Bug’, a cataclysmic computer-induced disaster that simply never materialised.



The ‘Millennium Bug’ never appeared.
Credit: Photo by Vincent Botta on Unsplash.

There is also *disinformation*. A tech giant announces a new product with no intention of releasing it yet, if at all. The idea is to frighten smaller rivals to stop pursuing their own version of the product, for fear of being blown out of the water by the much bigger company. Interestingly, this technique is known as ‘vaporising’, as the announced product vanishes into thin air.

It is clear that the tobacco industry has employed fear and uncertainty many times during the course of its history. But the emergence of safer nicotine products and the development of tobacco harm reduction has also been plagued by the use of a strategy of fear, uncertainty, and doubt over the safety of SNP, their ability to help smokers switch away from smoking, and the potential risks to young people. And this time, the proponents of it include some of the most trusted global health institutions and organisations.

As public awareness and the use of new products started to grow, there was understandable uncertainty and doubt among tobacco researchers, not least because of their perceived links with the tobacco industry. Alongside *doubt*, there was also

“‘fear, uncertainty and doubt’ [...] is a strategy that uses the propagation of negative or even false information in order to shape people’s beliefs and to play on their fears

“the tobacco industry has employed fear and uncertainty many times during the course of its history

“the emergence of safer nicotine products and the development of tobacco harm reduction has also been plagued by the use of a strategy of fear, uncertainty, and doubt

there has been disinformation about SNP from otherwise credible sources

numerous surveys from around the world...show increasing numbers of people believe that vaping is as, or even more, dangerous than smoking

disruption. Within the public health community, the narrative about the dangers of smoking was clear and had been so for decades. It is a narrative that lends itself to unambiguous public messaging. But the new products raised the prospect of a challenge to the narrative, as evidence grew that people could continue to consume nicotine with substantially less risk, both to their health and to bystanders.

And then there has been *disinformation* about SNP from otherwise credible sources like the WHO, the Campaign for Tobacco-Free Kids, and a host of government agencies, NGOs and individuals. Collectively they have promoted the idea that the new products are dangerous, and part of a 'Big Tobacco plot' to 'hook kids on nicotine' in the face of falling teen smoking. The result has been fear, uncertainty and doubt among smokers, health professionals, and policymakers. The impact can be seen in numerous surveys from around the world which show increasing numbers of people believe that vaping is as, or even more, dangerous than smoking and that nicotine causes cancer.

It is notable that earlier developments of THR products, such as nicotine patches, gums and lozenges, did not elicit the same kind of response, instead receiving support from doctors or public health academics. Not only were these products non-combustible, they were also manufactured by pharmaceutical companies, approved and regulated by government medical agencies, and initially available only on prescription, before being accessible over the counter at pharmacies.

Beyond those produced by the pharmaceutical industry, there was near total opposition to the use of all other nicotine-containing products in the context of reducing harm. An exception was Professor Brad Rodu, who – with colleagues – made the public health case for smokeless tobacco as a means for adult smokers to continue consuming nicotine at reduced risk outside of a medical context. This did not play well with the wider health community.¹⁴¹



Brad Rodu appeared on CBC's Good Morning America in June 1994 to discuss the harm reduction potential of smokeless tobacco.

Source: Brad Rodu's GFN Presentation 2022 ref. 141

The right to change your mind

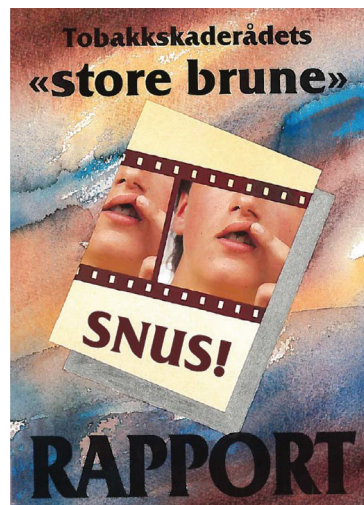
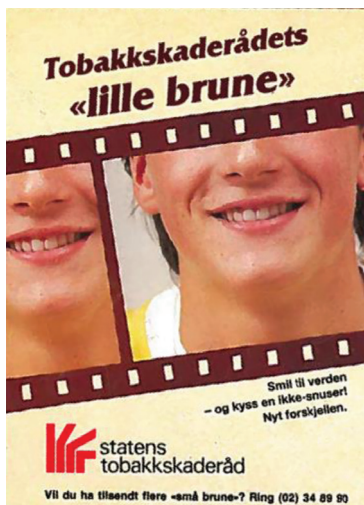
There was genuine FUD, or at least uncertainty and doubt, among respected academics and public health workers about the validity of commercial products to aid cessation or reduce harm. After reviewing the evidence, many subsequently became champions for the approach we now know as tobacco harm reduction. It is worth exploring how some of those who now advocate most strongly for the adoption of SNP

¹⁴¹ Professor Brad Rodu spoke about his experiences arguing the public health case for smokeless tobacco in two videos prepared for the Global Forum on Nicotine 2022. Both detail the opposition he faced. Rodu, B. (2022a, June 16). *Introductory video for panel session at the Global Forum on Nicotine 2022* [KAC-Communications]. Global Forum on Nicotine 2022 - 16-18 June. <https://gfn.events/programme/global-forum-nicotine-2022/youtube/MPUfyFokpAc>; (2022b, June 16). *U.S. Tobacco Harm Reduction Opposition—Déjà Vu and Nothing New Since 1994* [KAC-Communications, GFN Fives]. Global Forum on Nicotine 2022 - 16-18 June. <https://gfn.events/videos/117/us-tobacco-harm-reduction-opposition-deja-vu-and-nothing-new-since-1994>.

for smoking cessation reacted to the changing tobacco environment as it related to both existing and new products.

In 1986, Dr Karl Erik-Lund was appointed as a part-time researcher at the Norwegian Council on Tobacco and Health. In his capacity as a public health communicator, he produced a booklet and a report in which, by his own admission, he wrote ‘caring lies’ about snus. The product, it claimed, was toxic, possibly had a gateway effect, was linked to cancer and heart conditions, and delayed cessation. The text was accompanied by frightening photographs of oral disease – although in truth, the images actually depicted US consumers of more dangerous products.¹⁴² The Council felt obliged to act based on the ‘worst case scenario’, and it did so in order to protect children and young people. But this was in the absence of the robust evidence that was yet to emerge.

In [Dr Karl Erik-Lund’s] capacity as a public health communicator, he produced a booklet and a report in which, by his own admission, he wrote ‘caring lies’ about snus



The ‘Lille brunne’ leaflet (left) and ‘Store brunne’ report (right) about snus, from 1989. Source: Ref. 142

Dr Lars Ramström has gone on to become a strong advocate of snus from a harm reduction perspective, as we saw in Chapter 2. In 1990, however, while Director of Sweden’s National Smoking and Health Association, he issued this warning about another alternative product, snuff (Swedish snus): “The use of snuff is no prerequisite and no guarantee for a decrease of smoking. On the contrary, taking up snuff must be seen as an introduction to the tobacco habit and possibly a first step towards taking up cigarettes.”¹⁴³

However, by the early 2000s, Dr Ramström and Swedish colleague Dr Karl Fagerström were publishing research about snus that contradicted everything Ramström had believed in 1990 and the information that Lund had been promoting a little over a decade before. Based on the evidence, Lund rethought everything about snus.¹⁴⁴

Based on the evidence, Lund rethought everything about snus

In 2010, in the US, Professor David Abrams and colleagues wrote an editorial for the American Journal of Public Health.¹⁴⁵ The authors all worked for the Schroeder Institute for Tobacco Research and Policy Studies, part of the Legacy Foundation that had been paid for by the tobacco industry as one of the conditions of the Master Settlement Agreement.

¹⁴² Lund, K. E. (2018). *The long-time Scandinavian experience with snus – tobacco harm reduction in the real world*. Slide 15. E-Cigarette Summit, UK. <https://www.e-cigarette-summit.co.uk/wp-content/uploads/sites/82/2018/11/9.45-karl-lund.pdf>.

¹⁴³ Nordgren, P., & Ramström, L. (1990). Moist snuff in Sweden—Tradition and evolution. *British Journal of Addiction*, 85(9), 1107–1112. <https://doi.org/10.1111/j.1360-0443.1990.tb03435.x>.

¹⁴⁴ For example, both were co-authors of the paper by Foulds, J., Ramstrom, L., Burke, M., & Fagerstrom, K. (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control*, 12(4), 349–359. <https://doi.org/10.1136/tc.12.4.349>.

¹⁴⁵ Cobb, N. K., Byron, M. J., Abrams, D. B., & Shields, P. G. (2010). Novel nicotine delivery systems and public health: The rise of the ‘e-cigarette’. *American Journal of Public Health*, 100(12), 2340–2342. <https://doi.org/10.2105/AJPH.2010.199281>.



Portioned snus 'General' brand.

Credit: By Alekos on Wikimedia Commons, licensed under the Creative Commons Attribution-Share Alike 3.0 Unported license.

Abrams and his colleagues were the first researchers in America outside the Food and Drug Administration (FDA) to test e-cigarettes in the laboratory. Like all public health professionals in the field, they had been blindsided by the new products. The last section of their editorial neatly sums up the anxious climate of the period, but crucially also acknowledges the possibility that science could give these products a relatively clean bill of health:

“The ENDS [Electronic Nicotine Delivery Systems] tested so far have demonstrated poor quality control of toxic contaminants, albeit at low levels; misrepresentation of the nicotine delivered; and insufficient evidence of overall public health benefit. Ongoing, rigorous safety testing is needed, including determining real-world use patterns and further laboratory testing across device constructions to determine actual systemic nicotine delivery and exposure to harmful constituents.

“We recognize a manufacturer’s desire to market their product and advocates who say ENDS are logically safer than cigarettes. However, to allow their unregulated sale on presumption is not protecting public health. ENDS should be removed from the market and permitted back only if and when it has been demonstrated that they are safe, that their benefits outweigh their



Independent scientists and researchers began assessing e-cigarettes and nicotine liquids.
Source: HIRAMAN on iStockphoto

*harms to overall public health, and that a comprehensive regulatory structure has been established under an appropriate FDA division. It is possible that ENDS-like devices will eventually provide safer alternatives to smoking that do not increase youth uptake, that foster cessation, and that are less harmful or addictive than cigarettes. Until then, health and safety claims based on assumptions are unacceptable.*¹⁴⁶

Abrams' road to a 'scientific Damascus' can be tracked through publications in public health journals in subsequent years.¹⁴⁷ It is worth noting, however, that while Abrams and his colleagues at the Schroeder Institute moved away from initial scepticism of harm reduction to a more positive view based on the emerging evidence, the organisation they worked for went in the opposite direction.

From its inception in 2008 to 2016, the Schroeder Institute for Tobacco Research conducted science-based research and published systematic reviews and commentaries. In 2015, the Institute sent a letter and a literature review to the FDA, reflecting the best science at the time in support of THR. Then came a change of leadership and a change of name to the Truth Initiative. This heralded a significant shift in the organisation's stance towards a strongly prohibitionist line on nicotine vaping and other safer nicotine products, with little room left for the possibilities that THR offered for adults who smoked. By that time, Professor Abrams and other like-minded colleagues had left.

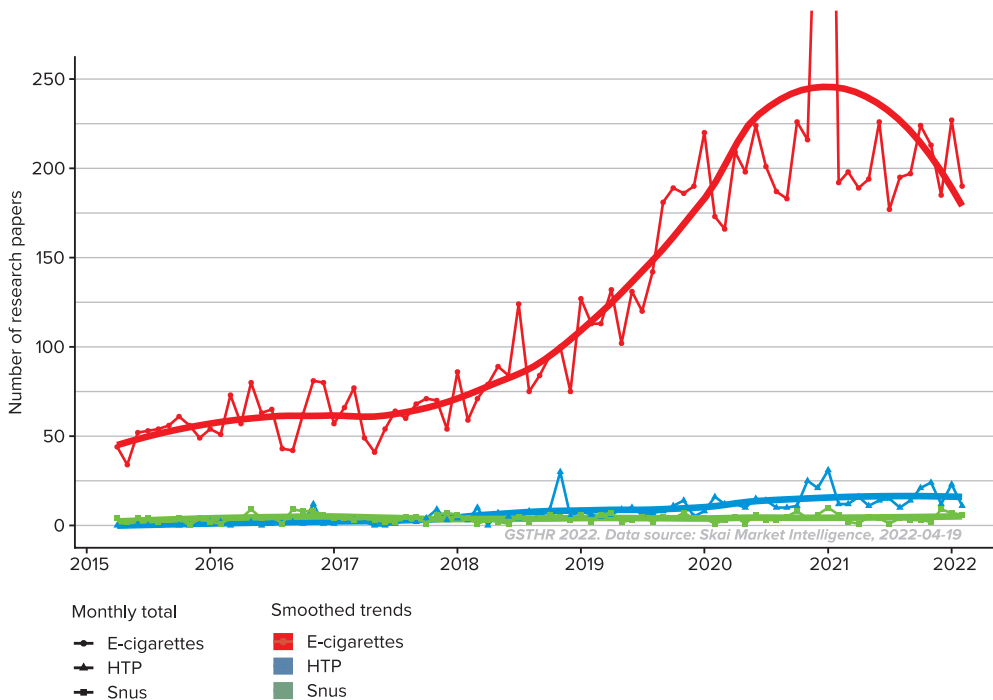
while Abrams and his colleagues at the Schroeder Institute moved away from initial scepticism of harm reduction to a more positive view based on the emerging evidence, the organisation they worked for went in the opposite direction

A new research field

As the chart below shows, the numbers of academic papers on vaping far exceed those researching smokeless or heated tobacco products. So the rest of this chapter focuses on the tobacco research community's response to vaping.

the numbers of academic papers on vaping far exceed those researching smokeless or heated tobacco products

Monthly number of research papers on EC, HTP and Snus



¹⁴⁶ Ibid.

¹⁴⁷ By 2018, he was the lead author on an Annual Review paper for the *American Review of Public Health* titled, 'Harm minimization and tobacco control: reframing societal views of nicotine use to rapidly save lives. Abrams, D. B., Glasser, A. M., Pearson, J. L., Villanti, A. C., Collins, L. K., & Niaura, R. S. (2018). Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annual Review of Public Health*, 39(1), 193–213. <https://doi.org/10.1146/annurev-publhealth-040617-013849>.

As the evidence in favour of vaping as a safer alternative to smoking gained momentum from 2015 onwards, the mist of uncertainty and doubt among many tobacco researchers began to clear. Importantly, the principle of relative risk was established. Two major evidence reviews were published in the UK. In 2015, Public Health England (whose function has now been incorporated into the Office for Health Improvement and Disparities) released an evidence review which included the oft-quoted statement that e-cigarettes were at least 95% safer than cigarettes.¹⁴⁸ Subsequent updates have continued to confirm the original relative risk statement. And, in 2016, the UK's Royal College of Physicians published *Nicotine without smoke: tobacco harm reduction* which stated:

*“Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure. [...] E-cigarettes are effective in helping people to stop smoking”.*¹⁴⁹

Other reviews of the evidence have supported the principle of THR, although some have remained hesitant to fully endorse it. This reluctance is grounded, at least in part, in the ‘precautionary principle’, a broad, epistemological approach to innovations, which is defined by the European Commission thus:

*“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically”.*¹⁵⁰

An over-interpretation of the precautionary principle by many who argue against THR demands that no progress be made towards the adoption of the approach unless and until everything is known about the possible risks of SNP. The argument is frequently made – which appeals to many outside the field – that decades passed for the true damage of smoking to be revealed. But there is a simple refutation to this argument. The science that is available today to understand, determine, and quantify potential health risks associated with SNP simply did not exist for cigarettes half a century ago.

It is also worth making the point that while we do not know everything, we do now know a lot: the evidence shows that in comparison to combustible cigarettes, SNP are substantially safer. As applies across all ‘harm reduction’ interventions including, for example, the provision of safer injecting equipment or substitution medication, ‘harm reduction’ does not equal ‘harm elimination’ – but it does deliver quantifiable and significant health gains to individuals and communities.

There are a number of notable authorities around the world which have issued statements highlighting the potential of safer alternatives. For example:

International Agency for Research on Cancer: “The use of e-cigarettes is expected to have a lower risk of disease and death than tobacco smoking. [...] E-cigarettes have the potential to reduce the enormous burden of disease and death caused by tobacco smoking if most smokers switch to e-cigarettes”.¹⁵¹

The science that is available today to understand, determine, and quantify potential health risks associated with SNP simply did not exist for cigarettes half a century ago

‘harm reduction’ does not equal ‘harm elimination’ – but it does deliver quantifiable and significant health gains to individuals and communities

¹⁴⁸ McNeill A, Brose LS, Calder R, Hitchman SC, & McNeill A, Brose LS, Calder R, Hitchman SC. (2015). *E-cigarettes: An evidence update*. Public Health England. <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>.

¹⁴⁹ Royal College of Physicians. (2016). *Nicotine without smoke: Tobacco harm reduction* (RCP Policy: Public Health and Health Inequality). Royal College of Physicians. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>.

¹⁵⁰ Hayes, A. W. (2005). The precautionary principle. *Arhiv Za Higijenu Rada I Toksikologiju*, 56(2), 161–166.

¹⁵¹ This statement, which appeared in documentation from the International Agency for Research on Cancer, a WHO agency, has since been removed.

The Society for Research on Nicotine and Tobacco: Fifteen past Presidents of the SRNT published a joint statement that “vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking’s [death] toll. [...] Frequent vaping increases adult smoking cessation [and] completely substituting vaping for smoking likely reduces health risks, possibly substantially”.¹⁵²

British Medical Association: “Significant numbers of smokers are using e-cigarettes (electronic cigarettes), with many reporting that they are helpful in quitting or cutting down cigarette use. There are clear potential benefits to their use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use”.¹⁵³

New Zealand Ministry of Health: “The Ministry considers vaping products could disrupt inequities and contribute to a Smokefree 2025. The evidence on vaping products indicates they carry much less risk than smoking cigarettes but are not risk-free. Evidence is growing that vaping can help people to quit smoking. There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth and may in fact be contributing to it”.¹⁵⁴

Royal Australian College of General Practitioners: “E-cigarettes can relieve cravings and symptoms of nicotine withdrawal as well as simulating the behavioural and sensory aspects of smoking. [...] It is reasonable to conclude that if used as a substitute rather than an addition, e-cigarettes are much less harmful than continuing to smoke”.¹⁵⁵

Cochrane Review: The gold-standard systematic review of randomised controlled trials has concluded that “for every 100 people using nicotine e-cigarettes to stop smoking, 9 to 14 might successfully stop, compared with only 6 of 100 people using NRT, 7 of 100 using nicotine-free e-cigarettes, or four of 100 people having no support or behavioural support only”.¹⁵⁶

US Federal Drug Administration: The FDA has granted a number of Modified Risk Tobacco Product orders (MRTPs). An MRTP authorises the marketing of a tobacco product that poses lower risks compared to other products on the market.¹⁵⁷ *General Snus* from Swedish Match became the first FDA-approved MRTP in 2019. In 2020, the FDA authorized the marketing of PMI’s *IQOS* heated tobacco product as an MRTP. And in 2021, Reynolds Vuse vaping device was also granted an MRTP order, followed by an NJOY vaping product in 2022. This means that while the situation regarding SNP in the US is not ideal from a THR perspective, all three main types of SNP have come through

¹⁵² Balfour, D. J. K., Benowitz, N. L., Colby, S. M., Hatsukami, D. K., Lando, H. A., Leischow, S. J., Lerman, C., Mermelstein, R. J., Niaura, R., Perkins, K. A., Pomerleau, O. F., Rigotti, N. A., Swan, G. E., Warner, K. E., & West, R. (2021). Balancing Consideration of the Risks and Benefits of E-Cigarettes. *American Journal of Public Health, 111*(9), 1661–1672. <https://doi.org/10.2105/AJPH.2021.306416>.

¹⁵³ British Medical Association. (2017). *E-cigarettes: Balancing risks and opportunities*. <https://beta-qa.bma.org.uk/what-we-do/population-health/drivers-of-ill-health/e-cigarettes-balancing-risks-and-opportunities>.

¹⁵⁴ New Zealand government. (2020, September 3). *Position statement on vaping*. Ministry of Health NZ. <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping>.

¹⁵⁵ The Royal Australian College of General Practitioners. (2011). *Supporting smoking cessation: A guide for health professionals*. <https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation>.

¹⁵⁶ Hartmann-Boyce, J., McRobbie, H., Butler, A. R., Lindson, N., Bullen, C., Begh, R., Theodoulou, A., Nottley, C., Rigotti, N. A., Turner, T., Fanshawe, T. R., & Hajek, P. (2021). Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews, 9*. <https://doi.org/10.1002/14651858.CD010216.pub6>.

Plain language summary: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub6/full#CD010216-abs-0002>

Full review: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub6/full>

¹⁵⁷ U.S. Food and Drug Administration, Center for Tobacco Products. (2022b). Premarket Tobacco Product Marketing Granted Orders. *FDA*. <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

U.S. Food and Drug Administration, Center for Tobacco Products. (2022a). Modified Risk Granted Orders. *FDA*. <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders>.

the highly bureaucratic and expensive review process allowing them to be marketed as safer than smoking. (See Chapter 6 for more on FDA processes).

Nicotine use without the smoke

Concerns continue among many, including some active within the tobacco harm reduction field, about young people's use of vaping products (for more on this, see below). Some in public health question just how effective these products are at encouraging people to quit. Others are concerned that, even if people do switch from smoking to vaping, nicotine use can still lead to dependence.

an important aspect about SNP is that they are safer consumer alternatives to a deadly legal product

A point worth exploring about these and other concerns related – or even outright hostilities – to vapes and other non-combustibles is that once you disaggregate the nicotine from the cigarette, many health professionals are left outside their comfort zone. SNP allow people to continue using nicotine without the harms that are associated with burning tobacco. The question becomes whether continued use of nicotine is a problem or not. And an important aspect about SNP is that they are safer consumer alternatives to a deadly legal product. Many people, particularly consumer advocates, would argue that they were not designed as smoking cessation alternatives to NRT or cessation medications, but as a new delivery system for a substance that lots of have people have found pleasurable, or beneficial in some way, for many centuries.

Before we consider D for Disinformation in the FUD dynamic, then, the history of THR throws up another critical version of FUD – where D equals *Disruption*.

Earlier in this report, we have outlined the various ways in which the SNP phenomenon has been disruptive. After seeing the rise of an independent global vaping industry, the major companies began looking to add SNP to their product portfolios. Pharmaceutical sales of NRT have come under threat as well, as more people who want to quit smoking switch to vaping or other products.

But arguably it is the public health community which has experienced the most acute disruption. Clinicians, public health officials and frontline smoking cessation workers have grown up with an unassailable understanding of the dangers of smoking and the



Vaping devices are safer consumer alternatives to combustible cigarettes, which are both deadly – and legal.
Credit: AndreyPopov, iStock photo

diseases it causes. Many mistakenly believed – and some still do – that nicotine was the primary culprit. The goal of public health regarding smoking was to promote all and every effort to persuade people to quit entirely, or at least to use NRT, preferably in conjunction with a smoking cessation intervention. For some, it was both inconceivable and undesirable to consider that once you took the nicotine out of the cigarette, people could continue to consume nicotine in relative safety.

Professor Gerry Stimson, Director of K•A•C, wrote about professional disruption for the *Spectator* magazine in April 2016 under the title, ‘*Public health should step aside: vapers are now leading the fight against smoking*’. He concluded:

*“[Public health’s] main role is to endorse the use of e-cigarettes, to reassure the public of their safety, and not to create obstacles to their use [and] to enable vapers to cascade information to their peers. It’s vapers who are now leading smoking cessation”.*¹⁵⁸

“It’s vapers who are now leading smoking cessation”

The divide in public health was large, and it has not yet been bridged. Rather than stepping aside and encouraging people who smoke to switch if they cannot quit, some long-standing figures in UK public health were virulently opposed to SNP (and remain so), while others who were supportive of THR nevertheless pushed for medical regulation in the early days. By contrast, in the 2010s, the UK Government’s Behavioural Insights Unit was all in favour.

The Behavioural Insights Unit was also known as the ‘nudge’ unit. ‘Nudge theory’ is a concept in behavioural economics and sciences and political theory that proposes positive reinforcement and indirect suggestions as ways to influence the behaviour and decision-making of groups or individuals. ‘Nudging’ contrasts with other ways to achieve compliance, such as education, legislation, or enforcement.¹⁵⁹

an “important tenet” of behaviour change is that it is “much easier to substitute a similar behaviour than to eliminate an entrenched one”

In 2015, Michael Hallsworth, the head of health and tax at the Unit, said e-cigarettes were now “the most successful product at helping people to quit smoking, and the evidence shows that almost all users of e-cigarettes are former smokers”. Reflecting on the trend, Hallsworth reasoned that an “important tenet” of behaviour change is that it is “much easier to substitute a similar behaviour than to eliminate an entrenched one”.¹⁶⁰

There are two further disruptive dimensions consequent to the SNP phenomenon. Both fall out of disaggregating nicotine from cigarettes, and both are equally awkward and disruptive to the global health community.

The first is what is known as ‘the pleasure principle’. Nobody ever smoked for the tar, or to get ill and die – they smoked in order to use nicotine, because it was a pleasurable experience, and/or it was beneficial to them. Unfortunately, due to the considerable nicotine illiteracy that still exists, even among some in the medical professions – let alone the wider public – any notion of individual pleasure or benefit is clouded by the misunderstanding that nicotine is a dangerous drug that causes cancer.¹⁶¹

considerable nicotine illiteracy [...] still exists

¹⁵⁸ Stimson, G. V. (2016). Public health should step aside: Vapers are now leading the fight against smoking. *Spectator Life*.

¹⁵⁹ Behavioural Insights Team. (2011). *Annual update 2010–11*. UK Cabinet Office. <https://www.gov.uk/government/publications/behavioural-insights-team-annual-update>, p. 7.

¹⁶⁰ Charles, G. (2015, July 27). *The e-cigarette craze and sweets for bankers get ‘Nudge unit’ thumbs-up*. Campaign US. https://www.campaignlive.com/article/e-cigarette-craze-sweets-bankers-nudge-unit-thumbs-up/1357606?utm_source=website&utm_medium=social.

¹⁶¹ The literature on the pleasure derived from nicotine without the guilt and shame of smoking is thin, but see for example: Bevan, I. (2016). E-cigarettes: Smoking Pleasure Reinvented? The Many Faces of Harm Reduction in France. *Contemporary Drug Problems*, 43(3), 228–241. <https://doi.org/10.1177/0091450916657348>. For pleasure as it relates to illegal drugs: Duff, C. (2008). The pleasure in context. *The International Journal on Drug Policy*, 19(5), 384–392. <https://doi.org/10.1016/j.drugpo.2007.07.003>; Moore, D. (2008). Erasing pleasure from public discourse on illicit drugs: On the creation and reproduction of an absence. *The International Journal on Drug Policy*, 19(5), 353–358. <https://doi.org/10.1016/j.drugpo.2007.07.004>.

Repeated nicotine use can be habit forming and is often described as ‘addictive’, which leads to the other disruptive element in the THR discourse: one which divides opinion even within the supportive THR scientific and public health network.¹⁶²

Considering nicotine and the concept of ‘addiction’

The term ‘addiction’ is ill-defined

The term ‘addiction’ is ill-defined; generally it refers to some kind of destructive behaviour attended by a psychological craving to continue, and physical, often traumatic withdrawal symptoms should the person try to cease the behaviour. For many, the term has become synonymous with the chaos and misery of serious drug use; with a life, often traumatised during childhood and adolescence, now only focused on the next self-medicating hit to the detriment of everything else – health, education, employment, relationships. These days, the term is frequently attached to a whole range of activities, including gambling, shopping, sex, video games, smartphone use and social media scrolling – creating a growth industry in experts and therapists.



An 1843 engraving showing Chinese opium smokers in a saloon experiencing various effects of the drug. Credit: Engraving by G. Paterson, 1843, after T. Allom. Credit: Wellcome Collection. Attribution 4.0 International (CC BY 4.0)

Nor has the concept of ‘addiction’ remained stable throughout history

Nor has the concept of ‘addiction’ remained stable throughout history. As historian Professor Virginia Berridge explains in her seminal work on 19th century drug use in England, the doctors of the period were beginning to organise themselves, developing

¹⁶² It is worth noting that it has been theorised that combustible cigarettes are more habit forming than other nicotine delivery systems due to additives which potentiate the effect of nicotine in the body – additives that are not found in vaping liquids. For a discussion of the possible biochemical effects of various additives in combustible cigarettes, see Rabinoff, M., Caskey, N., Rissling, A., & Park, C. (2007). Pharmacological and chemical effects of cigarette additives. *American Journal of Public Health, 97*(11), 1981–1991. <https://doi.org/10.2105/AJPH.2005.078014>. Research published in the *Journal of Preventive Medicine* in 2017 concluded that exclusive daily e-cigarette users are less dependent on their respective product than comparable cigarette smokers. See Liu, G., Wasserman, E., Kong, L., & Foulds, J. (2017). A comparison of nicotine dependence among exclusive E-cigarette and cigarette users in the PATH study. *Preventive Medicine, 104*, 86–91. <https://doi.org/10.1016/j.jypmed.2017.04.001>.

their status as middle-class professionals. Berridge argues that the medical profession took ownership of concepts like 'addiction' in order to explain the compulsive use of alcohol and opium – but contends that there was no scientific basis for this. What was presented as science-based objectivity in fact “disguised class and moral concerns which precluded an understanding of the social and cultural roots of opium use... Images of addiction [were] consistently and ruthlessly marketed in the nineteenth century to make opium the property of the medical profession”.¹⁶³

Psychologist Stanton Peele frames 'addiction' as a political moveable feast, focusing on whatever drug is causing the most political and social concerns, rather than an immutable biological fact. Early addiction science focused entirely on opioid drugs like opium and heroin. But there are no discernible physical withdrawal symptoms from cannabis or cocaine, so the scientific goalposts were repositioned, while the notion of what constituted 'addiction' remained entrenched in public discourse.¹⁶⁴

What about 'tobacco addiction'? In the 1950s, the WHO decided that smoking was a habit rather than an addiction, a position that the US Surgeon General's report on smoking and health agreed with in 1964.¹⁶⁵ In the 1964 report, 'drug addiction' and 'drug habituation' are characterised thus:

In the 1950s, the WHO decided that smoking was a habit rather than an addiction

Drug Addiction	Drug Habituation
Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug. Its characteristics include:	Drug habituation (habit) is a condition resulting from the repeated consumption of a drug. Its characteristics include:
1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;	1) a desire (but not a compulsion) to continue taking the drug for the sense of improved well-being which it engenders;
2) a tendency to increase the dose;	2) little or no tendency to increase the dose;
3) a psychic (psychological) and generally a physical dependence on the effects of the drug;	3) some degree of psychic dependence on the effect of the drug, but absence of physical dependence and hence of an abstinence syndrome [withdrawal];
4) detrimental effect on the individual and on society.	4) detrimental effects, if any, primarily to the individual.

Flash forward to 1988, when the US Surgeon General published a report entitled *The Health Consequences of Smoking: Nicotine Addiction*.¹⁶⁶ The document firmly attempted to establish the idea of addiction to and use of nicotine as a problem. Stanton Peele observed:

“Although the irreversible, neurobiological model of nicotine addiction is now considered ironclad, irrefutable, and destined by biology, this has never been the case, as demonstrated most clearly by key US government reports that

¹⁶³ Berridge, V., & Edwards, G. (1982). *Opium and the People: Opiate Use in Nineteenth-Century England* (Reprint edition). Yale University Press, p. 150.

¹⁶⁴ Peele, S. (2010). The fluid concept of smoking addiction. In C. V. Phillips & P. L. Bergen (Eds.), *Tobacco Harm Reduction 2010. A yearbook of recent research and analysis* (pp. 223–234). Published by Carl V. Phillips. <http://tobaccoharmreduction.org/thr2010ahi.pdf>.

See also, Alexander, B. K., & Schweighofer, A. R. F. (1988). Defining 'addiction'. *Canadian Psychology / Psychologie Canadienne*, 29(2), 151.

¹⁶⁵ World Health Organization. Expert Committee on Executive Board, 19. (1957). *Expert Committee on Addiction-Producing Drugs: Seventh report. World Health Organization; WHO IRIS*. <https://apps.who.int/iris/handle/10665/88527>, p. 351.

¹⁶⁶ Office on Smoking and Health United States. Public Health Service. Office of the *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*. (1988). Reports of the Surgeon General – Profiles in Science. <https://profiles.nlm.nih.gov/spotlight/nn/catalog.nlm:nlmuid-101584932X423-doc>.

“Addiction is politically and socially defined, despite repeated but mistaken claims to have identified a purely biological, asocial basis for defining and recognizing [it]”

have contributed to the creation of the currently dominant model of nicotine addiction. This model – and the image of smoking that underlies it – appeared relatively recently, despite centuries of experience with tobacco. It achieved supremacy as the definition of addiction shifted, a different cultural view of tobacco came to prevail, and tobacco moved from the non-addictive category to the addictive one. However, the underlying epidemiology of tobacco use has not changed. Addiction is politically and socially defined, despite repeated but mistaken claims to have identified a purely biological, asocial basis for defining and recognizing [it].”¹⁶⁷

There is even a counter-intuitive theory of rational addiction that was first conceptualised by Nobel laureate economist Gary Becker and his colleague Kevin Murphy. They theorised that consumption is partly motivated by the immediate payoff of consumption, and partly by the effects of that consumption on the individual in the future. The aim was to introduce the role of human behaviour into economic analysis.

Writing about the theory in *Addiction* journal, Ole Røgeberg of the Norwegian Frisch Institute for Economic Research used the cigarette as an example; cigarettes today will cause withdrawal tomorrow, but tomorrow’s cigarettes will eliminate withdrawals plus provide the other benefits derived from smoking. This is ‘rational addiction’ on the basis that the smoker knows in advance they are hooked on smoking. The theory prompted all kinds of reactions and extensions of the theory from both the medical and economic fields.¹⁶⁸ But in very simple terms, unlike the cigarette example with all the attendant health risks (and leaving aside any benefits), using nicotine alone is the very essence of the rational addiction (habit) argument. It becomes entirely a consumer choice – which, following this argument, would require no undue policy interventions.

Even daily use of nicotine without the attendant risks of smoking in no way equates with any popular image of the damage caused by ‘addiction’ either at a personal, community, or societal level. And this, it seems, is what some in the global health



Many people see their continued use of nicotine – using delivery systems that are much safer than smoking – as a consumer choice.

Credit: Photo by Chris Anderson on Unsplash

¹⁶⁷ Peele, 2010.

¹⁶⁸ Røgeberg, O. (2020). The theory of Rational Addiction. *Addiction*, 115(1), 184–187. <https://doi.org/10.1111/add.14822>.

community cannot process: the idea of people consuming a drug, outside of medical supervision, which when obtained by smoking is associated with a panoply of dangers, but isolated from smoking offers pleasure and benefit with relatively low risks attached. This discomfort is perhaps grounded in vague or nebulous moral objections; to 'not being free', or being a 'slave' to nicotine.

More science does not equal better science

Between 2007–2012, there were barely more than 50 academic papers on SNP. But that figure has skyrocketed in relation to vaping products, reflecting both their popularity and their emergence into the public consciousness.

It would be encouraging to report this huge increase in research has firmly established the benefits of SNP; that fears have been allayed while uncertainties and doubts have been successfully countered through balanced media reporting and official endorsement from world-wide medical and public agencies. Sadly, this is not the way things have played out.

There are overarching problems with much of the research.¹⁶⁹ The first is publication bias on the part of many peer-reviewed journals. In the main, journal editors like to publish positive research with exciting findings – like the successful trial of a new drug or innovative surgical procedure for a chronic disease. The latest 'cure for cancer' good news story is bound to make the headlines. Unfortunately, within the sphere of tobacco research publishing, it can seem as if the only good news about vaping is bad news.

The environment of suspicion that has been created in many people's minds around vaping means that many media outlets expect all news about vaping to be bad. This is confirmation bias in action.

“Even daily use of nicotine without the attendant risks of smoking in no way equates with any popular image of the damage caused by 'addiction' either at a personal, community, or societal level

“many media outlets expect all news about vaping to be bad



It seems many media outlets expect all vaping news to be bad news.
Credit: Bank Phrom on Unsplash.

¹⁶⁹ A number of sources regularly provide critiques of or commentaries on research on SNP including:
Clive Bates – <https://clivebates.com>
Professor Brad Rodu – <https://rodutobaccotruth.blogspot.com>
Dr Michael Siegel – <https://tobaccoanalysis.blogspot.com>

The problem with the peer-review process is well made by Richard Smith, former editor of the *British Medical Journal*, in his book, *The trouble with medical journals*. In it, he quotes Drummond Rennie, the deputy editor of *Journal of the American Medical Association*:

“There seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, too obscure and too contradictory, no analysis too self-serving, no argument too circular, no conclusions too trifling or unjustified, and no grammar or syntax too offensive for a paper to end up in print.”¹⁷⁰

One recent study that reflects these researcher and publication biases resulted in an academic paper which purported to show that “E-cigarettes are capable of causing dangerous damage to the brain, heart, and gut”. This was reported in *The Sun*, a major UK tabloid with a huge readership.¹⁷¹ The study was carried out at the University of California, a major source of scientific papers that focus on vaping risks. This university was the former employer of Stanton Glantz, author of one of the most highly publicised examples of bad science, whose paper on the impact of vaping on the heart was (reluctantly) retracted by the publishing journal. The paper attributed heart attacks in the study subjects to vaping, when these events had occurred an average of ten years prior to the individual’s uptake of vaping.¹⁷²

A second reason for skewed publication is confirmation bias linked to funding

A second reason for skewed publication is confirmation bias linked to funding. Why would a researcher go looking for harms caused by SNP? Firstly, because they may believe that these products are dangerous, and the public need to be warned about them. But research needs funding. Many of the agencies that offer funding for research in this field focus on supporting research that identifies problems with SNPs, or have even explicitly taken anti-vaping positions. When seeking funding in the US, researchers would likely turn to the US National Institutes of Health, or to organisations like the American Heart Association and the American Thoracic Society, both of which have clearly stated their antipathy towards vaping. Researchers shape their research questions in line with funders’ research priorities.

Researchers shape their research questions in line with funders’ research priorities

A third reason is the decision taken by some journals to refuse industry-derived science or papers from industry researchers – or anybody who ever has received industry funding, however indirect. This inadvertently is an own goal for journal editors, who are in effect saying that they have no confidence in either their judgement of the science, nor on the judgements of their peer reviewers.

At play is a one-sided notion of conflict of interest

At play is a one-sided notion of conflict of interest (COI), that researchers who are funded by industry are conflicted, and that those funded by government, health institutions, and philanthropic organisations are not. Yet if a study is funded by a source or sources who have a track record of explicitly taking a stance against the potential for vaping as a harm reduction option for people who smoke – whether that is through information on their websites, their associations, partners or other funded projects – these authors also have a COI. This is often ignored by authors and journal editors.

¹⁷⁰ Smith, R. (2006). *The Trouble with Medical Journals* (1st edition). CRC Press, p. 85.

¹⁷¹ Chalmers, V. (2022, April 13). *Popular e-cigarettes could trigger dangerous damage to brain and heart*. The Sun. <https://www.thesun.co.uk/health/18252409/popular-ecigarettes-trigger-damage-brain-heart/>. Also reported in *E-cigarettes alter inflammatory state of brain, heart, lungs and colon*. (2022, April 12). SCIENTMAG: Latest Science and Health News. <https://scienmag.com/e-cigarettes-alter-inflammatory-state-of-brain-heart-lungs-and-colon/>.

¹⁷² Retraction to: *Electronic Cigarette Use and Myocardial Infarction Among Adults in the US Population Assessment of Tobacco and Health*. (2020). *Journal of the American Heart Association*, 9(4), e014519. <https://doi.org/10.1161/JAHA.119.014519>. [original article URL: <https://www.ahajournals.org/doi/10.1161/JAHA.119.012317>]

Within much research into vaping there is publication and confirmation bias, accompanied by flawed methodologies. Research flaws include a lack of transparency with regards to raw data used to generate findings, laboratory research which does not reflect real world use of products (such as testing on animals or heating nicotine liquid to temperatures far in excess of those reached in vaping products while in use), the fact that study participants who vape may have spent decades smoking heavily prior to switching (making it hard to disaggregate the effects of long-term smoking on health from the adoption of vaping), and an absence of comparisons with continued use of cigarettes.

It appears as if many are looking for more bad news to report. For example, there have been claims that e-cigarettes cause erectile dysfunction, bone damage, and depression, when the evidence to support these claims is simply not there.¹⁷³

The impact of mis- and disinformation on public perceptions: Vitamin E acetate

FUD does not only reside in the rarefied atmosphere of the laboratory, the clinic, or on the pages of scientific journals. There has been much fear, uncertainty and disinformation circulating among the general public about vaping.

Yet every major scare story about vaping at a population level has so far been proved to be incorrect. Vaping has not been proven as a gateway to smoking, but rather out of it. So-called ‘popcorn lung’ was an occupational health issue limited to factory workers exposed to high levels of diacetyl, not vapers.¹⁷⁴ Nor was vaping shown to increase the risk of contracting COVID.

One major instance of mis- and disinformation about vaping that continues to have profound consequences for progress in THR concerns a number of lung injuries that occurred in the US in 2019, which sadly led to fatalities. In the summer of 2019, reports began to emerge from the US of people, many of them young adults, who were falling ill and dying of severe lung injuries. Initially, it was thought that what they all had in common was the use of nicotine vaping products. A new phrase entered the lexicon: E-cigarette or Vaping product use Associated Lung Injury (EVALI).

Health authorities in the affected areas fairly quickly established that the cause was Vitamin E acetate, an additive that had been used in some illicit and unregulated e-liquid products containing tetrahydrocannabinol (THC), the psychoactive element in cannabis. It had been used as a thickening agent in some THC liquids and the adulterant was damaging people’s lungs. However, even though the CDC was aware that it was a specific adulterant in certain THC e-liquids that was at fault, the organisation failed to clarify this for some months. The name EVALI – which is still misleadingly used now by some – contributed to the persistent narrative that any and all vaping could cause the condition.¹⁷⁵ By the time the CDC confirmed the truth, the story had gone global.

“Every major scare story about vaping at a population level has so far been proved to be incorrect

By the time the CDC confirmed the truth [about EVALI], the story had gone global

¹⁷³ See also English, C. (2022, July 19). *Lousy Vaping Studies: A Master List of Junk Science (Updated July 19, 2022)*. American Council on Science and Health. <https://www.acsh.org/news/2022/07/19/lousy-vaping-studies-master-list-junk-science-updated-july-19-2022-16142>; Hajat, C., Stein, E., Selya, A., Polosa, R., Alaimo, S., Anfuso, C. D., Barbagallo, I., Basile, F., Battiato, S., Benhamou, B., Bertino, G., Bianchi, A., Biondi, A. G., Brandi, M. L., Cacciola, E., Cacciola, R. R., Cacopardo, B. S., Calogero, A. E., Cambria, M. T., ... The CoEHAR study group. (2022). Analysis of common methodological flaws in the highest cited e-cigarette epidemiology research. *Internal and Emergency Medicine*, 17(3), 887–909. <https://doi.org/10.1007/s11739-022-02967-1>.

¹⁷⁴ For more information on popcorn lung, see Shapiro, H. (2018). *No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018*. Knowledge-Action-Change. <https://gsth.org/resources/thr-reports/no-fire-no-smoke-global-state-tobacco-harm-reduction-2018/>, pp. 65–66.

¹⁷⁵ For a full account of EVALI, see Shapiro, 2020, pp. 74–78. Download in PDF: <https://gsth.org/resources/thr-reports/burning-issues-global-state-tobacco-harm-reduction-2020/> Read online – under sub-heading *US lung injuries and deaths: mistakes, miscommunication and misinformation*: <https://gsth.org/reports/burning-issues-2020/chapter-4/>



Many of the severe lung injuries were linked to the use of THC products packaged as 'Dank Vapes'.
Credit: New York State Department of Health. Licensed under the Creative Commons Attribution 2.0 Generic license.

There were no confirmed reports elsewhere in the world of deaths caused by vaping Vitamin E acetate in illicit and unregulated THC liquids, let alone legitimately produced nicotine e-liquid. Yet because the information had come from a globally respected public health source, EVALI has entered the canon of false information about vaping. It was dutifully reported worldwide by government health ministries and NGOs that take an anti-vaping position worldwide. In 2022, EVALI was still being cited in Mexico as a reason to ban vaping. As Jonathan Swift wrote, "Falsehood flies, and truth comes limping after it, so that when men come to be undeceived, it is too late; the jest is over, and the tale hath had its effect".¹⁷⁶

In response, American retailers like Walgreens, Walmart and Kroger stopped selling nicotine vaping products. Vape stores recorded up to a 75% decline in sales, especially for starter kits. Those most affected by bad public health messaging grounded in *disinformation* causing fear, uncertainty, and *doubt* were people who were looking to switch away from smoking.¹⁷⁷

The EVALI scare accelerated public perception that vaping was as or if not more dangerous than smoking. But the blame for this failure of public health communication cannot just be laid at the door of the CDC. Clive Bates (a former Director of UK Action on Smoking and Health) demonstrated how a group of medical and public health agencies have contributed to worsening public perception over the safety of vaping in recent years, as tracked by the American Cancer Society Health Information National Trends Survey (HINTS). Bates writes;

"These results represent an outcome that many have strived for. I don't mean a sinister conspiracy, but the aggregate effect of the confirmation biases of thousands of academics and advocates who want, really want, this to be the reality and really do not want e-cigarettes to be much safer than cigarettes.

"Why? Because harm gives them a locus and a reason to be. It denies the viability of a solution to a problem that many have spent their careers working

¹⁷⁶ Swift, J. (1710, September 11). *Issue 14 of 'The Examiner' 9/11/1710*. <https://www.Ourcivilisation.Com/>. <https://www.ourcivilisation.com/smartboard/shop/swift/examiner/chap14.htm>.

¹⁷⁷ E-Cig Intelligence. (2019). *Scandal in the US and global implications*. E-cigarette Summit, London.

The EVALI scare accelerated public perception that vaping was as or if not more dangerous than smoking

on but that does not involve them and empowers its users instead of controlling them. If your culture is steeped in tobacco wars and your institution is geared up to find and fight harm, then these are the risk perceptions you are likely to seek and find.”¹⁷⁸

He goes on to write that the American public have been subjected to – and have paid for through taxes – fear-mongering messages with the inevitable result that increasing numbers of people falsely believe that vaping is more dangerous than smoking.

By contrast, UK medical and public health agencies have to date focused attention on encouraging adult smokers to quit or switch. Yet so pervasive is the global messaging, aided by sensationalist media reporting, that even in the UK – where the trusted National Health Service encourages people who smoke to try using e-cigarettes to quit – confidence has fallen. Public Health England reported in 2020 that the proportion of people who smoke in the UK who believe that vapes were equally or more dangerous than cigarettes rose after the EVALI scare. They concluded:

“Perceptions of harm from vaping among smokers are increasingly out of line with the evidence. The proportion who thought vaping was less harmful than cigarettes declined from 45% in 2014 to 34% in 2019. These misperceptions are particularly common among smokers who do not vape”.^{179 180}

Vaping and young people



Perceptions of a ‘youth vaping epidemic’ has influenced global policymaking, but the picture on youth use is complex. Credit: Photo by Sam Balye on Unsplash.

The perception that there is a ‘vaping epidemic’ among adolescents is perhaps the most highly publicised phenomenon associated with vaping. It is certainly the issue

¹⁷⁸ Bates, A. C. (2022, February 3). E-cigarette risk perceptions – an American crime scene. *The Counterfactual*. <https://clivebates.com/e-cigarette-risk-perceptions-an-american-crime-scene/>.

¹⁷⁹ McNeill, A., Brose, L. S., Calder, R., Bauld, L., & Robson, D. (2020). *Vaping in England: An evidence update including mental health and pregnancy* (Research and Analysis) [A report commissioned by Public Health England]. Public Health England (PHE). <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary>.

¹⁸⁰ Svenson, M. R. E., Freeman, T. P., & Maynard, O. M. (2022). The effect of conflicting public health guidance on smokers’ and vapers’ e-cigarette harm perceptions. *Nicotine & Tobacco Research*, ntac163. <https://doi.org/10.1093/ntr/ntac163>.

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that has caused the most significant political and legislative fallout in the US, and this has had knock-on implications for policy around the world. The word epidemic is most properly used to describe the spread of communicable disease. But, colloquially and in media reporting, it is often used in a value-laden way designed to elicit fear or concern, often in relation to substance use. The portrayal of nicotine use and vaping among young people in mainstream media reporting has frequently followed this pattern.

As well as honing in on the spectre of addiction, there have been concerted efforts by some campaigners to scare parents by claiming that nicotine is detrimental to the developing brain, even to the extent of impacting on educational attainment. This is another attempt to weaponise public health messaging. To establish a credible link between nicotine and brain development, you would need to conduct longitudinal studies in real-world situations with all co-founding factors taken into account. No such evidence base exists.

there is no doubt that there are teenagers, especially in the US (the world’s major vaping market) who have been attracted to try vaping – just as teenagers the world over are attracted to experimentation with a range of activities and substances

But there is no doubt that there are teenagers, especially in the US (the world’s major vaping market) who have been attracted to try vaping – just as teenagers the world over are attracted to experimentation with a range of activities and substances. However, recent figures show that smoking among American adolescents has been in rapid decline. During the same period, experimentation with vaping was rising until quite recently, when the trend seems to have slowed or entered a downturn.

According to the phrasing of the CDC’s National Youth Tobacco Survey (NYTS), “current use” is defined as use on one or more days in the last 30 days.¹⁸¹ In survey results from between 2011 and 2020, CDC data shows that past-30 day use of combustible cigarettes among high school students dropped significantly from 15.8% in 2011 to 4.6% in 2020. And, after increasing between 2017 and 2019, past-30 day use of vaping products dropped from 27.5% in 2019 to 19.6% in 2020 among high school students.¹⁸²

In 2021, the CDC reported that 11.3% of high school students had reported use of a vaping product in the last 30 days, and that 1.9% reported that they had smoked combustible cigarettes in the last 30 days.¹⁸³ However, the 2021 data must be excluded from trends data on youth use of nicotine due to the implementation of COVID protocols. Lockdowns meant that the survey was conducted online, meaning students were able to complete it at home, at school, or elsewhere; it has been recognised that young people’s reporting of tobacco use might vary due to the setting in which they completed the survey, and that therefore direct comparisons with previous surveys is not possible.¹⁸⁴

It is probable that many of the young people who were smoking, or crucially who *would have* initiated smoking, have instead switched to vaping

The current picture is therefore hard to ascertain, and the 2022 data will be key. If trends return to the trajectory they were on in the period 2011–2020, it can be hoped that smoking will continue to decrease rapidly, and use of vaping products, while higher than combustible cigarette use, will also continue falling.

A fall in current youth smoking rates of this magnitude – from 15.8% in 2011 to 4.6% in 2020 – is hugely significant. It is probable that many of the young people who were smoking, or crucially who *would have* initiated smoking, have instead switched to vaping. The definition of “current use” should also be borne in mind; the figures

¹⁸¹ Gentzke, A. S., Wang, T. W., Jamal, A., Park-Lee, E., Ren, C., Cullen, K. A., Neff, L., & Gentzke, A. S. (2020). Tobacco Product Use Among Middle and High School Students—United States, 2020. *MMWR. Morbidity and Mortality Weekly Report*, 69. <https://doi.org/10.15585/mmwr.mm6950a1>.

¹⁸² Ibid.

¹⁸³ CDC Tobacco Free. (2022, August 22). *Youth and Tobacco Use*. Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm.

¹⁸⁴ Ibid.

relate to a young person’s use of a product on “one or more days” in a 30-day period. Within those numbers, there will be those for whom “current use” remains infrequent and irregular experimentation, as well as those who may be smoking or vaping daily. In harm reduction terms, if those young people who either would have started smoking or used to smoke are switching to vaping, this represents a public health gain, given the hugely reduced health risks of vaping compared to combustible cigarette use.

Evidence from the UK appears to confirm the relationship between young people who vape and young people who are either current smokers or who used to smoke. In July 2022, Action on Smoking and Health (ASH) UK published new statistics showing that 92.2% of never smokers aged 11–17 have either never used an e-cigarette or are not aware of them. The data confirmed that “use of e-cigarettes remains largely confined to current or former smokers”.¹⁸⁵ Among young people aged 11 to 17 who had never smoked, 7.5% had ever tried an e-cigarette – of whom 5.6% had tried them “once or twice”, 0.9% used them “less than weekly” and 0.5% reported use “more than once a week”.¹⁸⁶

However, the ASH UK data did show that the percentage of all 11 to 17 year olds who have ever tried vaping has fluctuated over the last few years: from 13.9% in 2020, to 11.2% in 2021, and increasing to 15.8% in 2022. It also suggested the increased role of disposable vapes in the picture, with 52% of respondents who were current users of vaping devices favouring this type of product.¹⁸⁷

Concerns have been growing about the use of disposable vapes among young people in the UK, Australia, Canada and across Europe.¹⁸⁸ Primarily imported from China, they are cheap, and young people may be exposed to promotion via social media channels. In the UK, no-one under the age of 18 should be able to purchase vaping products. However, disposable vapes seem to be making their way onto the market and being sold to minors at retail outlets that are not observing the legal restrictions on their sale. Some disposable products have not undergone the approval process required by the UK regulatory and trading authorities – and, as such, their quality and safety cannot be determined.

Both the safety of poor quality, unregulated disposable products and their illegal sale to and use by young people are concerning. However, the response to these concerns should be the application of the regulatory and enforcement systems that already exist in the UK. According to some in the UK vaping industry, legitimate disposables are gaining popularity among adults. Taking action against a specific group of vaping products could undermine the wider public health argument for tobacco harm reduction. It could also hamper access to affordable products for adults on low incomes who smoke, and who may wish to try vaping using a disposable device that requires little upfront investment. Existing border controls must be used to prevent the importation of substandard products, and irresponsible retailers who are selling these products to minors should face prosecution or significant fines.

Mis- and disinformation about nicotine and vaping has real-world consequences for public health. As more people begin to believe the narrative that vaping is either as dangerous or more dangerous than smoking, fewer people will switch away from combustible cigarettes. Worse, some may stop vaping and return to smoking.

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Mis- and disinformation about nicotine and vaping has real-world consequences for public health

¹⁸⁵ Action on Smoking and Health. (2022). *Use of e-cigarettes (vapes) among adults in Great Britain*. <https://ash.org.uk/uploads/Use-of-e-cigarettes-among-young-people-in-Great-Britain-2022.pdf>.

¹⁸⁶ Ibid.

¹⁸⁷ Ibid.

¹⁸⁸ See Chapter Six for more on the availability of illegal disposables in Australia.

while there has been genuine fear, uncertainty and doubt in response to a disruptive technology, the evidence is now stacking up in its favour

But while there has been genuine fear, uncertainty and doubt in response to a disruptive technology, the evidence is now stacking up in its favour. It is a tragedy, therefore, that there are organisations – ostensibly working for the public good – which are actively and deliberately contributing to a global anti-vaping, anti-tobacco harm reduction narrative. And they are supported by funding that runs into hundreds of millions of dollars.

Chapter 6: Follow the money

As noted in Chapter Two, the World Health Organization was established in 1948 based on a constitution which declared, among other founding principles, that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”.¹⁸⁹

Up to the late 1990s, the primary focus of the WHO was to combat infectious diseases. In 1980, it achieved its most noticeable success, announcing the eradication of smallpox after a twenty-year vaccination campaign. However, success in eradicating infectious diseases has since been patchy; targets on polio and malaria have not been met. The WHO was criticised for over-reacting to the 2009 H1N1 swine flu outbreak, then conversely for acting too slowly over the 2014 outbreak of Ebola in West Africa which may have cost thousands of lives.¹⁹⁰ In what international health experts described as an ‘egregious failure’, the WHO waited months before declaring a Public Health Emergency of International Concern despite warnings, including from its own staff, that the epidemic was out of control.^{191 192}

The United Nations and donors’ disquiet about the ability of WHO to lead the response to the AIDS crisis led to the establishment of a new body, UNAIDS.¹⁹³ Most recently, the WHO was criticised for taking too long to identify COVID as a global pandemic, with claims the agency relied too heavily on China’s assertions that COVID could not be passed between humans.

Consider all the global issues to which the WHO now might be expected to respond – such as the current Director General’s lofty ambition to bring about universal healthcare; tackling the major non-communicable health harms such as obesity, cardiovascular disease, diabetes, and mental ill health; ongoing rampant infectious diseases such as tuberculosis, malaria, and childhood pneumonia – and now COVID. Add to these, the WHO must respond to a deteriorating climate crisis, in which the health of the planet and its people is going to be hugely affected. It is perhaps unsurprising that there is a growing view among global health analysts that the WHO as currently funded, managed, and structured is not fit for purpose.¹⁹⁴

Part of that recognition has resulted in the proliferation of global health agencies, not just UNAIDS, but over 200 other transnational actors. These include the Bill and Melinda Gates Foundation; the GAVI Vaccine Alliance; The Global Fund to Fight AIDS, Tuberculosis and Malaria, and Médecins Sans Frontières. Even the World Bank

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¹⁸⁹ Constitution of the World Health Organization, (1946). <https://www.who.int/about/governance/constitution>.

¹⁹⁰ This led to concerns from the Council of Europe that the WHO were influenced by its relations with the pharmaceutical industry, resulting public money spent on vaccines that were never used. http://assembly.coe.int/CommitteeDocs/2010/20100329_MemorandumPandemie_E.pdf

¹⁹¹ Kelland, K. (2015, November 22). Global health experts accuse WHO of ‘egregious failure’ on Ebola. *Reuters*. <https://www.reuters.com/article/us-health-ebola-response-idUSKBN0TB10K20151122>.

¹⁹² Cheng, M. (2015, March 20). *Emails: UN health agency resisted declaring Ebola emergency*. AP NEWS. <https://apnews.com/article/2489c78bfff86463589b41f3faaea5ab2>.

¹⁹³ Knight, L. (2010). UNAIDS: *The First Ten Years*. World Health Organization.

¹⁹⁴ Clift, C. (2014). *What’s the World Health Organization For?* [Final report]. Centre on Global Health Security Working Group on Health Governance; Costello, A. (2021). WHO in its present form is not fit for purpose—An essay by Anthony Costello. *BMJ*, 375, n2644. <https://doi.org/10.1136/bmj.n2644>; Goldson, B. (2020, August 11). Is the *World Health Organization still fit for purpose?* [Politics & Society]. Public Interest Media. <https://www.thebigq.org/2020/08/11/is-the-world-health-organization-still-fit-for-purpose/>; Russell, M. (2020, December 5). *World Health Organization: Is it fit for purpose?* Think Tank, European Parliament. [https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI\(2020\)651910](https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2020)651910).

funds health programmes. The global public health space is now very crowded and highly territorial; in many cases, there appears to be little cooperation or effective joint advocacy work.¹⁹⁵ As Charles Clift observes in his report for the Royal Institute for International Affairs: “The very existence of organisations such as GAVI or the Global Fund is a reminder of the WHO’s failure, and of the extent to which the international community (particularly the donor community) prefers to bypass a WHO that is perceived as clodhopping and ineffective”.¹⁹⁶

Funding shortfalls and the rise of the ‘philanthrocapitalists’

One key reason for the weakness of the WHO is undoubtedly the declining level of funding from the Member States

One key reason for the weakness of the WHO is undoubtedly the declining level of funding from the Member States. In the 1970s, Member States paid 75% of the WHO budget from contributions that were assessed based on population and national wealth. That figure is now down to around 10%. The bulk is made up of voluntary contributions; around 4% are flexible contributions which the WHO can spend on any projects. The majority of the remainder, around 88%, are earmarked by the contributing Member States for specific projects of their choosing, either by topic or geographical location, and must be spent within a specified timeframe. The downward trend of funding for the WHO is partly due to this lack of confidence in the effectiveness and efficiency of the WHO, and partly by the economic shocks of the financial crash of 2007–08, the COVID pandemic and now the uncertainties due to the war in Ukraine.

many would argue that the WHO has shown little appreciation for health as a human rights issue

As noted earlier in this report, many would argue that the WHO has shown little appreciation for health as a human rights issue. This is a huge failing, as harm reduction is interlinked with human rights and social justice. The WHO’s over-medicalised approach is demonstrated by its recruitment of a preponderance of medical staff to the detriment of other disciplines, such as economists and social scientists, whose expertise could prove essential to establish innovative or pragmatic responses to numerous global health challenges. Another criticism is that the WHO is hidebound by cultural inertia – in other words, that it is either incapable or unwilling to reassess traditional organisational mindsets. As previously shown, an ability to accept new approaches is very relevant to the issue of tobacco control and the response to tobacco harm reduction. The WHO’s response to date to harm reduction for tobacco has brought many of its deep-rooted flaws to light.

The shortfall in Member State funding has led the WHO to become increasingly reliant on money from what some have termed ‘philanthrocapitalist’ funders

The shortfall in Member State funding has led the WHO to become increasingly reliant on money from what some have termed ‘philanthrocapitalist’ funders, most notably the Bill and Melinda Gates Foundation (BMGF) and Bloomberg Philanthropies (BP). It would be naïve to imagine that billionaire philanthropists are entirely driven by altruism. As Bill Gates publicly admitted in *Time* magazine in July 2008, enlightened self-interest in making LMIC healthier and wealthier creates disposable income and so boosts consumerism. But concerns have been raised about the risks of a conflict of interest.¹⁹⁷ These interests might be indirectly commercial, but might also play to the personal interests and prejudices of the funder. This is especially relevant to the WHO Tobacco Free Initiative (TFI), now subsumed within the WHO Non-communicable Diseases Department, and funded by Bloomberg Philanthropies.

¹⁹⁵ Hoffman, S. J. (2015). *Mapping Global Health Architecture to Inform the Future*. https://www.academia.edu/14836138/Mapping_Global_Health_Architecture_to_Inform_the_Future.

¹⁹⁶ Clift, 2014, p. 10.

¹⁹⁷ Stuckler, D., Basu, S., & McKee, M. (2011). Global Health Philanthropy and Institutional Relationships: How Should Conflicts of Interest Be Addressed? *PLOS Medicine*, 8(4), e1001020. <https://doi.org/10.1371/journal.pmed.1001020>.

Across the global landscape of public health funding, Bloomberg Philanthropies is a relative bit-player; it does not appear in the top twenty list of key global health actors as voted by a panel of global health experts.¹⁹⁸ But within international tobacco control, Bloomberg Philanthropies has a commanding role.

Under the Framework Convention on Tobacco Control (FCTC), Member States are obliged to submit reports to the FCTC Secretariat detailing progress covering all the Articles of the Convention, including farming, trade and the provision of cessation services. But Bloomberg Philanthropies, it seemed, was not interested in funding farming, trade or cessation services; these are expensive and take time to demonstrate results. It appears that Bloomberg prefers funding programmes that are run on business lines, with quick, media-friendly headline wins. The WHO are in total lockstep with this aim – because the WHO needs to demonstrate to its funder that the money is being spent ‘effectively’.

So in 2006, as the ‘Bloomberg Initiative’, Bloomberg Philanthropies began funding the WHO TFI to establish MPOWER, a process and monitoring mechanism to implement the FCTC. Comprising six tobacco control measures, MPOWER set out to: **M**onitor tobacco use and prevention policies; **P**rotect people from tobacco smoke; **O**ffer help to quit tobacco use; **W**arn about the dangers of tobacco; **E**nforce bans on tobacco advertising, promotion and sponsorship; and **R**aise taxes on tobacco.

In its most recent progress report, the WHO stated that 5.3 billion people were ‘covered’ by at least one MPOWER measure to the ‘highest level of achievement’.¹⁹⁹ This made for excellent headlines. But closer analysis shows that 30 per cent of countries who have signed up to the FCTC have not enacted a single MPOWER measure – and that, of the 49 countries with no measures in place, 41 are low- and middle-income countries (LMIC).²⁰⁰ This is significant because 80 per cent of the world’s 1.1bn smokers live in LMIC, the countries least able to support people to quit, or to treat smoking-related diseases. The provision of cessation services – expensive and resource-heavy – shows the least progress in the MPOWER monitoring programme (**O**ffering help).

The emphasis has become focused on demand reduction programmes, such as public prevention campaigning, warning label requirements, legislation to ban smoking in public places and restrictions on sales to minors. Tobacco control seems to have reached a consensus that tax rises deliver fewer smokers; in response, Bloomberg Philanthropies’ work has become increasingly focused on the ‘**R**’ (**R**aise taxes) of MPOWER, for example by providing funds that aim to shape LMIC’s tobacco tax regimes.

The important thing to recognise about the interventions favoured by Bloomberg Philanthropies and the WHO is that they are all quick *output* wins. The *outcomes* might be very different. The total number of smokers has remained largely unchanged since 2000, despite MPOWER being launched 15 years ago. For LMIC, a combination of lack of resources, other more pressing health demands, creaking infrastructure, pressure from vested interests and a lack of political will, conspire to undermine real progress in improving health harms from smoking.

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¹⁹⁸ Clift, 2014, p. 14.

¹⁹⁹ WHO. (2021). *WHO report on the global tobacco epidemic 2021. Addressing new and emerging products*. World Health Organization. <https://www.who.int/teams/health-promotion/tobacco-control/global-tobacco-report-2021>.

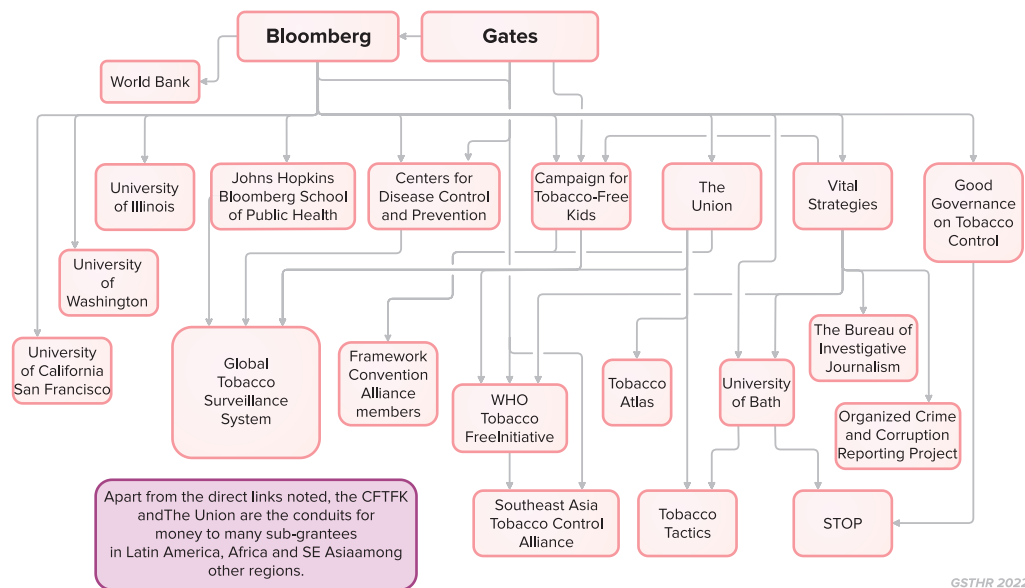
²⁰⁰ WHO, 2021.

Funding is available – but only for goals inimical to reducing harm

Despite the lack of tangible progress, it would nevertheless still be in line with philanthropic goals and the principles of global public health if funding and resources continued to be expended on trying to reduce the harms to smokers of combustible tobacco products.

Yet many would argue that this is not what is happening. A major criticism of Bloomberg Philanthropies is the lack of transparency on how funding decisions are made and how money is spent across its programmes. But the scale of Bloomberg Philanthropies' influence can be seen from the estimated \$1 billion that has been spent on tobacco control. Some of this is specifically focused on halting the development of tobacco harm reduction, for example, the \$160 million campaign against flavoured e-liquids in the US.

The diagram below shows just how intertwined international tobacco control agencies have become with funding from Bloomberg.²⁰¹ The primary conduits, particularly now for international activities focused in LMIC, are the Campaign for Tobacco-Free Kids (CTFK) and The International Union Against Tuberculosis and Lung Disease (commonly referred to as The Union).



Bloomberg Philanthropies' funding criteria specifically excludes the provision of support for smoking cessation services

Why the CTFK? In a revealing comment to Jamie Ducharme for her book about JUUL, Kathy Henning, who leads on Bloomberg's public health programmes, stated: "The priority of Bloomberg Philanthropies is to protect kids... Whether or not there is a role for these products for older adults who are highly addicted...that's not the focus of our campaigns".²⁰² To underline the point, Bloomberg Philanthropies' funding criteria specifically excludes the provision of support for smoking cessation services.

As we have seen, the US government's own statistics do not support the argument that the country is experiencing a 'teen vaping epidemic'. No other country has made similar claims supported by data about its own adolescent population. But in the world of politics, protecting hypothetical young people from hypothetical vaping is a win-win.

²⁰¹ For more detail about the global Bloomberg funding network see Shapiro, 2020.

²⁰² Ducharme, 2022, p. 151.

Which politician, especially in LMIC, is going to challenge the narrative about kids – especially if much-needed funds are on the table?

As US teen smoking has hit historical lows, the CTFK needed a new mission. This is the same for other tobacco control organisations; as smoking in more affluent countries has declined, anti-tobacco agencies are needing to find new battles to fight. Norwegian criminologist Nils Christie described this adeptly as ‘the good enemy’ in his book about Norwegian drug policy. He wrote: “Enemies aren’t always a threat, they can also be very useful. Enemies unite opposite sides, make it possible to change priorities, make it possible to focus all attention on just a small portion of reality and to forget everything else.”²⁰³

The new war on nicotine exemplifies this neatly. Attention has switched to SNP and the alleged threat they pose; they have become the ‘good enemy’ and usefully deflect attention away from the failed attempts to reduce death and disease from smoking. Moreover, in the case of the CTFK, it has found a new lease of life and significant funding streams by working overseas.

In tandem with the Union, the CTFK is now actively seeking to influence sovereign national tobacco control policies by calling for outright SNP bans in LMIC, where smoking rates are still sky high and rising. Sometimes this attempt at ‘neo-colonialism’ is exposed. The Philippine Parliament launched an enquiry into the potentially illegal funding received by the Philippine Federal Drug Administration from Bloomberg Philanthropies.²⁰⁴ A similar issue was uncovered in Panama, host nation for the next COP meeting; the Coordinator of the National Tobacco Control Commission of the Ministry of Health was revealed to have been in receipt of funds from Bloomberg Philanthropies in her capacity as founding member and coordinator of international relations of the Panamanian Coalition Against Smoking – a clear conflict of interest.²⁰⁵

In many cases, it seems, all that is required to convince politicians, the media and wider society about the ‘evils’ of SNP is to say ‘don’t forget the lies that Big Tobacco have told in the past’. One thing that unites Bloomberg Philanthropies, the WHO and the FCTC Secretariat is their antipathy to the tobacco industry. There is resistance to any insight that the industry could be part of the solution.

Intransigence in the face of innovation

With Bloomberg Philanthropies funding earmarked for demand reduction activities solely aimed at preventing the uptake of smoking among children and young people, it appears that the overall goal of reducing health harms from smoking among existing adult smokers has been neglected. What makes WHO opposition to THR so problematic is that the agency remains, particularly in LMIC, a trusted and credible source of global health policy and technical advice.

Since the 1970s, the direction of travel at a global health level was to try and generate consensus on tackling the growing death and disease from smoking. At that time, public health faced intransigence, opposition and denial by the tobacco industry.

Which politician, especially in LMIC, is going to challenge the narrative about kids – especially if much-needed funds are on the table?

In tandem with the Union, the CTFK is now actively seeking to influence sovereign national tobacco control policies by calling for outright SNP bans in LMIC

the overall goal of reducing health harms from smoking among existing adult smokers has been neglected

²⁰³ Christie, N., & Bruun, K. (1984). *The Good Enemy*. Universitetsforlaget. <https://osloliteraryagency.no/book/the-good-enemy/>, p. 56.

²⁰⁴ Manila Standard Business. (2021, January 27). Bloomberg faces mounting pressure to explain funding of Philippines’ FDA. *Manila Standard*. <https://manilastandard.net/business/biz-plus/345495/bloomberg-faces-mounting-pressure-to-explain-funding-of-philippines-fda.html>.

²⁰⁵ eldigitalpanama. (2022, May 4). Procurador de la Administración acoge queja contra la Coordinadora de la Comisión Nacional de Control de Tabaco del MINSA. *El Digital Panamá*. <https://eldigitalpanama.com/procuraduria-de-la-administracion-acoge-queja-contra-la-coordinadora-de-la-comision-nacional-de-control-de-tabaco-del-minsa/>.

there should be transparency between policymakers and the tobacco industry

Understandably, the narrative became enshrined that the tobacco industry is the enemy of public health and that all efforts must be made to neutralise its influence over domestic tobacco controls.

Article 5.3 of the FCTC states:

*“In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”*²⁰⁶

This is, of course, a highly appropriate statement – that there should be transparency between policymakers and the tobacco industry, and a clear assertion of how business between industry and governments should be conducted.

In 2008, however, the WHO published its first version of the ‘*Guidelines for implementation of Article 5.3*’.²⁰⁷ The Guidelines stated that no relationship between policymakers and the tobacco industry was possible. Principle One of the Guidelines declared: “There is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests.”

The Guidelines were published in the same year that the WHO made its first statement about e-cigarettes. Alongside a statement from the then Director-General of WHO’s Non-communicable Diseases and Mental Health Cluster, Dr Ala Alwan, the communiqué stated that “contrary to what some marketers of the electronic cigarette imply in their advertisements, the WHO does not consider it to be a legitimate therapy for smokers trying to quit”.²⁰⁸

In 2008, in terms of the available evidence at that time, this was likely to be accurate. The press statement does not rule out a future role for vaping devices for cessation: “WHO does not discount the possibility that the electronic cigarette could be useful as a smoking cessation aid. The only way to know is to test.”²⁰⁹

Crucially, at that time, the major tobacco companies were not involved at any level in the embryonic SNP industry. One former WHO employee says that the WHO was not that interested, possibly believing that e-cigarettes were just a passing fashion. However, a few short years later, it must have realised the existential threat posed by SNP, once the major tobacco companies claimed a stake.

Article 5.3 is now invoked way beyond the parameters of the FCTC, and is being used to promulgate a global cancel culture

A major block to progress in tobacco harm reduction is the way in which Article 5.3 is now subject to significant over-interpretation. Article 5.3 is now invoked way beyond the parameters of the FCTC, and is being used to promulgate a global cancel culture. This aims to exclude both researchers and their work investigating the possibilities offered by SNP and tobacco harm reduction from the global response to smoking. Exclusion is widespread, ranging from peer-reviewed journals, conference appearances or even attendance, and is frequently accompanied by implicit or explicit threats to individual careers and access to future funding. The WHO, FCTC Secretariat and their NGO and academic allies have extended the campaign against nicotine and SNP into a campaign against those holding views counter to their own.

As we have seen, in the 1970s, the WHO *had* conceived of the idea of the safer cigarette, and it had engaged with the industry during the consultations around the

²⁰⁶ WHO Framework Convention on Tobacco Control. Updated reprint 2004, 2005, § Article 5.3 (2005). <https://fctc.who.int/who-fctc/overview>, p. 7.

²⁰⁷ WHO Framework Convention on Tobacco Control. (2013). *Guidelines for implementation of Article 5.3*. <https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-5.3>.

²⁰⁸ *Marketers of electronic cigarettes should halt unproved therapy claims*. (2008, September 19). [News release]. World Health Organization. <https://www.who.int/news/item/19-09-2008-marketers-of-electronic-cigarettes-should-halt-unproved-therapy-claims>.

²⁰⁹ *Ibid.*

FCTC. As a result of the negotiations with the Parties to the Treaty, the WHO included harm reduction within its definition of tobacco control, and among the ‘Recitals’ in the Preamble to the Convention, it states that Parties are “determined to promote measures of tobacco control based on *current and relevant* scientific, technical and economic considerations [emphasis added]”.²¹⁰ The development of safer nicotine products would appear to be both “current” and “relevant”.

But in its 2013-2020 global plan for dealing with non-communicable diseases, there are several explicit references to the fact that the tobacco industry cannot be part of solving smoking-related disease. In contrast, no such exclusion is extended to the alcohol industry; by 2010, the WHO defined and endorsed the concept of alcohol harm reduction.²¹¹ WHO guidelines for reducing the harmful use of alcohol recognise the importance of working with the private sector and economic operators, i.e. the alcohol industry.²¹²

by 2010, the WHO defined and endorsed the concept of alcohol harm reduction

In his article for *Tobacco Reporter* on the implications of the ‘irreconcilable conflict’ principle for tobacco public health, Clive Bates underlines the problem of cultural inertia within WHO:

*“There should be one guiding principle for tobacco control: to reduce harm to the greatest extent and as quickly as possible. The irreconcilable conflict principle is a relic of the past and fails a modern reality check. It is the reason why tobacco control activists may now be doing more harm than good.”*²¹³

The position that the WHO holds as a globally trusted source of medical and public health information has enabled the publication of unarguably biased public messaging about SNP, messaging which has led to heavy criticism from global public health experts.²¹⁴

That public messaging has been backed by a series of papers casting doubt on SNP, commissioned and published by the WHO and the FCTC, and supplied to the Conference of the Parties (COP) Convention meetings. This has seen the FCTC Secretariat attempt to steer Parties towards the disproportionate regulations it believes would deliver a crippling blow to the tobacco industry.^{215 216}

But the FCTC is simply a framework agreement. Neither the WHO nor the FCTC Secretariat has any jurisdiction over what remains essentially a domestic public health issue. So how has the regulatory landscape for SNP rolled out over the last decade?

²¹⁰ WHO Framework Convention on Tobacco Control. Updated reprint 2004, 2005, 2005.

²¹¹ World Health Organization. (2013). *Global Action Plan for the Prevention and Control of NCDs 2013-2020* (Global Strategy). <https://www.who.int/publications-detail-redirect/9789241506236>.

²¹² World Health Organization. (2010). *Global strategy to reduce the harmful use of alcohol* (Guideline). <https://www.who.int/publications-detail-redirect/9789241599931>.

²¹³ Bates, C. (2020c). The Irreconcilable Conflict Principle. Is There a Governing Idea in Tobacco Policy? *Tobacco Reporter*. <https://tobaccoreporter.com/2020/11/01/the-irreconcilable-conflict-principle/>.

²¹⁴ The Counterfactual: World Health Organisation Bates, C. (2020a, January 30). *World Health Organisation fails at science and fails at propaganda – the sad case of WHO’s anti-vaping Q&A*. The Counterfactual. <https://www.clivebates.com/world-health-organisation-fails-at-science-and-fails-at-propaganda-the-sad-case-of-whos-anti-vaping-qa/>; Britton, J., Bogdanovica, I., McNeill, A., & Bauld, L. (2016). *Commentary On Who Report On Electronic Nicotine Delivery Systems And Electronic Non-Nicotine Delivery Systems*. <https://ukctas.net/news/commentary-on-who-report-on-ENDS&ENNDs.html>; Gunther, M. (2022, January 26). Michael Bloomberg loves data. Except when he doesn’t. *The Great Vape Debate*. <https://medium.com/the-great-vape-debate/michael-bloomberg-loves-data-except-when-he-doesnt-a6abb02d4d0a>.

²¹⁵ The prohibitionist/heavy regulation line was being pushed as far back as 2012 even though this paper admits that nothing like a proper evidence base existed. There was no acknowledgement of possible benefits, only possible harms. WHO Framework Convention on Tobacco Control, C. of the P. to the W. F. C. on T. C., fifth session, Seoul, Republic of Korea, 12-17 November 2012. (2012). *Electronic nicotine delivery systems, including electronic cigarettes: Report by the Convention Secretariat*. WHO IRIS. <https://apps.who.int/iris/handle/10665/75811>.

²¹⁶ For more information about the way COP meetings are conducted, see GSTHR. (2021). *Fighting the Last War: The WHO and International Tobacco Control* (GSTHR Briefing Papers). Knowledge•Action•Change. <https://gsthr.org/briefing-papers/fighting-the-last-war-the-who-and-international-tobacco-control/>.

Chapter 7: Regulating for health

Smoking-related mortality is a major global public health concern. In 1997, the Global Burden of Disease (GBD) study estimated that approximately three million people were dying annually from tobacco use, projecting a sharp increase in the decades to come. This analysis was sadly correct. The figure had risen to five million by 2002, with a WHO projection of eight million by 2030.²¹⁷ By 2021, the annual death toll, including those who died from exposure to secondhand smoke, had already exceeded eight million – virtually a decade earlier than expected.

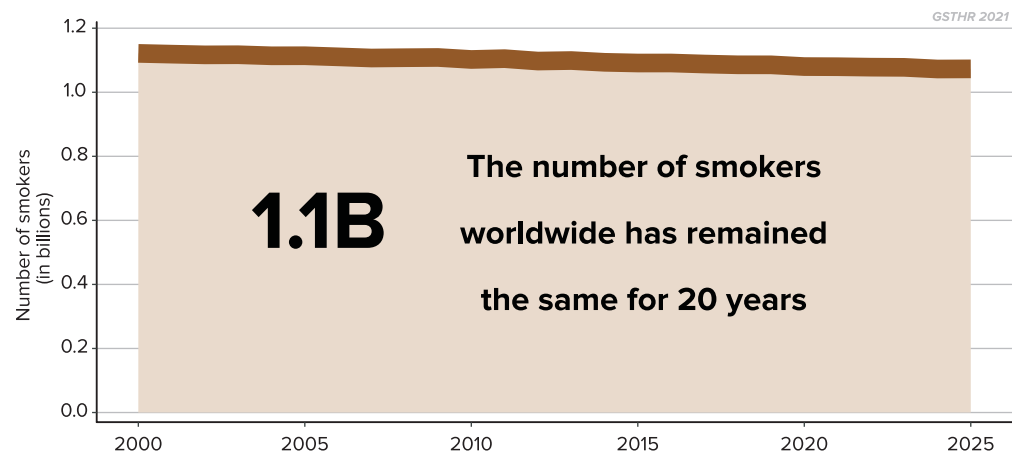
In 2001, Professor Richard Peto, a leading expert on tobacco-related mortality, estimated that one billion lives would be lost by the end of the 21st century and this forecast remains unchanged.²¹⁸ While there are deaths related to the use of oral tobacco products, the Institute for Health Metrics and Evaluation estimates that 99.9% of all tobacco-related deaths are caused by smoking.²¹⁹

As discussed in Chapter 2, the Framework Convention on Tobacco Control (FCTC) was adopted by the World Health Assembly in 2003 and it came into force in 2005. In 2001, when Professor Richard Peto made his prediction of a billion lives lost by 2100, there were approximately 1.1 billion smokers worldwide. In 2022, 17 years after the FCTC was enacted, there remain 1.1 billion smokers, of whom an estimated 80% live in LMIC.

Several countries – mainly LMIC – refer explicitly to the FCTC in framing their domestic tobacco control legislation. Aside from the impacts of increased taxation, there is limited evidence that the Convention has had a demonstrable impact on reducing cigarette consumption, and, by implication, little impact on reducing the deaths and disease related to smoking.²²⁰

In 2022, 17 years after the FCTC was enacted, there remain 1.1 billion smokers

there is limited evidence that the Convention has had a demonstrable impact on reducing cigarette consumption



Data source: WHO. (2019). WHO global report on trends in prevalence of tobacco use 2000–2025, third edition. World Health Organization. <https://www.who.int/publications/i/item/who-global-report-on-trends-in-prevalence-of-tobacco-use-2000-2025-third-edition>

GSTHR: Fighting the last war – the WHO and international tobacco control (2021), pg 9. K-A-C, London. <https://gsth.org/resources/thr-reports/fighting-the-last-war/>

²¹⁷ Loncar, D., & Mathers, C. D. (2005). Updated projections of global mortality and burden of disease, 2002-2030: Data sources, methods and results. *World Health Organization Report*.

²¹⁸ Peto, R., & Lopez, A. D. (2001). Future worldwide health effects of current smoking patterns. In C. E. Koop, C. E. Pearson, & M. R. Schwarz (Eds.), *Critical Issues in Global Health* (pp. 154–161). Wiley. <https://espace.library.uq.edu.au/view/UQ:114032>.

²¹⁹ Ritchie, H., & Roser, M. (2013). Smoking. *Our World in Data*. <https://ourworldindata.org/smoking>.

²²⁰ Hoffman, S. J., Poirier, M. J. P., Katwyk, S. R. V., Baral, P., & Sriharan, L. (2019). Impact of the WHO Framework Convention on Tobacco Control on global cigarette consumption: Quasi-experimental evaluations using interrupted time series analysis and in-sample forecast event modelling. *BMJ*, 365. <https://doi.org/10.1136/bmj.l2287>.

As discussed in the previous chapter, the Bloomberg-funded WHO MPOWER programme claims 5.3 billion people are ‘protected’ or ‘covered’ by at least one MPOWER measure to the ‘highest level of achievement’. However, globally, the gap between the enforcement of tobacco control measures, and the reality of a continuing public health crisis caused by smoking, is self-evident. This has been further demonstrated by Lars Ramström’s 2022 study showing that the national availability of snus is clearly associated with lower rates of tobacco-related mortality in Europe, while the implementation of MPOWER measures is not (discussed in Chapter 2).²²¹

In earlier chapters, we explored some of the disruption that the emergence of safer nicotine products has caused to the tobacco industry. Understandably, it has also been highly disruptive to policymakers and politicians around the world, who hold responsibility for tackling the ongoing public health crisis of smoking-related death and disease in their countries using legislative and regulatory instruments. Over time, they have become used to enacting policies that are aimed at discouraging smoking, through banning tobacco advertising, increases in taxation on tobacco products, the adoption of warning labels, and public smoking bans.

the gap between the enforcement of tobacco control measures, and the reality of a continuing public health crisis caused by smoking, is self-evident

the emergence of safer nicotine products has [understandably] been highly disruptive to policymakers and politicians around the world



Many countries now have public smoking bans in force.
Credit: Cristian Guerrero on Unsplash.

The emergence of safer nicotine products has posed a number of challenges for those responsible for national and international tobacco control policies, and continues to do so today. The questions are manifold. While some form of control and regulation is evidently necessary, should new nicotine-containing products be treated in the same way as existing tobacco products? Is it possible or desirable for regulations and taxation to reflect their reduced health risk to consumers in comparison to combustible cigarettes? And what would be the impacts of various regulatory pathways on moving individuals away from smoking?

²²¹ National availability of snus is clearly associated with lower rates of mortality attributable to tobacco – while country-level implementation of WHO tobacco control measures is not. Ramström, L. M. (2022). *New research*. KAC-Communications, Global Forum on Nicotine 2022 - 16-18 June. <https://gfn.events/new-research>.

Harm reduction is complementary to, and not mutually exclusive from, other tobacco control interventions

Governments should make it as easy as possible for people who smoke [...] to switch

Risk-proportionate regulation is a way of regulating for better public health

Harm reduction is complementary to, and not mutually exclusive from, other tobacco control interventions. In this light, the advent of SNP provides a new exit strategy for adults who smoke and for whom NRT or other cessation strategies have not proved successful. As we have seen in previous chapters, these products enable people who wish to continue to consume nicotine to do so without the attendant risks of smoking.

To fulfil the global public health potential of a tobacco harm reduction approach, a strategy pursuing *risk-proportionate regulation* is required. Evidence-based tobacco control policies should continue in order to discourage smoking, encourage smoking cessation, and prevent initiation. *In addition*, governments should make it as easy as possible for people who smoke – and who cannot quit, or want to continue using nicotine – to switch away from combustibles to products that the evidence base shows are significantly less risky to health.

In order to facilitate this, safer nicotine products need to be treated as consumer products with proper consumer safety regulations in place. Products should not be banned outright. Nor should they be subject to *de facto* bans, such as those that result when they are categorised as medical devices or products, or when specific elements of their use are prohibited or restricted, such as with flavour bans for vaping liquids.

In pursuit of public health gains, safer nicotine products should not be treated the same as combustible tobacco products. If they are taxed, this should be at substantially lower levels than cigarettes. Governments should ensure that safer products are both available and affordable to people who want to switch to them. This creates an environment conducive to switching away from combustible cigarettes to safer products. In turn, manufacturers can then ascertain which specific products are appropriate and accessible in different countries.

People who cannot quit smoking, or who do not want to stop using nicotine, should be empowered to make decisions about their own health. They need access to evidence-based information from trusted sources on the benefits of switching. Policymakers should therefore communicate the benefits of switching away from smoking. Alternatively, or in addition, governments should allow manufacturers to share information with people who smoke about the relative safety of SNP in comparison with continued use of combustible cigarettes.

Let us now consider what progress has been made towards the introduction of risk-proportionate legislation for SNP.

International tobacco control leadership remains opposed to THR

To date, all the indications are that the WHO prefers countries that are Parties to the Convention to treat safer nicotine products as being similar to combustible tobacco, with little recognition that they are significantly safer than smoking. This is evidenced both in reports and public statements by the WHO, and in papers and reports to the Conference of the Parties emanating from the FCTC Secretariat.²²²

²²² For further detail on the history of how the WHO and the FCTC COP has responded to the emergence of safer nicotine products, see the GSTHR report *Fighting the last war: the WHO and international tobacco control*, GSTHR, 2021, pp. 32–38.

Health officials in many government ministries around the world are – naturally – confused by the conflicting information they receive about SNP and governments often announce that they will act against SNP. This may be based on WHO statements, for example, that there is a lack of evidence that SNP help people to quit smoking, despite the considerable number of independent studies published to the contrary.

Many governments have also been influenced by the long-uncorrected theory that the spate of severe lung injuries in the US in 2019 were caused by vaping nicotine, and not an additive in illicit, unregulated THC e-liquids (see the discussion of EVALI-related misinformation in Chapter 5). And, without the context of a concurrent decline in US youth smoking, the spectre of a so-called US ‘teen vaping epidemic’ (again, see Chapter 5) has prompted reactions in countries where no epidemiological evidence about teen use exists.

Given that the WHO, its partners in the FCTC Secretariat, and NGO allies and funders predominantly based in the US, have recommended that governments follow a prohibition track, politicians may feel obliged to signal intent, by degrees of public health posturing about ‘tackling the threat’ of SNP. In some LMIC, western NGOs have taken advantage of uncertainty and doubt to campaign that the best (and easiest) approach is to ban everything. A straightforward prohibition approach lets politicians and officials off the hook while earning plaudits – and even awards – from the WHO.²²³

At the biennial FCTC COP meetings, decisions are taken by consensus, and voting is very rare.²²⁴ There is peer pressure on delegates not to challenge the status quo; they have no wish to be publicly embarrassed, or have their country singled out for criticism.

The global vs the national picture

Overall, despite the international nature of the FCTC, tobacco control laws and policies are a domestic issue determined by national governments. Of course, it would be impossible to give a detailed narrative on the whole global landscape in this report. However, the Global State of Tobacco Harm Reduction Database provides detailed individual profiles for over 200 countries and regions. National level data gives insights into the extent of the tobacco-related health crisis, as well as the state response to, and population use of, safer nicotine products.²²⁵

Currently, 75 countries regulate the sale of vaping products. 84 countries have no specific laws or regulations on nicotine vaping products while 36 have banned them altogether. In some of these countries, there is no vaping market to speak of; in others, people who vape – or who might switch from smoking to vaping – are left at risk of buying poor quality or unsafe products on illicit markets.

Heated tobacco products (HTP) are banned in 14 countries. There are 39 countries with regulations permitting their sale, although market data suggests they may be sold in up to 52 countries. 38 countries ban the sale of snus.

No countries currently ban the sale of combustible cigarettes.²²⁶

Health officials in many government ministries around the world are – naturally – confused by the conflicting information they receive about SNP

politicians may feel obliged to signal intent, by degrees of public health posturing about ‘tackling the threat’ of SNP

84 countries have no specific laws or regulations on nicotine vaping products while 36 have banned them altogether

Heated tobacco products (HTP) are banned in 14 countries

38 countries ban the sale of snus

No countries currently ban the sale of combustible cigarettes

²²³ In 2022, a WHO Director-General Special Award was given to the President of Mexico, Mr. Andrés López Obrador. At the presentation of the award, Obrador also signed the decree which prohibited the ‘circulation and marketing’ of vaping products. *World No Tobacco Day 2022 awards—The winners*. (2022, May 27). World Health Organization, Departmental News. <https://www.who.int/news/item/27-05-2022-world-no-tobacco-day-2022-awards---the-winners>.

²²⁴ For more on the processes of the COP, see the GSTHR Briefing Paper, *The Framework Convention on Tobacco Control (FCTC) Conference of the Parties (COP): An explainer* (GSTHR Briefing Papers). (2021). Global State of Tobacco Harm Reduction. <https://gsth.org/briefing-papers/september-2021/>.

²²⁵ To access the GSTHR’s ‘Global smoking and tobacco harm reduction database’, go to <https://gsth.org/countries/>

²²⁶ For current information on the number of countries that control, regulate or have enacted bans on SNP, visit the GSTHR website at: <https://gsth.org/faq-smoking-and-nicotine/>

Digging deeper, a vast range of regulatory and legislative policies relating to SNP are revealed. The differing responses include total bans, products that are controlled as medical devices, as tobacco products or regulated as consumer products.

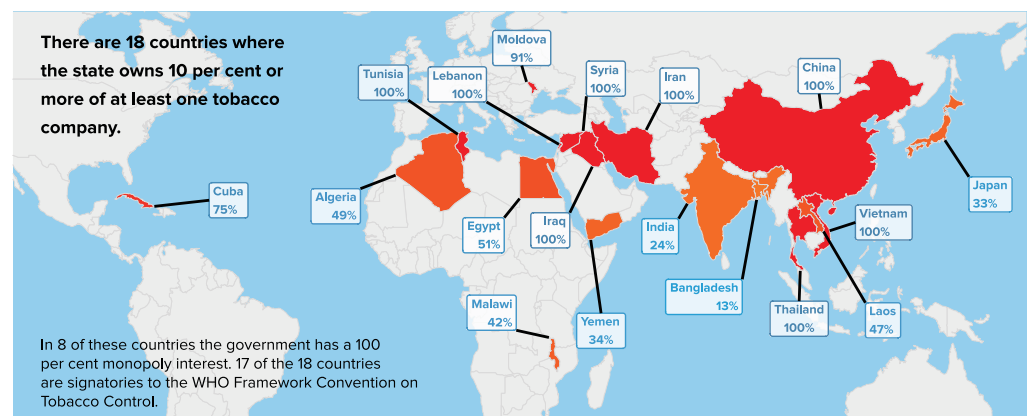
Some countries ban the domestic sale of SNP and/or various types of advertising, for example, media, point of sale, or billboards. There are also policies that target consumers more directly – for example, through bans on the possession of various SNP products, bans on public and/or indoor vaping, bans on personal importation and/or buying products online.

If SNP are controlled as tobacco products, this may mean that they are taxed as heavily as cigarettes. There is also an increasing trend to ban or severely restrict flavours (usually to tobacco, mint and menthol). These are often enacted on the grounds that flavours attract young people at a population level. While evidence to support this assertion is scant, there is strong evidence to support the important role that flavours play in encouraging adult smokers to switch.²²⁷

In many countries, health ministries hold less political influence than their colleagues in the national treasuries, or those departments concerned with finance, economics and taxation. It was suggested by one of the US FCTC negotiators, Greg Jacob, that health officials saw the FCTC as an aid to push through domestic tobacco control policies.²²⁸ But over time, it is arguable that the subtext of domestic financial interests have become more dominant at the COP meetings.

In the introduction to this report, we highlighted whose vested interests were threatened by SNP. Because of the profits to be made selling cigarettes, arguably the availability of SNP does not (yet) pose a huge threat to the profits of multinational tobacco companies.

It is possible that governments with a stake in domestic tobacco industries may take this into account when developing policies on SNP. Governments in 18 countries have a monopoly on, or significant stake in, the domestic tobacco industry; 17 of those 18 countries are signatories to the WHO FCTC.



There are also the interests of tobacco farming to consider. The top four tobacco producers in the world are China, India, Brazil, and the USA, with Turkey and Argentina joining them in the top ten. Of these, four have outright bans on SNP.

²²⁷ Friedman, A. S., & Xu, S. (2020). Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. *JAMA Network Open*, 3(6), e203826. <https://doi.org/10.1001/jamanetworkopen.2020.3826>; Russell, C., McKeganey, N., Dickson, T., & Nides, M. (2018). Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduction Journal*, 15(1), 33. <https://doi.org/10.1186/s12954-018-0238-6>.

²²⁸ Jacob, G. (2004). Without Reservation. *Chicago Journal of International Law*, 5(1). <https://chicagounbound.uchicago.edu/cjil/vol5/iss1/19>.

What follows is a series of snapshots and country contrasts, to highlight some of the different ways that countries have regulated safer nicotine products.

Brazil



Brazil, home to approximately 22 million current smokers (GSTHR Database).
Credit: Raphael Nogueira on Unsplash.

In 2022, the national Brazilian health agency Anvisa launched a consultation on the existing SNP laws, with a recommendation that the government should not only retain the current blanket prohibitions, but launch “educational and informational actions”.

One informant to this report from Brazil suggested that the strength of hostility among some government departments towards the traditional tobacco industry was enough to spill over and drive prohibitionist policies towards SNP, with this work being supported by Bloomberg-funded NGOs in the country.

As we have said, however, in countries that depend on tobacco for revenues and employment, there are often competing interests and forces in play. In 2010, Brazil established the National Commission for the Implementation of the WHO Framework Convention on Tobacco Control and its Protocols (CONICQ). It included representatives from every government department with interests and obligations under the Convention.

In 2014, the American Cancer Society (ACS) published a report assessing the political economy of tobacco in Brazil. One informant for the ACS report, from the Ministry of Agrarian Development, noted that, beyond their ministry, the only members supporting tobacco control within CONICQ were those from Health and External Affairs. According to the informant, “all others don’t support [it]”. A second informant suggested that Brazil’s Sectorial Chamber on Tobacco, another arm of government, works to protect the commercial interests of the tobacco sector, and that it is politically stronger than CONICQ.²²⁹

in countries that depend on tobacco for revenues and employment, there are often competing interests and forces in play

²²⁹ Bialous, S., da Costa e Silva, V. L., Drope, J., Lencucha, R., Grady, B., & Richter, na. (2014). *The Political Economy of Tobacco Control in Brazil: Protecting Public Health in a Complex Policy Environment*, p. 25.

Turkey



There are approximately 18 million people who currently smoke in Turkey (GSTHR Database).
Credit: Meg Jerrard on Unsplash.

Turkey was the first country to act against SNP back in 2008: the population went on to consume more than one trillion cigarettes in the next nine years, costing Turkish consumers around \$86bn according to Turkish media and accounting for more than half a million deaths in same period.^{230 231} A report from the World Bank offered this analysis of the Turkish market for cigarettes:

*“Turkey’s government increased tobacco tax revenue and lowered tobacco consumption by increasing tobacco tax rates significantly between 2003 and 2013. However, both per capita tobacco consumption and total cigarette sales in Turkey have begun to increase again in recent years. Although the recent rise in cigarette sales might be attributed to the influx of Syrian refugees into Turkey, our analysis reveals other factors. First, average cigarette price increased more slowly than inflation. Thus, cigarettes became relatively cheaper compared to other goods and services. Second, cigarette affordability has increased. Turkey’s economy has grown steadily, and the demand for cigarettes has risen as the population has become wealthier over time”.*²³²

In 2015 alone, the Turkish government earned over \$12bn in tobacco tax revenues

In 2015 alone, the Turkish government earned over \$12bn in tobacco tax revenues. Just five years earlier, in 2010, the government of Turkey received a WHO award for “the struggle against smoking”.²³³

²³⁰ Daily Sabah. (2018, February 8). \$154.1B went up in ‘smoke’ over past decade due to Turkish tobacco addiction, data show. Daily Sabah. <https://www.dailysabah.com/turkey/2018/02/08/1541b-went-up-in-smoke-over-past-decade-due-to-turkish-tobacco-addiction-data-show>.

²³¹ Smoking, vaping, HTP, NRT and snus in Turkey. (2022). Global State of Tobacco Harm Reduction. <https://gsth.org/countries/profile/tur/>.

²³² Cetinkaya, V., & Marquez, P. V. (2017). *Tobacco Taxation in Turkey: An Overview of Policy Measures and Results*. World Bank. <https://doi.org/10.1596/26387>.

²³³ In 2010, the Turkish PM received a WHO Award for the “struggle against smoking”. *WHO awards Turkish PM for struggle against smoking*. (2010). worldbulletin.dunyabulteni.net/. <https://worldbulletin.dunyabulteni.net/general/who-awards-turkish-pm-for-struggle-against-smoking-h61507.html>.

China



Despite being the global vaping manufacturing centre, vaping rates in China remain very low.
Credit: Zhang Kaiyv on Unsplash

The Chinese government has a state tobacco monopoly, servicing the cigarette demands of its 300 million smokers with nearly 1000 different brands. The Chinese National Tobacco Company is the world's biggest tobacco company, on a scale that outstrips all the big, recognisable tobacco industry names combined.

As seen in Chapter 3, there are now also thousands of Chinese companies that together form the world's major supply centre for vaping, providing 90% of global vaping products. To date, the Chinese domestic market is small. But, as noted in Chapter 3, new regulations may yet have an impact. Reuters reported in April 2022 that the State Tobacco Monopoly Administration would tighten control over the Chinese vaping industry and manage the scale of e-cigarette production “to prevent overcapacity”.²³⁴

“Foreign investment in the retail of e-cigarette products would be banned”, the regulator said, and it would “review foreign investment in production, requiring e-cigarette firms that want to list in China or abroad to obtain pre-approval”. In 2021, the tobacco monopoly law was amended to include vaping products, and the State Tobacco Monopoly Administration “ruled that e-cigarette companies may only sell their products through authorised channels”, barring vendors from selling products in flavours other than tobacco.²³⁵

There is a view that the Chinese government wants to control the industry to initiate its own standards regime, similar to the EU CE electrical standard. This might enable China to exert some influence on the vaping market in countries that currently have no such standards. Ultimately, however, what this may mean for vaping products exported from China remains unclear.

The Chinese government has a state tobacco monopoly, servicing the cigarette demands of its 300 million smokers with nearly 1000 different brands

²³⁴ China issues draft rules to control e-cigarette production. (2022, April 25). *Reuters*. <https://www.reuters.com/article/china-ecigarettes-idAFL2N2WN0RL>.

²³⁵ *Ibid.*

India



India enacted a ban on vaping in 2019.
Credit: Naveed Ahmed on Unsplash.

Around 120 million people smoke in India, but only about 8% smoke commercially manufactured cigarettes. Most consume locally produced cigarettes called ‘bidis’ or similar local combustibles. However, India is also home to millions of tobacco users who consume traditional smokeless tobacco (SLT) products. In 2010, one in four of the Indian population used such products. Due to their contents and manufacturing processes, these traditional SLT products pose very high risks to health, and India has high rates of oral cancer as a consequence.²³⁶

The tobacco industry is the largest commercial sector in India

The tobacco industry is the largest commercial sector in India. It employs around 45 million people, both directly and indirectly, across all sectors of the business. Annually, India exports some 800 million kilos of tobacco.²³⁷

With one million deaths a year from smoking and oral tobacco-related diseases, it would be of clear public health benefit to enact risk-proportionate SNP regulation in India. Instead, in 2019, the country banned e-cigarettes.²³⁸

Given the importance of the tobacco industry to the Indian economy, it is interesting to note that the press statement on the ban came from the finance minister, who declared, “The decision was made keeping in mind the impact that e-cigarettes have on the youth of today.” According to the latest Global Youth Tobacco Survey data for India, around seven million school students had used tobacco in the previous 30 days, as opposed to around 3,000 who had ever tried an e-cigarette (including one-time use).²³⁹

²³⁶ For further information about smokeless tobacco use in Asia, see the GSTHR report, *Tobacco Harm Reduction: A Burning Issue for Asia*. (2020). Knowledge-Action-Change. <https://gsthr.org/reports/tobacco-harm-reduction-a-burning-issue-for-asia/>.

²³⁷ Sharma, R. K. (2021, June). Tobacco Industry in India: Prospects and Challenges. *Just Agriculture*, 1(10). <https://justagriculture.in/files/newsletter/2021/june/119.%20Tobacco%20Industry%20in%20India-Prospects%20and%20Challenges.pdf>.

²³⁸ Agence France-Presse. (2019, September 18). India bans e-cigarettes as global vaping backlash grows. *The Guardian*. <https://www.theguardian.com/society/2019/sep/18/india-bans-e-cigarettes-as-global-vaping-backlash-grows>.

²³⁹ *Global Youth Tobacco Survey (GYTS)—4. Fact Sheet, India 2019*. (2019). International Institute for Population Sciences. https://www.iipsindia.ac.in/sites/default/files/other_files/GYTS4_India_Fact_Sheet.pdf.

Japan



Japan has seen combustible cigarette sales plummet since 2016.
Credit: Jezael Melgoza on Unsplash

In Japan, the tobacco industry was a government monopoly until 1985, and the state still held appreciable stocks in 2013, when a sell-off reduced its holding to one third. Compared to many developed economies, the Japanese government has lagged behind on enacting mainstream tobacco controls.

However, cigarette sales have fallen sharply, with data showing they have dropped by close to 43% in the five years between 2016 and 2021. This rapid reduction in cigarette consumption has in Japan never been seen before anywhere in the world. Experts are attributing the reduction in the combustible market to the legal availability, promotion and widespread adoption of heated tobacco products by smokers looking to switch. Market analysis suggests that Japan has the world's biggest heated tobacco market, with around 85% of global sales.²⁴⁰ This is good public health news, yet it is a story that is rarely told.

Interviewed for *Filter* magazine in 2021, David Sweanor, tobacco industry expert and chair of the Advisory Board for the Centre for Health Law, Policy, and Ethics at the University of Ottawa, said: "All Japan has done is not obstruct the efforts for this single category [of safer nicotine product], and still we have the most rapid decline in cigarette sales that we've ever seen".²⁴¹ Sweanor's point raises the question of what more could be accomplished with a favourable environment for THR.

Yet even in Japan, where adoption of heated tobacco products has shown that, if possible, people will switch away from smoking, a risk-proportionate regulatory system is not applied equally across all safer nicotine product categories. It is illegal to sell e-liquid containing nicotine, and vaping devices that contain nicotine are designated as medicinal products. This does not provide an attractive incentive for smokers to switch. People who wish to vape are permitted to import up to one month's supply of nicotine-

This rapid reduction in cigarette consumption has in Japan never been seen before anywhere in the world

²⁴⁰ Norcia, A. (2021, May 13). Why Japan's Huge Drop in Smoking Is a Story Prohibitionists Ignore. *Filter*. <https://filtermag.org/why-japans-huge-drop-in-smoking-is-a-story-prohibitionists-ignore/>.

²⁴¹ Ibid.

containing vaping devices for their own use. Current vaping prevalence remains very low, at approximately 1.9 per cent of the adult population.²⁴²

The US



There are an estimated 9.1 million people who vape in the US (GSTHR Database).
Credit: Nik Shuliahin on Unsplash

In 2009, the Federal Drug Administration (FDA) was granted oversight on the regulation of most combustible and smokeless tobacco products. This was extended in 2016 to cover all tobacco products, including vaping products. The FDA issued a 'deeming rule', which required that any new product on the market since 2007 must go through a Pre-Market Tobacco Application (PMTA) process to stay on the market, and also make a Modified Risk Tobacco Product Application (MRTPA) to make health claims of relative risk compared to smoking. As there were no SNP available before 2007 (apart from safer forms of oral tobacco), this meant that all SNP had to go through what turned out to be complicated and highly expensive processes.

the US FDA has been working to limit access to SNP [and] pursuing a twin track, with proposals to introduce very low nicotine cigarettes

Yet throughout the period that the FDA has been working to limit access to SNP, it has also been pursuing a twin track, with proposals to introduce very low nicotine cigarettes (VLNC). The Administration first promoted the idea back in 1994. In 2017, it announced the intention to adopt VLNC as the central plank of its tobacco and nicotine control strategy, and in 2022, the proposal was given legislative teeth. A policy of favouring VLNC appears to many to be counterintuitive to public health goals.

It is now widely accepted that nicotine is the main reason why people smoke. Why would smokers continue to buy cigarettes containing vastly reduced amounts of nicotine? The proposal relies on consumers buying VLNC, being less satisfied by the products and therefore smoking less until eventually they give up entirely. The introduction of VLNC into the FDA's policy mix appears based more on wishful thinking than credible public health evidence.

²⁴² *Smoking, vaping, HTP, NRT and snus in Japan.* (2022). Global State of Tobacco Harm Reduction. <https://gsth.org/countries/profile/jpn/>.

There are also concerns that perverse consequences may result. For example, it is possible that some people who switch to VLNC may end up smoking more to extract what little nicotine remains, so putting themselves at even more risk of the harms associated with combustion.

Evidence also suggests that people think VLNC are safer than regular combustible cigarettes, believing them to be less carcinogenic.²⁴³ This belief is an example of nicotine illiteracy. The FDA's VLNC policy therefore acts against nicotine while retaining the smoke – and therefore the most harmful toxins – in combustible cigarettes. Inevitably, the illegal tobacco market will flourish, too. One study showed that people reported that they would start buying cigarettes from illicit sources, once they realised that the cigarettes on the regulated market would have up to 95% of nicotine removed.²⁴⁴

In a 2017 press statement, FDA Commissioner Scott Gottlieb stated that part of the Administration's plan was "to encourage the development of products that can deliver nicotine to currently addicted adult smokers without all of the harmful effects of combustion."²⁴⁵ It certainly does not appear as if this is the FDA's current plan. The FDA now appears focused on the issue of 'nicotine addiction', suggesting that their approach, politically at least, is aimed more at concerned parents than where the current problem really lies – among the 30 million US adults who smoke. If the intent was to help the smoking population to reduce their health harms, then the FDA would be doing all it could to smooth the path for people who smoke to switch to SNP. In this case, the VLNC argument would be redundant. With the introduction of VLNC, and simultaneous inhibition of access to safer products through the PMTA and MRTA processes, the overall tobacco control strategy of the FDA could now be described as the worst of both worlds.²⁴⁶

the overall tobacco control strategy of the FDA could now be described as the worst of both worlds

In its oversight of SNP, the FDA has faced a number of significant setbacks. As we saw in Chapter 3, the Administration failed to ban vaping imports back in 2009, and failed to gain control of the SNP market after the passing of the Family Smoking Prevention and Tobacco Control Act in the same year. It took a further five years for the final publication of the deeming regulations in 2016, with another grace period to 2021 for manufacturers to submit their product applications. And the FDA faced another obstacle in October 2021, when a judge stayed the FDA's Marketing Denial Order (MDO) against vaping company Triton. An MDO means the company must take its products off the market. Triton appealed, saying the FDA had shifted the goalposts by unveiling previously undisclosed decision criteria when issuing the Order. The judge was unimpressed with the specificity demanded by the FDA when it came to Triton's requirements to provide evidence, while issuing the MDO on the vaguest of reasons such as the youth 'vaping epidemic' and the alleged role of flavours in this.²⁴⁷

In 2022, JUUL had its market approval application rejected and was ordered to remove their products from the market. JUUL have launched a similar appeal against the FDA, saying the agency had failed to properly evaluate the evidence submitted.

In a bizarre turn of events, the FDA then said it would review its decision. Some

²⁴³ Byron, M. J., Jeong, M., Abrams, D. B., & Brewer, N. T. (2018). Public misperception that very low nicotine cigarettes are less carcinogenic. *Tobacco Control*, 27(6), 712–714. <https://doi.org/10.1136/tobaccocontrol-2017-054124>.

²⁴⁴ Hall, M. G., Byron, M. J., Brewer, N. T., Noar, S. M., & Ribisl, K. M. (2019). Interest in Illicit Purchase of Cigarettes Under a Very Low Nicotine Content Product Standard. *Nicotine & Tobacco Research*, 21(Supplement_1), S128–S132. <https://doi.org/10.1093/ntr/ntz159>.

²⁴⁵ Center for Tobacco Products. (2021). FDA's Comprehensive Plan for Tobacco and Nicotine Regulation. FDA. <https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation>.

²⁴⁶ In their paper on VLNC, David Abrams and Caitlin Notley argue that while they can be part of an overall smoking reduction strategy, the policy must co-exist with efforts on the part of government to encourage the availability of SNP. Abrams & Notley, 2020.

²⁴⁷ McDonald, J. (2021, October 26). Judges Reject FDA's 'Surprise Switcheroo,' Issue Stay to Triton. *Vaping360*. <https://vaping360.com/vape-news/111687/federal-court-issues-stay-to-triton/>.

observers concluded that in rejecting JUUL's market approval application, the FDA was punishing the company for its past mistakes, instead of acting as a result of rigorous scientific evaluation of their products.

The only products to receive marketing approval so far are those produced by Reynolds (for a vape product), PMI (for a heated tobacco product), and Swedish Match (for an oral product). This suggests the FDA is only comfortable dealing with large corporations and their legal teams, although an NJOY product has also earned FDA market approval. It remains to be seen what will happen to the significant US vaping industry, and to the many millions of American adults who have already switched from smoking to vaping.

The European Union



The EU Tobacco Products Directive has global as well as regional significance as a legislative model.
Source: Guillaume Périgois on Unsplash

One of the most extensive control regimes affecting all the countries in the European Union is that administered by the EU under the Tobacco Products Directive (TPD). The TPD has global as well as regional significance; firstly, as regulators worldwide look to it as a legislative model, and secondly, because the EU works closely with the WHO and the FCTC Secretariat, and so is influential at the COP. The tobacco control field does not operate in silos. There is considerable overlap and interconnectivity between tobacco control activity and actors, at global, regional and national levels.²⁴⁸

The TPD came into force in May 2014. There were moves, led paradoxically by the UK, to have e-cigarettes controlled as medicinal products. This did not happen. However, the TPD does limit e-liquid tank capacity in vaping devices to 2ml. Refill containers are limited to a maximum of 10ml, and e-liquid is subject to a nicotine limit of 20mg/ml.

Despite the clear clinical and epidemiological evidence of the role that national availability of snus plays in reducing smoking-related harms, the product remains banned across the EU except in Sweden, which – as previously noted – received an exemption as part of its agreement to join the EU.

²⁴⁸ EU TPD. (n.d.). European Tobacco Harm Reduction Advocates (ETHRA). Retrieved 11 October 2022, from <https://ethra.co/eu-tpd>.

A review of the TPD was published in 2021.²⁴⁹ A key document in determining the conclusions and direction of travel for THR was the opinion of the EU Scientific Committee on Health, Environment and Emerging Risks (SCHEER) concerning e-cigarettes. The report had a number of failings in the exploration of the harm reduction potential of vaping, ranging from a lack of risk comparison with combustible cigarettes, to over-emphasis on secondhand vapour, overplaying the uncertainty concerning long-term effects, exaggerating risk based on biomarkers rather than observable effects in the real world and ignoring countervailing evidence.²⁵⁰

But SCHEER was not the only actor in trying to influence EU politicians against THR. A freedom of information request from the Association of Swedish Snus Manufacturers revealed that the EU Health and Food Safety Commission (DG Sante) had made misleading statements about Member States' desire to ban tobacco-free nicotine pouches.

At a meeting in December 2021, DG Sante announced the results of an 'informal' survey of Member States. Only nine responses were received, with nicotine pouches legally available as consumer products in six countries. Two member states regulated pouches with medicinal products legislation, while four were considering regulating pouches under such legislation. Finland, the only one of the survey respondents to be identified publicly, was also the only member state that had specific regulations for nicotine pouches. However, at the meeting and in minutes available to the public, it was claimed that "most Member States have called for an EU-level legislation that regulates these products (including banning nicotine pouches)".²⁵¹

In a surprise move, however, in February 2022, the European Parliament voted to adopt the final report of the Special Committee on Beating Cancer. For the first time, vaping products have been recognised in the EU as helping people who smoke switch away from combustible cigarettes. And in contrast to the SCHEER Report, this report recommended that risk evaluations must compare SNP to continued smoking. Nevertheless, flavour bans are still on the table in some Member States and may feature in the next revision of the TPD.²⁵²

Contrasting the UK and Australia

Until recently, the UK has been tied to the regulatory limitations imposed by the EU TPD, some of which hamper the progress of THR using SNP. Even so, UK government health agencies and medical and public health NGOs have consistently supported THR in policy documents, clinical reviews and public statements, particularly the use of vaping products for smoking cessation.

In June 2022, the UK government Office of Health Improvement and Disparities published *The Khan review: making smoking obsolete*, an independent review considering the way forward for UK tobacco control policy.²⁵³ Many hoped the Khan

the EU Health and Food Safety Commission had made misleading statements about Member States' desire to ban tobacco-free nicotine pouches

vaping products have been recognised in the EU as helping people who smoke switch away from combustible cigarettes

UK government health agencies [...] have consistently supported THR, [...] particularly the use of vaping products for smoking cessation

²⁴⁹ Report From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products. (2021). European Commission. <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1621500846386&uri=COM:2021:249:FIN>.

²⁵⁰ Bates, C. (2020b, September 30). European Commission SCHEER scientific opinion on e-cigarettes – a guide for policymakers. *The Counterfactual*. <https://clivebates.com/european-commission-scheer-scientific-opinion-on-e-cigarettes-a-guide-for-policymakers/>.

²⁵¹ Landes, D. (2022, May 11). Docs expose DG SANTE 'duplicity' on nicotine pouch regulation. *Snusforumet*. <https://snusforumet.se/en/docs-expose-dg-sante-duplicity-on-nicotine-pouch-regulation/>.

²⁵² EU recognises tobacco harm reduction with the adoption of the BECA report. (2022, February 22). European Tobacco Harm Reduction Advocates (ETHRA), THR News. <https://ethra.co/news/102-eu-recognises-tobacco-harm-reduction-with-the-adoption-of-the-beca-report/>.

²⁵³ Khan, J. (2022, June 9). The Khan review: Making smoking obsolete. Department of Health, UK. <https://www.gov.uk/government/publications/the-khan-review-making-smoking-obsolete>.



The UK and Australia have taken divergent paths on tobacco harm reduction.
Credit: Aleksandra Aleshchenko on iStockPhoto

Review would provide the UK with a blueprint for a more ambitious approach, free of EU restrictions, in order to harness the potential of THR. This would include, for example, reducing the EU TPD restrictions on nicotine liquids to ensure they were appropriate for heavy smokers looking to switch, legalising the sale of snus to increase the range and choice of safer nicotine products on offer, and allowing the targeted promotion of the relative safety of these products in comparison with continued smoking. However, the Review very much retained the existing status quo.

Overall, the Review remains supportive of THR, but makes no recommendations to move away from EU restrictions. For example, on snus, Dr Khan concluded:

“During this review, I carefully examined the case for permitting snus on the UK market. I have listened to a range of views from stakeholders. I was struck by how differently the evidence is understood and how polarised the discussion can become.

“While snus offers tobacco companies a useful alternative to cigarettes, it offers little that is new to smokers in the UK. Given the range of tobacco-free alternatives that we already have readily available in the UK, I have not been persuaded that snus adds additional value.

*“Introducing a new tobacco product, albeit a less harmful one, should not be a priority for the government’s legislative time. Instead, the government must facilitate access to the various already available safer alternative nicotine products such as nicotine pouches (a tobacco-free equivalent of snus), maximising their value to help smokers to quit, without creating new risks to young people”.*²⁵⁴

The report goes on to say that with “such an array of tobacco-free alternatives already available (vapes, patches and gum) **the primary distinction** in government policy-making and regulation should be between nicotine products that do or do not contain tobacco” [emphasis added]. Nevertheless, despite the focus on tobacco-free products, the Review does recommend “further independent research” into heated tobacco products and that “manufacturers should be made to pay for independent toxicological testing”, with the government tracking and monitoring “the patterns of HTP use and population effects”. Armed with this information, Khan suggests,

²⁵⁴ Ibid.

“the government should ensure the regulatory framework is appropriate for these products”.²⁵⁵

For many in favour of the adoption of a broader tobacco harm reduction approach in UK policymaking, the Review exhibits a number of lost opportunities. But even so, the history of the UK’s policy response to safer nicotine products for tobacco harm reduction provides a strikingly different model of regulation in comparison to Australia.

Initially this is surprising to many observers, as both the UK and Australia have been leaders in the adoption of harm reduction measures to address drugs and HIV/AIDS since the 1980s across both government and public sector agencies. Drug harm reduction policies saw the UK register the lowest drug-related cases of HIV in Europe. Whereas Dr. Judy Pettingell concludes, in a paper titled ‘*Harmspeak: the origins of harm reduction in Australia*’, “The incorporation of a harm discourse into national drug policy represents a triumph for the health lobby. This achievement was assisted by the political strategies of some powerfully placed and enlightened medical figures”.²⁵⁶ Yet contemporary responses to harm reduction for tobacco have been diametrically opposed in Australia. Why?

As the opportunities offered by SNP began to become apparent, many UK tobacco control academics provided policymakers with evidenced-based research in support of THR, although it should be noted that, initially, some wanted vaping products controlled under medical regulations.

In the 2010s, John Britton, a professor of epidemiology and expert in smoking prevention and other causes of respiratory disease, influenced the supportive policy advice given to the then Prime Minister David Cameron by the Behavioural Sciences or ‘Nudge Unit’. Other important champions included Clive Bates, when he became Director of Action on Smoking and Health (ASH UK), and Martin Dockrell. Dockrell was a former head of policy at ASH, who had previously been involved in AIDS prevention, and went on to become tobacco policy lead at Public Health England (which has now been subsumed into the Office for Health Improvement and Disparities, where Dockrell still works). Collectively, the developing independent evidence was adopted by the UK government and many of the most important medical and public health agencies.

In Australia, the situation is very different. The only acknowledgement of harm reduction for tobacco in the Australian National Drug Strategy is NRT. The National Tobacco Strategy 2012–2018 (NTS), which is a sub-strategy of the National Drug Strategy, is still in force at the time of writing.²⁵⁷ The NTS states: “alternative nicotine delivery systems are products that have not been classified as safe and effective means of NRT”. The current NTS identifies vaping products as “the main type of alternative nicotine delivery systems on the market at present”.²⁵⁸ A new NTS for 2022–2030 is yet to be published.

As early as 2009, nicotine vaping liquid was designated as a Schedule 7 ‘dangerous poison’ in Australia. Under the regulatory framework currently in place, anyone wishing to access nicotine liquid for vaping products must go to a doctor and obtain

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²⁵⁵ Ibid.

²⁵⁶ Pettingell, J. *Harmspeak: The origins of harm reduction in Australia*. Undated article hosted on the Drugfree Australia website: https://www.drugfree.org.au/images/pdf-files/library/Needle_Syringe/HARMSPEAKTHEORIGINSOF'HARM%20REDUCTION'NAUSTRALIA.pdf

²⁵⁷ *National Tobacco Strategy 2012–2018. A strategy to improve the health of Australians by reducing smoking rates*. (2012). Australian Government Department of Health and Aged Care. <https://www.health.gov.au/resources/publications/national-tobacco-strategy-2012-2018>.

²⁵⁸ Ibid.

anyone wishing to access nicotine liquid for vaping products [in Australia] must go to a doctor and obtain a prescription

a prescription. In effect, this has led to a *de facto* vaping ban. Only nicotine-free liquids are available without a prescription, and these are controlled as tobacco products. Vendors who have flouted these restrictions have been prosecuted and fined, and e-liquids imported for personal use have been seized.²⁵⁹

The inevitable consequences of prohibition have been reported, with illegal vape shops opening, and the emergence of a bureaucratic muddle between state and federal authorities over jurisdiction.²⁶⁰ A raid on two storage units in Queensland in 2022 revealed thousands of unmarked vapes, with no indication of how safe these products might be. An Australian informant for this report wrote:

“Unregulated disposables are sold at a huge profit on social media, in convenience stores and tobacconists, and a small number of vape shops. Devices can be purchased for \$2-3 and are sold for \$25 or more.

“There is negligible enforcement of these illegal sales by the state health departments that are responsible. Many individuals [...] have made official reports, but action is rarely taken. Large shipments of these products are being imported and the Border Force has been given the power to intercept them, but very few interceptions are taking place. Imported products with nicotine are deliberately labelled as having 0% nicotine to evade detection.

“A survey by a popular Chinese vendor of 1200 Australian vapers found that 70.8% did not have a prescription. I contacted another major New Zealand supplier who told me last week that only 38% of customers supply a prescription. The law requires that all imported nicotine orders are accompanied by a prescription”.

Australian advocates for tobacco harm reduction within academic and clinical circles are somewhat at a loss to explain the situation. One possible explanation is fallout from some bitter struggles between the government, public health campaigners, and the tobacco industry. In 2010, for example, the Australian government announced that in future, all cigarettes would be sold in plain packaging with no branding and carrying graphic pictorial warnings. Philip Morris launched a flurry of litigation, perhaps in an effort to warn other jurisdictions of expensive consequences of similar actions. The company ultimately failed to get this decision overturned, both in the Australian courts and through the World Trade Organisation – something that was hailed as a great victory for tobacco control and public health.

a febrile political and media environment on tobacco control issues has persisted [in Australia]

It is possible that this experience has led to a refusal to accept that *any* products remotely connected to the tobacco industry could be of public health benefit. Unlike in the UK, there have been no “powerfully placed and enlightened medical figures” voicing support for THR within the academic, medical, or public health communities. Instead, there remains prominent and vocal opposition, driven in part by a number of public health campaigners who had been influential in actions taken against the tobacco industry in Australia. Some of these individuals had suffered harassment from the tobacco industry because of their opposition to industry goals. Unfortunately, a febrile political and media environment on tobacco control issues has persisted. In Australia in 2022, those advocating for tobacco harm reduction are now often similarly subject to harassment, this time from some campaigning for public health.

²⁵⁹ Berridge, V., Hall, W., Taylor, S., Gartner, C., & Morphet, K. (2021). A first pass, using pre-history and contemporary history, at understanding why Australia and England have such different policies towards electronic nicotine delivery systems, 1970s–c. 2018. *Addiction*, 116(9), 2577–2585. <https://doi.org/10.1111/add.15391>.

²⁶⁰ Doneman, P. (2022, April 7). Illegal vape and tobacco trade booms across Queensland amid ‘bureaucratic buck-passing’. *ABC News*. <https://www.abc.net.au/news/2022-04-08/illegal-vape-tobacco-trade-booming-in-queensland/100964858>.

New Zealand



The New Zealand Government has recently unveiled proposals it hopes will lead to smokefree status by 2025.
Credit: Aaron Birch on Unsplash

By contrast, Australia's near neighbour, New Zealand, has taken a more proportionate regulatory response to SNP. The key messages from the Ministry of Health have acknowledged the role of vaping in the country's overall journey towards being smokefree. Currently there are few restrictions on vaping products, apart from the requirement to have tamper-proof containers, warning labels and an 18-year-old minimum age requirement for sales.

Snus is banned in New Zealand, as the importation and sale of any tobacco product 'for chewing, or for any other oral use (other than smoking)' is prohibited under the Smoke-free Environments Act. On the basis that the 'Heet sticks' used in IQOS heated tobacco products were for inhalation (but not smoking), the Ministry of Health also banned them. However, in 2018, a court overturned this ban. The judge did so following a legal principle called *ejusdem generis*, meaning that if specific words are used to describe a class or group of things, then the application of the law must be limited to the same class or group of things. Following this principle, the judge's decision was that the products fell beyond the scope of the legislation as it currently stands (i.e. 'Heet sticks' are not for chewing, oral use or smoking).

In 2021, the New Zealand government announced it would outlaw smoking for the next generation. People aged 14 and under will never be able to buy tobacco legally. The aim is to reduce smoking to 5% or less (generally used by policymakers as the definition of 'smokefree') by 2025. Other demand reduction measures to make smoking both unaffordable and inaccessible included reducing the legal amount of nicotine in tobacco products to very low levels (VLNC), cutting down the number and type of shops where cigarettes could legally be sold, and increasing funding to cessation services.

The government says this new initiative will not impact current vaping laws. But critics say that the end goal is not just to make New Zealand 'smokefree', but to prohibit or severely restrict access to SNP by, for example, cutting back on the number of retail outlets able to sell them. One purpose of the legislation is stated as to "prevent the normalisation of vaping", and there are several references to "discouraging" vaping as a next step, once smoking itself has been reduced to a very low level.²⁶¹

“the New Zealand government announced it would outlaw smoking for the next generation

²⁶¹ Smokefree Environments and Regulated Products (Vaping) Amendment Bill, Government Bill – New Zealand Legislation, no. 222–2 (2020). <https://legislation.govt.nz/bill/government/2020/0222/latest/whole.html#d16822133e2>.

Bhutan



Bhutan's unique national tobacco ban was lifted during the COVID pandemic.
Credit: rarrarorro on iStockPhoto

In 2004, Bhutan became the first country in the world to ban the sale, manufacture, and distribution of tobacco

In 2004, Bhutan became the first country in the world to ban the sale, manufacture, and distribution of tobacco, but allowed limited personal imports on the payment of high taxes. The WHO gave an award to Minister of Health, Lyonpo Tandin Wangchuk.

In 2011, the law was further tightened, with people jailed for illegal importation of tobacco. A study published that year considering Bhutan's tobacco situation after the 2004 ban found "a thriving black market and significant and increasing tobacco smuggling[...] 23.7% of students had used any tobacco products (not limited to cigarettes) in the last 30 days[...] Tobacco use for adults has not ended or is even close to ending[...] Cigarette prohibition is instrumental in encouraging smuggling and black markets[...] The results of this study provide an important lesson learned for health practitioners and advocates considering or advocating, an albeit gradual, but total cigarette ban as a public policy".²⁶²

Another study concluded that smoking prevalence remained high in Bhutan despite the law.²⁶³ During the COVID pandemic, amid rising levels of smoking and the use of smokeless products, the tobacco ban was lifted. An increase in smuggling prompted fears that smugglers would carry the virus into the country, while citizens might cross borders in search of cigarettes. There were also concerns that domestic tensions due to lockdown could worsen if tobacco remained legally unavailable. The government has insisted that lifting the ban was only temporary, but currently there is no sign of it being reimposed.

South Africa

In another initiative related to the COVID pandemic, South Africa banned tobacco in March 2020, arguing that people who smoke are more prone to the virus. There was no evidence to support this claim. The inevitable result was that many people switched to buying their cigarettes on the illicit market. A research study confirmed what was obvious on the ground:

²⁶² Givel, M. S. (2011). History of Bhutan's prohibition of cigarettes: Implications for neo-prohibitionists and their critics. *The International Journal on Drug Policy*, 22(4), 306–310. <https://doi.org/10.1016/j.drugpo.2011.05.006>.

²⁶³ Gurung, M. S., Pelzom, D., Dorji, T., Drukpa, W., Wangdi, C., Chinnakali, P., & Goel, S. (2016). Current tobacco use and its associated factors among adults in a country with comprehensive ban on tobacco: Findings from the nationally representative STEPS survey, Bhutan, 2014. *Population Health Metrics*, 14(1), 28. <https://doi.org/10.1186/s12963-016-0098-9>.



In South Africa, a brief ban on tobacco during the COVID pandemic failed in its aims.
Credit: Den Harrson on Unsplash

*“Our findings suggest that the ban on cigarette sales is failing in what it was supposed to do. While the original intention of the ban was to support public health, the current disadvantages of the ban may well outweigh the advantages. Smokers are buying cigarettes in large quantities, despite the lockdown, and unusual brands are becoming prevalent”.*²⁶⁴

The ban was lifted in August 2021.

Global SNP regulation: a missed opportunity to improve public health outcomes

These brief glimpses into the regulation and control of safer nicotine products around the world reveal little global progress towards the widespread adoption of risk-proportionate regulation in support of harm reduction and better health outcomes for adults who smoke.

While some countries have adopted legislative frameworks that recognise the benefits of risk-proportionate regulation for safer nicotine products, these are often partial, and not applied equally across product categories. Consumer choice is an important element in supporting people to switch away from smoking; for example, while some people may find that vaping helps them to switch, others may find that snus, nicotine pouches or heated tobacco products suit their needs better.

Elsewhere, politicians and policymakers in many countries are expressing their own uncertainty and doubt about safer nicotine products through legislative and regulatory responses that are, at their worst, running counter to public health goals. In some cases, state responses to safer nicotine products might also be interpreted as evidence of a desire to protect the economic benefits brought by combustible tobacco, either through tax revenues or domestic production. The resulting picture

The resulting picture is a confusing patchwork of regulatory responses, and a major missed opportunity to improve global public health outcomes

²⁶⁴ Walbeek, C. van, Filby, S., & Zee, K. van der. (2020). ‘Lighting Up The Illicit Market’ Report: Smoker’s Responses to the Cigarette Sales Ban in South Africa. University of Cape Town, Research Unit on the Economics of Excisable Products (REEP). <http://www.reep.uct.ac.za/news/lighting-illicit-market-report-smoker%E2%80%99s-responses-cigarette-sales-ban-south-africa>.

is a confusing patchwork of regulatory responses, and a major missed opportunity to improve global public health outcomes.

Meanwhile, many of the world's 1.1 billion smokers remain uncertain and doubtful about the benefits of switching to the use of safer nicotine products to reduce the harms from tobacco. It is these citizens who are left to pay the price with high rates of preventable smoking-related disease – as countries and communities struggle with the resulting healthcare costs and loss of economic activity.

In many areas of public policymaking, especially in health matters, affected populations are rightly considered to be stakeholders, whose views and opinions should be sought. This does not routinely apply to people who are directly impacted by policymaking on safer nicotine products. Most of the time, they are explicitly excluded from the debate. But, as we shall see in the next chapter, it is not for the want of trying.

Chapter 8:

The right to use and the right to choose

The right to health – aspiration or reality?

Since the WHO came into existence, a raft of international health agreements have reiterated that the enjoyment of the highest attainable state of health is a universal right, and that governments have a duty to empower their citizens to have control over their own health.

But in the real world, the legally binding nature of these treaties can appear to count for little. Consider the billions of people worldwide whose health is jeopardised by a lack of safe water and sanitation, or affordable medicines, by pollution, climate change, or restricted access to COVID vaccines – the list goes on. In all of these situations, the citizen is at the mercy of action or inaction by the state, and can exert little or no control over their health outcomes in relation to these factors.

In some situations, however, options for individual self-determination do exist. Individuals can choose to take steps to improve their own health *if* they are given the freedom to do so. Depending on the issue, affording people these freedoms – or removing them – can be a source of significant debate. In terms of individual self-determination, for example, one of the most hotly disputed issues in global healthcare policy is women's reproductive rights.

Looking at how drug harm reduction intersects with the right to health brings us a little closer to the issues around tobacco harm reduction. Above all, there are lessons to be learned from the inefficacy of drug prohibition: it is widely accepted that 'the war on drugs' was lost a long time ago. For people who use state-prohibited drugs, prohibition has detrimental effects, both on health and life outcomes through criminalisation.

the enjoyment of the highest attainable state of health is a universal right

there are lessons to be learned from the inefficacy of drug prohibition



The 'war on drugs' is widely accepted as a failure.
Source: Kindel Media on Pexels.

“harm reduction – with access to relevant treatments – is now embedded in a number of global health policies

People experiencing problems with state-prohibited drugs must still be able to exercise their right to health. This means that they must be able to access treatments that help to keep them safe. After lengthy campaigns from human rights and harm reduction organisations in the 2000s, Anand Grover, the UN Special Rapporteur on the Right To Health, set out the principles for a health-based approach to drug control to the UN General Assembly in 2010. Grover’s report stated: “the enjoyment of the right to health of all people who use drugs – and are dependent on drugs – is applicable irrespective of the fact of their drug use”.²⁶⁵ His primary recommendation to the UN General Assembly was that Member States should “ensure that all harm-reduction measures [...] are available to people who use drugs”.²⁶⁶

While application of this principle is by no means universal, harm reduction – with access to relevant treatments – is now embedded in a number of global health policies. But many governments around the world still do not support harm reduction for people who use drugs, with abstinence-focused therapies seen as the only politically palatable option. They may believe that people who use state-prohibited drugs have forfeited their human rights. This is not the case.



Provision of safe injecting equipment for people who use drugs is a key harm reduction intervention.
Source: ezza116 on iStockphoto

“For the best outcomes, people need access to a range of options at different times

Moreover, the most effective and humane drug treatment systems take into account the fact that people who experience drug problems do not all respond to the same treatments. For the best outcomes, people need access to a range of options at different times, from harm reduction interventions such as opiate substitution therapies and access to safer injecting equipment, to abstinence-focused therapies. This gives people agency and choice.

Human rights, harm reduction and the international response to tobacco

Enacted in 2005, the FCTC was the first health-based international treaty under the auspices of the WHO. Harm reduction is specifically cited alongside demand and

²⁶⁵ Anand Grover. (2010). *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (A/65/255; Human Rights and Drugs)*. United Nations. <https://www.hr-dp.org/contents/1052>.

²⁶⁶ Ibid.

supply reduction as the central tenets of tobacco control in Article 1(D) of the Preamble to the Convention.²⁶⁷ But harm reduction is not defined. As discussed in Chapter One, the inclusion of the term was intended to allow for the opportunity to re-examine the FCTC, in light of new scientific, clinical or technological developments.

The Preamble to the FCTC does refer to two important international agreements that set out human rights. One is the International Covenant on Economic, Social and Cultural Rights, which states everyone has the right “to enjoy the highest attainable standard of physical and mental health”. It also refers to the Constitution of the World Health Organization, which states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”.

As Professor Gerry Stimson has argued in a 2022 GSTHR Briefing Paper on *The right to health and the right to tobacco harm reduction*, while “the FCTC does underscore the significance of human rights, it is not a human rights treaty, and a human rights framework was not incorporated into the text. There was little consideration of human rights issues during the negotiations and no delegate or NGO involved in the process raised the issue”.²⁶⁸

When the FCTC was being drafted and negotiated, the only rights arguments put forward to governments came from industry-backed pro-smoking groups. The groups variously tried to argue against tobacco control on the basis that their individual rights to liberty, self-determination and privacy provided a ‘right to smoke’. Understandably, these arguments did not sit well with people working to reduce smoking.

Discussions of human rights in relation to tobacco control have subsequently tended to focus on the obligation of the state to protect people from the infringement of their rights by third parties – resulting in the need for states to regulate the tobacco industry to defend people against the damaging effects of tobacco. This can be seen in a range of measures which, for example, are designed to discourage the consumption of tobacco and to protect people, including bystanders, from tobacco smoke. These measures take a ‘negative liberty’ or ‘freedom from’ position.

Something that has been missing entirely from the global health rights debate, however, is the right of adults who smoke to access SNP as a positive step to improve their own health.

As we have seen, pursuing the highest standard of health also involves enabling people to protect themselves – which can be thought of as a ‘positive liberty’ or ‘freedom to’ position. This includes the individual’s right to control their own health and body. For someone who uses nicotine, this should include the freedom to choose evidence-based safer alternatives to combustible cigarettes or risky oral tobacco products. Most public health approaches incorporate a mixture of ‘freedom to’ and ‘freedom from’ elements. People are a key resource in determining their own health, and when people are empowered and enabled to make positive and informed choices about their health, they will generally do so.

The emergence of safer nicotine products poses a challenge to the current interpretation of the FCTC. When the FCTC was being written, safer nicotine products, with the exception of snus, were not yet available. In 2022, a range of evidence-based products that can help significantly reduce smoking-related harm now exists. But the FCTC already names harm reduction as a central tenet of tobacco control. It already makes explicit reference to promoting measures “based on current and relevant

Something that has been missing entirely from the global health rights debate is the right of adults who smoke to access SNP as a positive step to improve their own health

There is space for the FCTC to incorporate a ‘right to choose’ interpretation of harm reduction

²⁶⁷ WHO Framework Convention on Tobacco Control. Updated reprint 2004, 2005, 2003.

²⁶⁸ GSTHR, 2022b.



People should have the freedom to choose safer alternatives to combustible cigarettes.
Source: dragana991 on iStockphoto

scientific, technical and economic considerations”. There is space for the FCTC to incorporate a ‘right to choose’ interpretation of harm reduction.

Advocating for the right to tobacco harm reduction

“the rights landscape in tobacco and nicotine policy has been transformed by a growing movement advocating for the rights of people who smoke to choose to use safer nicotine products

Over the past decade, the rights landscape in tobacco and nicotine policy has been transformed by a growing movement advocating for the rights of people who smoke to choose to use safer nicotine products. The call is coming from a wide range of groups. They include consumers, scientific and clinical tobacco researchers, public health advocates, smoking cessation professionals, political commentators, and some policymakers.

Not everyone approaches the issue from the same viewpoint. Although all are united on the use of safer nicotine products as an exit route from smoking, some groups would push the argument further, saying that adults should have the right to choose to use safer nicotine products, regardless of their smoking status.

The role of consumer advocacy in the tobacco harm reduction field is important and growing. As we explored in Chapter 4, ahead of any professional or major commercial involvement in vaping, communities of people who had discovered the products banded together for mutual support and information exchange. This type of peer-to-peer solidarity is in many ways reminiscent of the actions of gay and drug-using communities in the 1980s, sharing harm reduction advice as the HIV/AIDS crisis emerged. Vaping communities began to coalesce around various online forums and at in-person meet ups. While many were happy to simply exchange information or tips on the latest products, others began to take note of policies and official responses to the use of safer nicotine products, in their home countries or internationally.

One of the first major instances of consumers advocating for access to safer nicotine products took place in the UK in 2010. As outlined in Chapter 4 the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) opened a consultation on bringing vaping devices within the medicines licensing regime.²⁶⁹

²⁶⁹ *Electronic Cigarettes. Volume 508: Debated on Wednesday 7 April 2010, 2010.*

UK vapers were concerned. Over a thousand responses were submitted to the open consultation.²⁷⁰

The vast majority were from individuals, most of whom shared their personal experiences of quitting smoking by using vaping products. One said they had tried “all the other stop smoking products out there and none have worked”.²⁷¹ Many expressed their fear that licensing vaping products as medicines would effectively remove them from the market, while leaving combustible cigarettes legally available. Many also expressed their fear that a return to smoking would be inevitable for them. One simply said: “please don’t make me go back to cigarettes”.²⁷²

The phenomenon of the ‘accidental quitter’ was also apparent in a number of submissions. For example, one respondent reported that he had been smoking 20-25 cigarettes a day since the age of 15, and that, aged 51, he had had “no inclination to give up smoking cigarettes until [he] discovered e-cigs”. He went on: “after nearly a year without having smoked a real cigarette I do not cough any more or get out of breath from walking, my home does not smell of tobacco, my wife and children are extremely happy.”²⁷³

One woman wrote in support of maintaining access to vaping products on behalf of her adult son, who was experiencing health problems due to his smoking. His doctor had instructed him to quit smoking immediately. Instead, he switched to vaping. His mother wrote: “After one and a half years of using e-cigarettes, my son’s morning cough has greatly reduced [and] his doctor has confirmed that his lung capacity has improved. [His] carbon monoxide levels have gone down to trace amounts [...] I share his belief that the flavourings and nicotine found in e-cigarettes has to be better than the 4000 toxic chemicals found legally in cigarettes”.²⁷⁴

In March 2011, the MHRA announced its intention to take no action regarding the status of vaping products, while committing to further research and assessment. The announcement was timed to coincide with the publication of the new Tobacco Control Plan for England. People with experience of benefitting from the use of safer nicotine products had shared their views en masse. And it appeared to have worked.

Then in 2013, proposals to regulate vaping devices as medicines emerged again, this time in the draft EU Tobacco Products Directive (EU TPD). The MHRA confirmed that if the EU TPD regulated the products as medicines, the regulator would be obliged to follow suit. There was significant media reaction to this announcement in the UK, and some misinterpretation of its impact. James Dunworth of E-Cigarette Direct reported: “one of our shop managers telephoned us in a panic when he heard on the radio that e-cigarettes, from tomorrow, could only be sold in pharmacies”.²⁷⁵

A grassroots campaign formed across Europe in response to the EU TPD proposals. It was not orchestrated by any one individual or organisation. The shared focus, however, was to galvanise people to write to their elected representatives at the European Parliament and national parliaments, to share their experiences, and to give their views.

People with experience of benefitting from the use of safer nicotine products had shared their views en masse. And it appeared to have worked

A grassroots campaign formed across Europe in response to the EU TPD proposals

²⁷⁰ Medicines and Healthcare Products Regulatory Agency. (2010, February). *Public consultation (MLX 364): The regulation of nicotine containing products (NCPs)*. Archived on 6 Dec. 2014. UK Government Web Archive. <https://webarchive.nationalarchives.gov.uk/ukgwa/20141206013310/http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>.

²⁷¹ Ibid. Submission number 114.

²⁷² Ibid. Submission number 1185.

²⁷³ Ibid. Submission number 679.

²⁷⁴ Ibid. Submission number 947.

²⁷⁵ Dunworth, J. (2013a, June 13). MHRA Aims for End Of E-Cigarettes In the UK, But Don't Panic—Yet! *Ashtray Blog*. <https://www.ecigarettedirect.co.uk/ashtray-blog/2013/06/mhra-aims-for-end-of-e-cigarettes-in-the-uk-but-dont-panic-yet.html>.

Vaping forums offered basic advice on how forum members could identify and contact their MEPs and MPs.²⁷⁶



People across Europe concerned about the EU TPD implications wrote to their MEPs.
Source: Guillaume Périçois on Unsplash

Prominent UK vaping advocate David Dorn interviewed Clive Bates, the former head of ASH UK, on his ‘Vapour Trails TV’ online broadcast. Bates encouraged people who were concerned about the EU TPD proposals to write a letter to their MEPs and MPs: “Everybody can do this. Everyone who feels at risk from this type of regulation should do it. We live in a democracy, and it requires people to stand up and be counted when things are happening that they don’t like.”²⁷⁷ During the broadcast and on his website, Clive Bates provided advice on what to include in letters – namely, people’s authentic and personal experiences with safer nicotine products and the individual impact of proposed changes.²⁷⁸

European Members of Parliament from many different countries were flooded with individual consumer correspondence. On 9th January 2013, one UK-based All About E-Cigarettes forum member, known as ‘lordbarby’, uploaded the text of a letter from their Conservative MP (the name is not shared). The MP had been in touch with fellow Conservative and member of the Environment, Public Health and Food Safety Committee in the European Parliament, Martin Callanan MEP.

Callanan had replied to the MP, in a letter clearly intended to be shared with the original constituent (the forum member): “You are not alone in contacting me on this issue – many constituents feel similarly strongly. I have examined the arguments and I see the potential e-cigarettes offer as harm-reduction devices to improve human health”.²⁷⁹ In the letter, Callanan encouraged other vapers to write to their representatives, saying “if we bring to the attention of the public, the political world and

²⁷⁶ *If you want to Write, email, Tweet your MEP, MP etc...* (2013, December 17). Vaping Forum – Planet of the Vapes. <https://www.planetofthevapes.co.uk/forums/ecig-discussion/general-chat/threads/if-you-want-to-write-email-tweet-your-mep-mp-etc.24516/>.

²⁷⁷ Dorn, D. (Director). (2013, January 10). *VT Talk 9-01 Clive Bates and the EU Proposition*. VapourTrailsTV. <https://www.youtube.com/watch?v=fJ5YnW4Mw48>.

²⁷⁸ Bates, C. (2013, January 6). EU draft Tobacco Products Directive: Who to write to and what to say (a short guide). *The Counterfactual*. <https://clivebates.com/eu-draft-tobacco-products-directive-take-action/>.

²⁷⁹ *The UK will be against the Directive*. (2013, January 9). All About E-Cigarettes UK. <https://allaboute-cigarettes.proboards.com/thread/16450/uk-directive>.

the media the strong arguments in favour of e-cigarettes as a harm reduction device and the number of lives which can be saved through their use, we have a very strong chance of winning the argument”.²⁸⁰

Martin Callanan went on to play a key role in the European Parliament in preventing the Commission’s plans for medical regulation of vaping devices. On 8th October 2013, it became clear the European Parliament had rejected the proposals. The efforts of vapers across Europe had demonstrated to policymakers that people who used vaping devices had found a reduced-harm alternative to smoking. It showed policymakers that in switching, people had exercised both agency and choice, and that – when given the opportunity and the freedom to do so – people will generally take positive steps to improve their own health.

The early successes in 2010 and 2013 proved to the vaping community that the collective power of many individual voices should not be underestimated. This grassroots campaigning may have helped encourage the development of the current consumer advocacy movement. Increasingly, a more structured approach has emerged, with various consumer advocacy groups forming around the world.

“The efforts of vapers across Europe had demonstrated to policymakers that people who used vaping devices had found a reduced-harm alternative to smoking

“the collective power of many individual voices should not be underestimated

Consumers arguing for, not against: the unusual position of the SNP advocate

Most consumer advocacy groups are formed to campaign against the products of major companies. It is usually in response to a need to protect and promote the welfare of consumers, often on the grounds of health and safety. For example, in the 1970s, the doyen of consumer activism in the US, Ralph Nader, led the charge against cars that were unsafe to drive, and later against companies that were polluting the environment.

Other groups have formed along more political or social justice lines, for example, to campaign against poor working conditions for those in low- and middle-income countries producing consumer goods for people in high-income countries. Some groups campaign to boycott the products of companies that have followed poor practices, such as Nestlé, for encouraging bottle-feeding over breastfeeding even in countries where a safe water supply is far from guaranteed. And there is a long history of class actions taken against the pharmaceutical industry by people negatively affected by various medicines, ranging from thalidomide, through to tranquillisers, antidepressants, and opioids.

By contrast, there are very few campaigns focused around access to a consumer product. Depending on where they are located in the world, consumer advocates for safer nicotine products may be campaigning to protect the legal *availability* of a commercial product from laws that are detrimental to the health of consumers. In other countries, they may be *demanding legal access to and/or appropriate regulation* of those consumer products in the face of prohibition. These campaigns are, however, always set against consumers’ ability to access the most harmful product – combustible cigarettes – which remain on sale in every country in the world.

Perhaps an interesting harm reduction parallel can be drawn with Ireland’s campaigns for unrestricted access to condoms in the early 1990s. Set against the AIDS crisis, campaigning began against a law that was due to ban condoms being sold from ordinary shops and vending machines, and restricting sales to

²⁸⁰ Ibid.

young people. A 2018 paper by Máiréad Enright and Emilie Cloatre explores this campaign and advances the concept of ‘transformative illegality’.²⁸¹ This was seen in short-term, high-profile acts of illegal sale and organised campaigns in the early 1990s.

However, Enright and Cloatre argue that these acts were built on two decades worth of a ‘world-making practice’ of transformative illegality within the Irish family planning movement. The Irish Family Planning Association had recognised condoms as a “life-saving device” since the emergence of AIDS in the mid 1980s and had been supplying them to people who needed them, despite the illegality of doing so.

In 1993, the law changed. Condoms could be sold legally in Ireland, with no restrictions. Enright and Cloatre assert that “although the effect of direct action campaigns on this deregulation are important, activists also built on a much longer history of campaigning through illegality. Years of campaigning for easier access to condoms had enabled a historical change from condoms as shameful objects of deviance, to everyday devices of health, care, and sexuality.”



Condoms are vital harm reduction resources against HIV/AIDS.
Source: Reproductive Health Supplies Coalition on Unsplash.

Results of the first global survey of consumer groups advocating for SNP

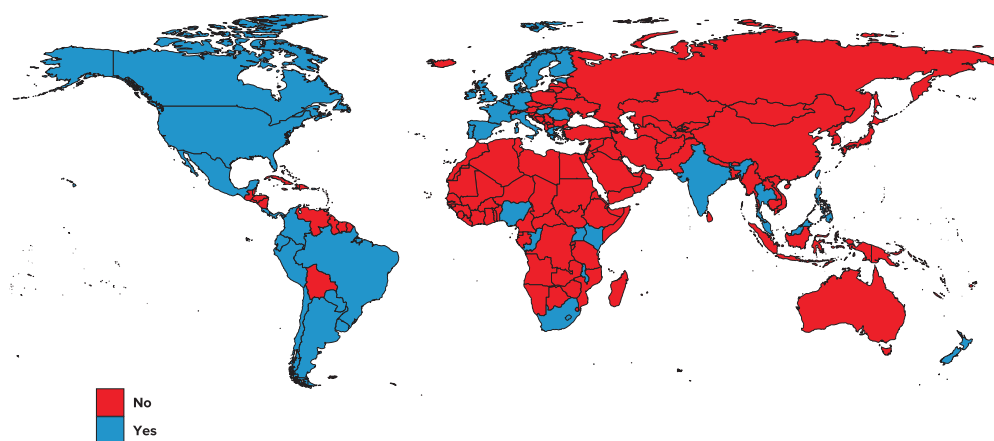
K•A•C has recently completed the first “Global Survey of Consumer Organizations Advocating for Safer Nicotine Products” of all kinds.²⁸² It gives a unique overview of the current state of the global tobacco harm reduction advocacy movement.

The survey identified 52 active nicotine consumer organisations operating in 27 different languages, spanning Asia, Africa, North America, South America, and Europe. For inclusion, the groups had to be organised by consumers and to undertake awareness-raising or advocacy work (associations of traders, distributors, or vendors were excluded). The earliest formation date of any group was 2009; most were more

²⁸¹ Enright, M., & Cloatre, E. (2018). Transformative Illegality: How Condoms ‘Became Legal’ in Ireland, 1991–1993. *Feminist Legal Studies*, 26(3), 261–284. <https://doi.org/10.1007/s10691-018-9392-1>.

²⁸² Forthcoming publication. Jerzyński, T., Stimson, G. V., Harding, J. (2022) ‘Global Survey of Consumer Organizations Advocating for Safer Nicotine Products’

Countries with surveyed nicotine consumer organizations



All the countries with consumer organisations advocating for safer nicotine products surveyed K•A•C are indicated in blue. Source: The K•A•C 'Global Survey of Consumer Organizations Advocating for Safer Nicotine Products', 2022.

recent, with 36 having formed from 2016 onwards. The number of members ranged from below 100 up to 10,000.

The objectives of most organisations were to raise awareness among smokers, the public, government, and the media about safer alternatives to smoking, and to advocate for a legal and regulatory environment in which products are available. Activities common to many groups included: providing information about safer nicotine products and about their work on their own websites; being active on social media; attending events; responding to government consultations; and trying to engage with their local and/or national media.

Most of these groups consist of few individuals operating with little or no financial resources: 42 ran with volunteer teams only; only seven had any contracted or paid staff.

The K•A•C survey reveals that the majority of the groups are operating with very low levels of funding. 31 had no funding whatsoever. Ten received support from individual donations and nine had funding from membership fees. Three had donations from vaping companies; none had funding from tobacco or pharmaceutical companies. One respondent stated “our statutes don’t admit any interference, economic or otherwise, from industry: be it big tobacco, pharmaceutical, philanthropist, vaping sector or tobacco control”. Overall, in 2021, the total funding for all 52 organisations surveyed was \$309,810. 16 organisations had an income of between \$250 and \$10,000.

Some of the groups have come together under umbrella organisations to increase the power of their voice. Examples include, INNCO (global membership), CAPHRA (Asia Pacific), ETHRA (Europe), Campaign for Safer Alternatives (Africa) and ARDT IBEROAMERICA (Latin America).

The European Tobacco Harm Reduction Advocates (ETHRA) can be considered as an example of an umbrella organisation that has been successful in moving things forward politically. At various important moments, ETHRA has been successful at advocating in favour of THR to policymakers and legislators. The organisation was interviewed as part of the EU TPD review, invited to present to DG Sante, had comments and an article included in a briefing for parliamentarians on the Beating Cancer Plan, and was interviewed for the EU tax authority on proposals around taxing SNP.

ETHRA has also been adding to the evidence base. The organisation conducted the largest ever survey of SNP consumers, attracting 35,000 replies. Among those who had ever smoked, 83.5% of vapers and 73.7% of snus users had quit smoking. Harm reduction was the most strongly cited reason for adopting snus (75%) and vaping

Most of the consumer organisations advocating for SNP consist of few individuals operating with little or no financial resources

(90.7%). Nearly a third feared that if a vaping liquid flavour ban was introduced, they might return to smoking.²⁸³

Voices that are not listened to – and voices that are silenced

What facts and figures hide are the unheard voices of tobacco harm reduction, of lives improved or even saved by switching away from smoking

What facts and figures hide are the unheard voices of tobacco harm reduction, of lives improved or even saved by switching away from smoking. If somebody can quit smoking by the time they are 40 years old, many of the health risks of smoking can be avoided.

But age is no barrier to health improvement. Smokers switching in their sixties report improved lung capacity, better breathing and being more able to do exercise. Many SNP consumers report encouraging others, including family members, to switch, and they in turn encourage their friends.



Older people who switch away from smoking experience health improvements.
Source: Sergey Dementyev on iStockphoto

The US consumer group Consumer Advocates for Smoke-free Alternatives Association (CASAA) has over 250,000 members. There are over 13,000 testimonials on the CASAA website from people who report that using SNP has improved – and may even have saved – their lives.²⁸⁴ For example, one states: “I smoked for 41 years until my husband found out his sister had lung cancer. The same day, he stopped at a vape shop and bought a vape home. I tried it [and] haven’t smoked cigarettes in years”.²⁸⁵ The website is home to pages and pages of similar testimony. The words of CASAA members in 2022 echo the feelings, experiences and opinions shared by those who submitted their views to the UK MHRA way back in 2010.

²⁸³ *ETHRA EU Nicotine Users Survey Report*. (2021, June 8). European Tobacco Harm Reduction Advocates. <https://ethra.co/news/80-ethra-eu-nicotine-users-survey-report>.

²⁸⁴ Vape Stories—Real Consumer Testimonials. (2022). *Consumer Advocates for Smoke-Free Alternatives Association (CASAA)*. https://casaa.org/_testimonials/.

²⁸⁵ *Ibid.* Submission number 13471 by user LTS123.

A question of philosophy?

The disruptive force of safer nicotine products has brought together some strange bedfellows. Some approach the issue of access to these products mainly from a harm reduction, human rights and social justice point of view. They see the campaign for tobacco harm reduction as motivated by the need to improve the lives of the many disadvantaged and marginalised groups who continue to smoke, and who could benefit hugely from easy access to affordable safer products.

Then there are those who take a more libertarian perspective, echoing the utilitarianism of English philosophers Jeremy Bentham and John Stuart Mill. Bentham's 'strapline' was "the greatest good for the greatest number". Smoking takes a huge toll on global human health. If people who smoke are actively encouraged to switch to affordable, accessible and acceptable safer products, it can be argued that this would be the greatest good for the greatest number.

J.S. Mill took a different tack in *On Liberty*, focusing on state intervention in the life of the individual. He used the example of drugs to suggest that it was the duty of the state to warn people of the risks, but then to step aside, and let people make up their own minds as to the degree of risk they were willing to take. In the case of continued use of nicotine, some advocates in favour of tobacco harm reduction also adhere to this view.

As we noted earlier, the evidence in favour of the relative safety of SNP compared to smoking is beginning to persuade a growing list of respected figures in public health, clinical medicine, and tobacco research from all over the world of the transformative role these products could play in the fight against smoking-related death and disease.

There are now former senior WHO employees, such as Professor Tikki Pangestu (WHO Director Research Policy & Cooperation, 1999-2012), Professor Ruth Bonita (WHO Director of Surveillance, NCD Cluster, 1999-2005) and Professor Robert Beaglehole (WHO Director of Chronic Disease and Health Promotion, 2004-2007) who are willing to question the response of the WHO and international tobacco control.²⁸⁶ Increasing numbers of politicians are now on board.

There are also now more journalists willing to question the actions of government agencies in over-zealous regulation, and the undermining of democratic processes in the tobacco control space by private philanthropic organisations.²⁸⁷ Contrast, for example, the total 2021 income of \$309,810 split between some of the world's 52 consumer advocacy organisations with the tens of millions of dollars spent over many years by Bloomberg Philanthropies on activities that work directly against the interests of a tobacco harm reduction approach.²⁸⁸ Millions of these dollars go to fund the University of Bath's Tobacco Tactics project, for example, a 'wiki leaks' style resource which focuses on the activities of the tobacco industry. While the industry must be scrutinised and held to account, the Tobacco Tactics project 'names and shames' those who advocate for tobacco harm reduction, including consumer groups and individuals, undermining research, and suggesting that advocacy is motivated only by links (financial or otherwise) to the tobacco industry.

There are now former senior WHO employees [...] who are willing to question the response of the WHO and international tobacco control

While the tobacco industry must be scrutinised and held to account, the Tobacco Tactics project 'names and shames' those who advocate for tobacco harm reduction, suggesting [they are] motivated only by links [to] industry

²⁸⁶ See: Beaglehole, R., & Bonita, R. (2022). Tobacco control: Getting to the finish line. *The Lancet*, 399(10338), 1865. [https://doi.org/10.1016/S0140-6736\(22\)00835-2](https://doi.org/10.1016/S0140-6736(22)00835-2); Pangestu, T. E. (2019, May 14). *Ethical, moral tobacco harm reduction*. The Jakarta Post. <https://www.thejakartapost.com/academia/2019/05/14/ethical-moral-tobacco-harm-reduction.html>.

²⁸⁷ Gunther, 2022.

²⁸⁸ For more information and analysis of Bloomberg Philanthropies' expenditure on activities that act against tobacco harm reduction, see Chapter 5 of Shapiro, 2020.

what binds many individuals and organisations who do advocate in favour of tobacco harm reduction is experience of 'cancel culture' and 'no platforming'

Sadly, as a consequence of these and similar activities of tobacco control activists and funders, what binds many individuals and organisations who do advocate in favour of tobacco harm reduction is experience of 'cancel culture' and 'no platforming'. This can take many forms.

The WHO and other organisers of tobacco control events ban speaking or participation by consumers advocating for safer nicotine products, or any researcher who may have had any links to the industry, however tangential or assumed. Politicians, health officials and others will be warned against events where tobacco industry executives might be present. Researchers on the career ladder will be similarly warned against attending such events, with the implication that doing so could impede their career development.

Tobacco Tactics, for example, lists the names of individuals who speak at certain conferences. The assumption must be that this aims to intimidate others from future participation or attendance. In certain instances, such as on the Tobacco Tactics page about the Global Forum on Nicotine, the list is selective, and does not include speakers from tobacco control. This suggests the motivation is political.

Many academic journals refuse to accept papers from academics who have had any connection, however small, to manufacturers of safer nicotine products or the tobacco industry. When or if papers by such academics are published, journal editors often receive complaints and demands to retract.



Over a billion people continue to smoke every day while safer alternatives are available.
Source: Karbuz Horbuz on Unsplash.

The divide is extreme and, like all 'culture wars', is stifling any opportunities either for reasoned debate or finding a way forward

The divide is extreme and, like all 'culture wars', is stifling any opportunities either for reasoned debate or finding a way forward. Meanwhile, in the real world, as the GSTHR has shown, over 80 million people worldwide have improved their own lives by switching from smoking to vaping, reducing their smoking by vaping, or even going towards complete cessation from all nicotine products. Add in people who now use snus, nicotine pouches and heated tobacco products, and the number of people using safer nicotine products is over 112 million.

No other public health intervention could have achieved this much in so short a time. But progress is being hampered, leaving over a billion people still smoking, of whom millions are either unable to access safer nicotine products, or unaware that they are safer than continued use of combustible cigarettes.

Chapter 9: Future shoot

It took nearly 40 years – from the invention of the Bonsack rolling machine to the start of the First World War – for cigarettes to become the primary method of consuming nicotine. Without the war, this market dominance may well have taken longer.

Vaping devices, so far the most popular and therefore the most prominent SNP, have only been available as mainstream consumer products for a little over a decade, followed by heated tobacco products, which arrived in the mid 2010s. Snus, meanwhile, has enjoyed something of a renaissance, and most recently nicotine pouches have joined the oral nicotine product category.

The pace of the disruption brought about by vaping has been dizzying. Following the establishment of thousands of e-cigarette start-up companies in China, the growth of an independent vaping industry elsewhere, and the eventual investment from multinational tobacco companies, the SNP business has grown substantially, in line with consumer demand.

Understandably, many are sceptical about how much tobacco companies can possibly commit to a world without combustible tobacco products. People often say that if the companies were serious, they would stop selling cigarettes tomorrow.

But the reality is that these companies have legal obligations to their shareholders and investors. They are not going to simply cease the production of cigarettes; hoping that they will is unrealistic. Transition to a different type of future, as in other legacy sectors such as oil and gas, is a more achievable aim. As noted earlier in this report, industry divestment from cigarettes has occurred in the past; Swedish Match sold off its combustibles business to concentrate on snus.

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Cost vs. profit: the challenges and opportunities of SNPs for industry

In 2022, then, where are the major tobacco companies in relation to SNP? It seems likely that whatever regulators do, the global market across all SNP will continue to grow. But how much of a dent will these products ever make in the global cigarette market, which is still worth an eye-watering \$800 billion a year?

Combustible cigarettes are an extremely high-margin product. Compared to the sale value of combustibles, the costs that tobacco companies incur to get cigarettes from the tobacco farm to the tobacco counter are extremely low. Regular price rises also contribute to profitability, not least because there are minimal research and development (R&D) costs. Combustible cigarettes have remained largely the same for over a century. Compare that to the hugely disruptive and still evolving new nicotine delivery systems.

Innovation costs. From what is in the public domain, it appears that two tobacco companies, PMI and BAT, are leading the charge with regard to investment in SNP development at present. By 2019, PMI had invested \$9 billion in R&D on SNP. During the fiscal years December 2017 to December 2021, PMI's median R&D expenses stood at \$495 million. They peaked in the year ending December 2021 at \$617 million.

the bottom line for the tobacco industry is the profit margin

most tobacco companies [...] are not hastening on the speed of transformation and are happy to continue reaping the profits from selling combustibles

Euromonitor expects the global retail value of SNP to jump from an estimated \$40 billion in 2020 to \$100 billion by 2025

Since 2012, BAT has spent more than \$2.6 billion on R&D, while JTI invested \$2 billion between 2015-2020.²⁸⁹ All of these companies have expended significant sums in pursuit of developing new products.

As with all corporations, the bottom line for the tobacco industry is the profit margin. In the case of a transition away from combustible cigarettes, this also coincides with public health benefit. The HTP IQOS was introduced to the market in 2015; PMI forecasts that 50% of its global revenues will come from IQOS sales by 2025, albeit mainly in high-income countries, where prices are higher. For every person who switches from smoking to using IQOS, PMI make more money than if that person stayed smoking cigarettes.²⁹⁰ While the profit margins in vaping products are not as large, the major companies cannot ignore the fact that vaping products outsell other SNP by volume. The world's most valuable vaping company is Chinese company SMOORE – and the biggest customer for the devices they manufacture is BAT.

A company like PMI might be making a good profit on a HTP, but it must reinvest significantly in R&D to keep ahead of its rivals. As shown by the Tobacco Transformation Index, published by the Foundation for a Smoke Free World, most tobacco companies, with a few notable exceptions, are not hastening on the speed of transformation and are happy to continue reaping the profits from selling combustibles.²⁹¹

The substantial R&D spending of both the multinational tobacco companies and the major vaping companies is reflected in the number of patents filed. Between 2010-2020, nearly 75,000 patents were published, covering vaping, heated tobacco, and smokeless products. PMI, BAT, and the Chinese National Tobacco Corporation hold the largest SNP patent portfolios, and vaping products are the fastest growing area of this technology.²⁹² The patents lodged speak to major innovation across the vaping and HTP market, from devices that reduce toxicant levels almost to zero, to those that provide health data to the people who use them.

And – although outside the scope of this report – around 48% of the patents filed between 2010-2020 relate to products with a potential medical application, for example, through inhalation of pharmaceutical drugs.²⁹³ Industry investment in science and scientists has meant that some tobacco companies are now looking to move into areas beyond their core business of consumer nicotine use, as part of their move away from combustible cigarette sales.

Predictions for growth in the SNP market vary enormously, but Euromonitor expects the global retail value of SNP to jump from an estimated \$40 billion in 2020 to \$100 billion by 2025.²⁹⁴ Market analysts predict substantial growth in safer oral products such as nicotine pouches. If the conditions are right, these products have the potential to impact significantly on tobacco-related health harms in LMIC. They require little of the consumer (they do not require electrical charging), they can be reasonably affordable, and they could substitute existing risky oral tobacco consumption in countries where traditional oral products are currently causing significant population-level harms.

Even if companies have determined that there is good money to be made in SNP, people who smoke must be persuaded to switch. Just as in the past, the companies

²⁸⁹ Rossel, S. (2022, April 1). In the Pipeline. *Tobacco Reporter*. <https://tobaccoreporter.com/2022/04/01/in-the-pipeline/>, p. 21.

²⁹⁰ Sun, L. (2019, October 18). *4 Things to Know About Philip Morris International's Fastest-Growing Business*. The Motley Fool. <https://www.fool.com/investing/2019/10/18/4-things-to-know-about-philip-morris-international.aspx>.

²⁹¹ 2022 Tobacco Transformation Index®. (2022, September). *Foundation for a Smoke-Free World*. <https://tobaccotransformationindex.org/2022-index-results/>.

²⁹² Rossel, 2022.

²⁹³ Ibid.

²⁹⁴ Ibid.

have found to their cost that the consumer remains the final arbiter of success. The question remains: how do companies do that when they are prevented from promoting the relative safety of the products – while at the same time, people who might consider switching are faced with misinformation about SNP?

Stick or twist?

In 2021, Reuters reported that Imperial Tobacco had lowered its aspirations for SNP, mainly vaping products, after missing several sales targets over the previous five years. Imperial wrote down the value of that part of its business by £124m (\$170.02m) in 2021, after sales fell by 27% in 2020. Recently appointed CEO, Stefan Bomhard, said: “The new strategy will have a renewed emphasis on a more focused group of priority tobacco markets and a more disciplined execution in new generation products”. It is likely that, similarly to PMI, Imperial believes that the most profitable future SNP market probably lies in HTP.²⁹⁵

In 2021, the magazine *Tobacco Asia* surveyed regional tobacco executives about the future of combustibles. Korea Tobacco and Ginseng Corporation (KT&G) is the world’s fifth largest tobacco company. Although the company acknowledges the disruption to the industry caused by SNP and the need to watch developments, it was not rushing ahead with new products. Its executive vice-president, Kyung-Man Bang, said: “For the time being and generally speaking, there still is a much greater number of conventional smokers in the world than there are users of alternative products. Although South Korea is among the countries with the highest growth rate in the new generation product segment, heated tobacco products still account for less than 15% of the [domestic] tobacco market”.²⁹⁶

He continued: “It also seems reasonable to argue that the demand for conventional cigarettes is going to remain stable for quite some time to come, even in mature markets. But [KT&G] will have to keep up with its efforts to strengthen the competitiveness of conventional cigarettes as one of [our] flagship business sectors, and keep developing its growth potential”. Representing BMJ Industries FZE, Dubai’s largest privately owned tobacco manufacturer, Malik Warrayat, head of sales, observed: “While it is perhaps possible to innovate combustible alternatives, smokers expect a certain level of pleasure from tobacco smoke. And at the end of the day, the by far easiest and most convenient way of smoking is through a combustible cigarette”.²⁹⁷

Ultimately, the tobacco industry can afford to sit back and watch the spectacle of the political sphere and the public health world battle it out over harm reduction, safe in the knowledge that their core business is rock solid. The volatility and uncertainties of regulation and control also encourage companies to play a waiting game. If anyone believed that legislating SNP out of existence would seriously dent tobacco industry profits, even a cursory look at the figures would show this is simply not going to happen. Yet it seems that this is precisely how the ‘war against nicotine’ is being prosecuted.

In business terms, the most vulnerable sector of the SNP industry is vaping. It is the biggest sector of the SNP market, and is often in the public eye. But despite the eventual arrival of some of the big tobacco industry players into the vaping market, most stakeholders in the business are still small- to medium-sized enterprises. Most

“the tobacco industry can afford to sit back and watch [the battle] over harm reduction, safe in the knowledge that their core business is rock solid

²⁹⁵ Reuters, & Cavale, S. (2021, January 27). Imperial Brands sets five-year focus on top five cigarette markets. *Reuters*. <https://www.reuters.com/world/uk/imperial-brands-focus-top-five-cigarette-markets-2021-01-27/>.

²⁹⁶ Schmid, T. (2021, October 4). *Tobacco Executive Survey: The Future of Combustibles*. Tobacco Asia. <https://www.tobaccoasia.com/api/content/095e3d78-24c6-11ec-ae8d-12f1225286c6/>.

²⁹⁷ Ibid.

the interests of public health will not be well served either by prohibition or disproportionate regulation [of SNP], but combustible cigarette sales will

politicians hold the future of tobacco harm reduction in their hands, and they would do well to learn from the lessons of the past

there have been positive moves on the regulatory front recently

do not have the means to independently submit swathes of documentary evidence to prove product safety or to launch litigation to challenge government decisions.

Realistically, though, the SNP business – backed by consumer demand – might be too big to fail. There are now over 80 million people who use vaping products around the world. From 1920-33, Prohibition outlawed alcohol in the US. People still drank alcohol. Throughout the decades of the global war on drugs, people who wanted to use state-prohibited drugs have found a way. In both instances, the substances ended up under the control of organised crime, with predictably negative consequences. When it comes to safer nicotine products, the interests of public health will not be well served either by prohibition or disproportionate regulation, but combustible cigarette sales will. Politicians hold the future of tobacco harm reduction in their hands, and they would do well to learn from the lessons of the past.

Where next for tobacco harm reduction?

At the time of writing, it is hard to be overly optimistic. A discussion about SNP due to be held at the 2021 FCTC Conference of the Parties (COP) meeting was deferred to the 2023 COP in Panama. The expectation is that the WHO, via the FCTC Secretariat, will be urging member states to further tighten controls. Flavour bans remain on the table as part of the revision of the EU TPD, and as a headline proposal in several other countries.

But there have been positive moves on the regulatory front recently. Despite all the politics, as seen in Chapter 7, the FDA has given market approval to three main SNP categories (a vape product, a HTP and an oral product). This put the FDA at odds with WHO policy – and FDA decisions do carry weight around the world. Documents obtained by *Filter* magazine point to a possible scenario within the Byzantine world of FDA pre-market authorisation, where flavours other than tobacco and menthol might gain FDA approval.²⁹⁸ As previously noted, the EU may be showing signs of becoming more open to tobacco harm reduction by its adoption of the final report of the Special Committee on Beating Cancer (BECA); the report stated that vaping can play a role in smoking cessation and that any risks posed by SNP must be evaluated against combustibles.

Elsewhere, too, there are some interesting developments – particularly in southeast Asia, which to date has been home to some of the most stringent anti-tobacco harm reduction activities. All SNP are banned in Thailand. The Thai government enjoys a 100% monopoly on the domestic tobacco industry; the Ministry of Health could not be expected to advocate for SNP, as it receives millions of dollars in earmarked funds from tobacco revenues.²⁹⁹ Yet recently, a sub-committee of Thailand's Parliament began considering proposals to relax the harshest controls on SNP use. As they stand, these controls could lead to SNP consumers or vendors being fined or imprisoned for up to ten years.³⁰⁰

Chaiwut Thanakamanusorn, the Thai Minister for the Digital Society and Economy, said that people should have access to unbiased information about safer alternatives. He criticised the National Tobacco Control Board for its “wrongful resolution”, as it failed

²⁹⁸ Norcia, A. (2022, May 26). Documents Shed New Light on the FDA's Vape Authorization Plans. *Filter*. <https://filtermag.org/fda-documents-vape-authorization-pmta/>.

²⁹⁹ The Thai health tax, a surcharge tax of 2% of excise payable on tobacco and alcohol taxes, was established by the Thai Health Promotion Foundation Act of 2001. By 2010, it was generating an estimated \$100 million per year. Source: Visaruthvong, C. (2010). *Thailand Tobacco Tax Report Card*. Southeast Asia Initiative on Tobacco Tax. https://portal-uat.who.int/fctcapps/sites/default/files/kh-media/e-library-doc/2019/12/Google_24.-Thailand-Simulation_TetSim.pdf.

³⁰⁰ Caruana, D. (2022, May 25). *New Legislation to Legalize Vapes is Being Reviewed by Thai Parliament*. Vaping Post. <https://www.vapingpost.com/2022/05/25/new-legislation-to-legalize-vapes-is-being-reviewed-by-thai-parliament/>.

to take into account stakeholder opinions and academic data. “A complete ban on e-cigarettes is not the best solution for the country in the present social context,” he said. The Ministry of Health has stuck to its opposition to lifting the ban, for now.³⁰¹

And as recently as November 2019, the then Philippine President Rodrigo Duterte was urging police and the military to arrest people who were vaping. Now the Philippines is also considering new laws to allow greater access to SNP. Similar reforms are in play in Malaysia.³⁰²

These shifts show that some politicians from LMIC are prepared to consider more closely what is appropriate for the benefit of public health. There is anecdotal evidence that some countries might have lost faith in the WHO over its handling of COVID, which may have weakened its influence in other areas of public health.

“some politicians from LMIC are prepared to consider more closely what is appropriate for the benefit of public health”

The FCTC: “no longer fit for purpose”?

One central issue remains the current interpretation of the FCTC and, in particular, the Guidelines for Article 5.3, which insist that the divide between public health and the tobacco industry can never be bridged. Article 5.3 itself reasonably exhorts Parties to the FCTC to be open and transparent in any dealings with the tobacco industry and not to allow undue interference in policy – which is right and proper. But the Guidelines on implementation of Article 5.3 have been increasingly overinterpreted, and are now used by those who are against tobacco harm reduction as justification to exclude or dismiss alternative views.

As mentioned in Chapter 8, Professor Robert Beaglehole was a former Director of Chronic Diseases and Public Health at the WHO. He is currently Chair of New Zealand’s ASH - Action for Smokefree 2025. In a keynote address for the E-Cigarette Summit in 2021, Beaglehole said that the effects of widespread availability of SNP products, and his conversations with people who had switched to vaping, had prompted a sea change in his views in support of a smokefree world over a tobacco-free world.³⁰³

In a scorching critique of the WHO and the FCTC Secretariat, Beaglehole argued that Bloomberg funding for the MPOWER initiative has been “detrimental to the WHO and the issues in general because of Bloomberg’s personal prohibitionist approach to less harmful products”. He observed that the FCTC had not lived up to its promise; that even where MPOWER had been fully implemented, smoking rates were either only falling very slowly, or were even rising. He attributed these failings to a primary goal of nicotine abstinence, a failure to acknowledge the benefits of THR while over-emphasising dangers to youth to the detriment of adult health. He called the actions of countries who banned SNP as “inexplicable” and expressed disbelief that the WHO should then reward them.³⁰⁴

Beaglehole called for an independent review of the WHO leadership in tobacco control, and argued that more progressive countries should work together to bring about reform in both the WHO and the COP. In his opinion, the role of the FCTC Secretariat, who orchestrate the COP meetings, needs to be held up to democratic scrutiny.³⁰⁵

³⁰¹ Thailand ready to legalize smoke-free products like the Philippines. (2022, May 19). Manila Bulletin. <https://mb.com.ph/2022/05/19/thailand-ready-to-legalize-smoke-free-products-like-the-philippines/>.

³⁰² Ibid.

³⁰³ Beaglehole, R. (2021, November 23). Opening keynote: What will success look like? The E-Cigarette Summit. <https://vimeo.com/649001613>.

³⁰⁴ Ibid.

³⁰⁵ Ibid.

These views were reiterated in a letter to *The Lancet* in 2022, co-authored with Professor Ruth Bonita, in which they argued:

“The FCTC is no longer fit for purpose, especially for low-income countries. Neither the WHO nor the FCTC are grounded in the latest evidence on the role of innovative nicotine delivery devices in assisting the transition from cigarettes to much less harmful products.

“Equally, the focus on youth vaping, most of which is experimental, detracts from the crucial public health goal of reducing cigarette-caused deaths in adults. The missing strategy in WHO and FCTC policies is harm reduction.

“Unfortunately, the WHO and the FCTC Conference of the Parties reject harm reduction. This opposition is not grounded in 21st century technological advances and is unduly influenced by vested interests who promote nicotine abstinence. This opposition privileges the most harmful products – cigarettes”.³⁰⁶

Final note

Nicotine is a relatively harmless substance, enjoyed by millions of people all over the world for its paradoxical stress-relieving and stimulating properties. Unfortunately, however, the quickest, easiest and – until recently – cheapest way to obtain these benefits is through the most dangerous delivery system: the combustible cigarette. Over the last century, smoking has killed an estimated 100 million people and subjected millions more to life-threatening diseases.³⁰⁷ Smoking remains the world’s number one cause of preventable, non-communicable diseases.

During the last 40 years, smoking rates have been falling in higher income countries due to public smoking restrictions, taxation, and public health concerns. But those falling graphs are levelling out in many countries; the decreases have slowed, smoking rates are predicted to rise in some regions – mostly in LMIC – and globally, the number of smokers remains stubbornly high due to population growth. Smoking rates also remain disproportionately high in communities who face marginalisation and discrimination.

Over the last four decades, efforts were made, largely in secret, to produce a nicotine-based product without all or most of the attendant health risks that, crucially, would be acceptable to people who smoked. It took a Chinese scientist experimenting at home to come up with the answer: a vaping device.

An effective, pragmatic, and compassionate global tobacco control strategy should have readily embraced the range of new SNP to complement existing efforts to reduce the death and disease from smoking. Instead, influential political, financial and ideological powers have been set against such policies.

One key rationale for a prohibitionist response is the involvement of the tobacco industry. But would it not be better to facilitate these companies to transition as far and as fast as possible away from their current core business, and in so doing, assist the improvement of public health? Placing obstacles in the way of industry transition only serves to make their core legacy business both more profitable and more attractive than attempts at innovation.

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An effective, pragmatic, and compassionate global tobacco control strategy should have readily embraced the range of new SNP to complement existing efforts to reduce the death and disease from smoking

³⁰⁶ Beaglehole & Bonita, 2022.

³⁰⁷ Ritchie & Roser, 2022.

A refusal to engage with industry, however it is defined, makes as much sense as excluding the automotive industry from debates about reducing emissions because car manufacturers still sell polluting petrol and diesel vehicles, at the same time as developing electric alternatives. By contrast, meetings of the Framework Convention on Climate Change include all stakeholders, ranging from the most polluting global industries to environmental groups.

Furthermore, there are thousands of businesses worldwide, producing and selling SNP of all types, that have no connection with the tobacco multinationals. Some may reasonably argue that who produces SNP does not matter, as long as adults who smoke can obtain products that are safer than combustible cigarettes, as well as being accessible, affordable, appropriate, and acceptable.

It took 60 years from the invention of the cigarette rolling machine for the links between smoking and cancer to be confirmed in the early 1950s. This timeframe is used as an excuse not to endorse SNP because we do not know everything. But not knowing everything does not mean that we do not know *anything* – scientific techniques for assessing harms have dramatically improved since then, and the evidence that these products are safer than combustible cigarettes is clear and growing.

One thing is certain: we cannot wait another 60 years for tobacco harm reduction to be mainstreamed into global public health. Otherwise, we will have no chance of reducing the predicted toll of one billion smoking-related deaths by 2100. There is a lot at stake.

