BRIEFING PAPERS

Global State of Tobacco Harm Reduction

Dead ends – the tobacco industry's quest for a 'safe' combustible cigarette

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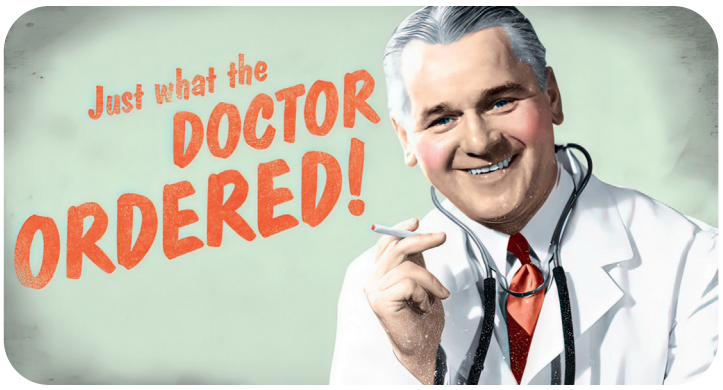
Introduction

From the 1950s onwards, the tobacco industry spent decades denying any link between smoking and disease. Yet at the same time, it dedicated much time and money trying to develop a 'safe' combustible cigarette. This would be a product that achieved the challenging dual aims of satisfying consumer demand for taste and nicotine delivery, while reducing concerns about public health. The search would not be simple.

This Briefing Paper sets out to tell the story of the roles played both by those within and outside of the tobacco industry.

When were the dangers of smoking revealed?

In the early 1600s, James I of England wrote that tobacco was "dangerous to the lungs",[1] and yet hundreds of years later, tobacco companies in the USA were using doctors to promote the idea that smoking was safe. Well into the 20th century, one company even featured a doctor cheerfully smoking under the tag line 'Just what the doctor ordered'.[2] People were being led to believe that if doctors smoked, it must be safe.



It wasn't until the release of two landmark studies in the 1950s, linking smoking to cancer, that perceptions started to change. In the UK, Sir Richard Doll and Sir Austin Bradford Hill's 1954 study revealed that those smoking 35 cigarettes or more a day increased their risk of lung cancer by a factor of 40 compared to non-smokers.[3] It was the first report published anywhere in the world to widely publicise information about the negative effects of smoking on health. The same year a second study from the American Cancer Society came to the same conclusion.[4]

Another American study from the 1950s which really captured the public's imagination was an animal experiment conducted by Ernst Wynder and colleagues. This research focused not on cigarette smoke, but on the tar. They proved that painting tar on the backs of mice could create tumours.[5] The study received widespread coverage, and *Time* magazine quoted one of the research team, Evarts Graham, who said the link between cigarette smoke and cancer had now been proved 'beyond any doubt'. Graham's conclusion was further underlined by signal reports, both called *Smoking and Health*, from the UK Royal College of Physicians in 1962 and the US Surgeon General in 1964.[7,8]

How did the tobacco industry approach making a 'safe' cigarette?

The major UK and US research studies in the early 1950s were the catalyst for the tobacco industry's pursuit of the 'safe' cigarette. And the media storm caused by the Wynder study forced the industry to respond publicly.

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In 1954, the companies published 'A Frank Statement To Cigarette Smokers' declaring they would not dream of selling a harmful product.[9] They established the Tobacco Industry Research Committee to spread confusion and doubt about the alleged link between smoking and cancer.[10] They did this through papers in medical journals, magazine and newspaper articles, and media interviews.

But the industry also knew it had to respond more tangibly to public concerns – concerns that ultimately threatened their profits, either through falling sales or costly litigation. In fact, in a memo of July 1958, a Philip Morris scientist wrote that he thought the company could capitalise on health concerns by developing a safe cigarette, while attacking rivals who failed to follow suit.[11] The most obvious first step was to find a way to filter out the toxic chemicals in the smoke that were causing harm. This proves that company scientists already knew of the harms faced by consumers.

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As early as 1936, Brown & Williamson had launched Viceroy, their first filter cigarette, refining the product in 1952 with the Health-Guard filter for the brand. The company went head-to-head with Lorillard and its Kent brand. Kent cigarettes had filters made of asbestos, a now infamous substance which paradoxically rendered their version of the 'safe' cigarette even more dangerous.

For the rest of the 1950s and 1960s, all the major tobacco companies took part in what became known as the 'tar derby', promoting filter cigarettes as the 'safe' option. But as there was no evidence of relative safety, the advertising for filter cigarettes traded on the public assumption that if a product had a filter, it must be filtering out something potentially harmful.

As a Philip Morris executive said in an internal memo in 1966, "the illusion of filtration is as important as the fact of filtration".[12] In 1976, Ernest Pepples, vice-president and General Counsel for Brown & Williamson, wrote that despite the industry claims made about filter cigarettes, "in most cases, the smoker of a filter cigarette was getting as much or more nicotine and tar as he would have gotten from a regular cigarette".[13] At the same time, company lawyers were concerned about the reputation of their non-filter brands, which, by implication, were more dangerous.

But industry documents reveal the tobacco companies were exploring different avenues towards the development of a 'safe' combustible cigarette. These included investigating the production of synthetic tobacco, increasing nicotine levels in low-tar cigarettes to compensate for any loss of nicotine in the process of reducing tar, and selective filtration of the most toxic substances in cigarette smoke, such as carbon monoxide. Research also focused on the removal or lowering of three of the deadliest cancer-causing chemical compounds: nitrosamines, aldehydes and polycyclic aromatic hydrocarbons.

James Mold, Liggett's chief scientist, worked for more than a decade on a secret project variously called XA, Tame and finally Eclipse. The research goal was to neutralise cancer-causing compounds by introducing additives to the production process. Using Wynder's

skin painting test, Mold did manage to eliminate some tumours when a mixture of magnesium nitrate and palladium was added to tobacco.[14]

When he presented to the board in 1978, members could not believe millions of dollars had been spent without their knowledge. Again, the lawyers were worried about the impact not just on Liggett, but on the whole industry. How could the company use the mouse test to prove the safety of their product when its own lawyers were in court attacking the test as part of Liggett's defence against other lawsuits? Liggett faced pressure from other companies not to go ahead as the implication would be that all other cigarettes were unsafe. Tobacco companies would then be faced with an avalanche of litigation. But like many much-vaunted new tobacco products, Eclipse failed the consumer test who said it tasted awful, so industry concerns were allayed.

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Experiments were conducted to develop tobacco substitutes, for example using wood pulp. However, the US federal government's view was that if health claims were being made in respect of substances not derived from a natural plant, such as tobacco, then they would be deemed unproven drugs, tangling the companies up in red tape. In 1977, to work around FDA regulations, some brands using tobacco substitutes were launched in the UK. Health campaigners complained but, in any case, the products failed.

Companies continued to claim, at least for PR purposes, that they were serious about making their products safe. Again, filters were to the fore. Early in the 1980s, Brown & Williamson announced the launch of the Barclay brand which the company claimed was 99% tar free thanks to the new filter. Rival company Reynolds complained to the Federal Trade Commission that the product gave such high readings because it had been designed to cheat the latter's testing machines.[15]

After spending millions of dollars, Philip Morris launched a very-low nicotine product called Next. It was criticised for having a higher tar content than other brands and was probably more dangerous because consumers would be smoking more to extract the nicotine. It was trialled in some local US regions but gained only 0.2% market share and was quickly withdrawn.[16]

Did the tobacco industry experiment with potential alternatives to the combustible cigarette?

While publicly denying the dangers of smoking, at the same time as trying to develop a 'safe' cigarette, other secret industry projects were underway to devise a radical new approach to nicotine consumption that avoided the harms of combustion that came with cigarettes.

Charles Ellis was a nuclear physicist who became BAT's Chief Scientist in 1955. His research project into consumer smoking behaviour confirmed his belief

that it was nicotine that consumers craved. Despite internal opposition, he persuaded the board to pursue the idea of a device giving full customer satisfaction without the inherent risks of smoking.

The team created Ariel, a two-tier aluminium device where heat from the outer section containing tobacco would liberate the nicotine extract inside; in effect, Ariel was a cigarette inside a cigarette.[17] However, Ellis was replaced as project leader, the project stalled and was abandoned in 1969. It seems BAT then lost interest in the idea, not least because the expected legislative fall-out from the medical reports of 1962 and 1964 did not materialise.

The pioneering effort in this endeavour did not come from within the tobacco industry, but a private individual, a business studies graduate named Herbert Gilbert. A 40-a-day smoker from Pennsylvania, he patented a 'Smokeless Non-Tobacco Cigarette' back in 1963. While Ellis' Ariel contained tobacco, Gilbert had devised something that was more like a basic modern-day vape.[18] However, Gilbert's device was nicotine-free, so even if it had gone into production, it probably would have failed.

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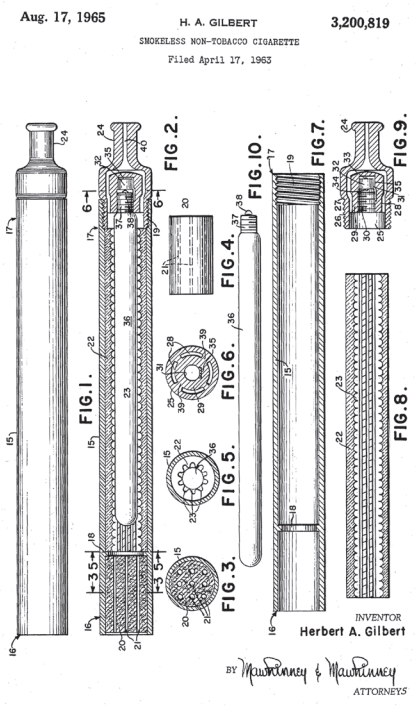
There was another collaboration outside the tobacco industry between a doctor called Norman Jacobson and one of his patients, Phil Ray, a NASA space engineer. Together they produced a device called Favor (as in doing smokers a favour).[19] Made of plastic and shaped like a cigarette, it contained a filter paper soaked in nicotine, which users inhaled. A small clinical trial provided proof of concept, particularly as the trial subjects ingested dramatically less carbon dioxide than regular smokers, as well as consuming less nicotine, making it easier to quit altogether.

But Favor was yet another commercial failure. As nicotine evaporates quickly, it had too short a shelf-life in the cartridges to be a practical replacement for cigarettes. The killer blow was an FDA ban in 1987 deeming it an unproven drug delivery system because the nicotine had been removed from tobacco. So, it was back to the industry to try to crack the conundrum of producing a non-combustible substitute for the cigarette that consumers actually liked.


Aug. 17, 1965 H. A. GILBERT 3,200,819
SMOKELESS NON-TOBACCO CIGARETTE
Filed April 17, 1963
FIG. 1. FIG. 2. FIG. 3. FIG. 4. FIG. 5. FIG. 6. FIG. 7. FIG. 8. FIG. 9. FIG. 10.
INVENTOR
Herbert A. Gilbert
BY Mawhinney & Mawhinney
ATTORNEYS

What did the tobacco industry do next?

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. In the tobacco industry, however, it was Reynolds that picked up where BAT and Ariel left off, with the arrival of Premier in 1987.

The research that led to Premier began back in 1981, but like Liggett's Eclipse, it remained hidden from the Reynolds board. In July 1986, Reynolds' board members were stunned to

receive a presentation about a project they knew nothing about. The new product resembled a normal cigarette, and, inside it, 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 $68 million had already been spent in research and development costs, they allowed the project to proceed. The final bill Reynolds footed for the development of Premier is estimated to be in the region of $300 million. Some estimates were significantly higher, putting the development cost at $800 million, with a projected final cost of a nationally distributed product at close to $1 billion.[20]

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, consumers said they did not like its taste or smell.[21] Reynolds banked on the idea that smokers would get used to the charcoal taste after two or three packs, but most gave up after one cigarette.

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 to swerve around the combustion problem using different heat sources, including battery technology. Meanwhile 'Project Leap' briefly took Philip Morris down the nicotine inhaler route.

In May 1992, an internal Philip Morris document, *Products of the Future*, stated the reason for this experimentation, noting "Premier probably changed the cigarette business forever."[22] It is interesting 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 begun to wonder how long 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.

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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.[23]

But this was a dangerous time for the industry. In just over 640 pages, the 1988 US Surgeon General's report set out the evidence that nicotine was an addictive drug.[24] Eventually, this led to an investigation by the Food and Drug Administration in the mid-1990s seeking to deem, and then control, any new devices as drug delivery systems and so subject them to medical regulation.

In the meantime, the avalanche of litigation about to hit the industry was focusing 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 and ultimately led to the Master Settlement Agreement.[25]

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The litigation and close scrutiny the industry was 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.

When and where did the concept of 'tobacco harm reduction' emerge?

From the 1970s onwards, the view was growing among some tobacco researchers and clinicians that nicotine and nicotine addiction were not, in fact, directly responsible for the death and disease caused by smoking.

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.[26] 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".

In a 1971 paper, Dr Michael Russell, a psychiatrist at the Addiction Research Unit based at the Maudsley Hospital in south London, concluded that nicotine was the motivating force underlying smoking behaviour.[27] Then, in a 1976 *British Medical Journal* paper on low-tar cigarettes, Dr Russell acknowledged that simply asking people to stop smoking or smoke fewer cigarettes would not work.[28] 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 amount of nicotine.

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In a paper commenting on the Hunter Committee deliberations, Dr Russell and his colleague, Martin Jarvis, concluded that "an approach aimed simply at further 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".[29]

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Dr Russell's observations aside, there was little scientific support behind the idea that if nicotine could be successfully liberated from tobacco, the result could be a dramatic improvement in public health – not least because substantial numbers of doctors believed caused cancer. (This misperception remains the case today.[30])

Then, in 2001, the US Institute of Medicine published *Clearing the smoke: assessing the science base for tobacco harm reduction*.[31] This was the product of work by a distinguished committee drawn from the Institute's Board on Health Promotion and Disease Prevention. It sparked a national debate about nicotine and provided one of the first definitions of tobacco harm reduction from an official and highly credible source. It said: "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".

Among the report's principal recommendations, it said "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".

The idea of nicotine products that were safer than smoking was being afforded increasing scientific heft. However, the potential benefits were impossible to demonstrate at a population level. No commercially viable and safer nicotine product was available, at least not one that delivered sufficient consumer acceptance to the extent they were willing to switch away from smoking.

When did the breakthrough arrive – and where did it come from?

In 2001, the search for a safe and popular way to consume nicotine took a significant step forward thanks to a Chinese man called Hon Lik. He did not work for a tobacco company, and while he was a pharmacist, he was not working for a major pharmaceutical company in a related field. Hon Lik's motivations were more personal. Like many millions of Chinese men, he smoked heavily and, although he tried to quit using nicotine patches, he found they had little effect.

Hon Lik says that the idea of delivering nicotine in a vapour came to him in a dream; apparently, he went to bed one night and forgot to remove his nicotine patch. Vivid dreams are a known effect of nicotine patch use during sleep.[32] 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 from the nicotine high of a cigarette and reckoned that vaporising nicotine – in an echo of the vaporised ocean of his dream – would simulate more of the cigarette experience.[33]

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," he said, "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".[34] 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.

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In 2003, Hon Lik came up with the idea of using a high-frequency piezoelectric ultrasound-emitting element to vaporise a pressurised jet of liquid containing nicotine. This new electronic cigarette design 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 filed the first patent in 2003 and eventually dispensed with ultrasound in favour of a smaller but equally effective heating element to vaporise the liquid containing nicotine. Now those who wanted to switch away from smoking had an alternative that could satisfy their needs without the risks posed to their health by cigarettes.

Hon Lik's invention has led to a revolutionary new global industry producing vaping products. By 2023, there were an estimated 114 million people using vapes.[35] This has been accompanied by the growth of other safer nicotine products. The rising consumption of snus in Norway and Sweden, as well as heated tobacco products in Japan, has led to significant falls in smoking at speeds well beyond anything that could have been achieved by traditional government-led smoking prevention initiatives. The use of nicotine pouches is also rapidly expanding around the world as they offer consumers a discreet and effective way of consuming nicotine.

Final thoughts

From the early 1950s, the tobacco industry went to extraordinary lengths to conceal what they knew about the harms of smoking – first denying there were any, and then claiming they were now producing 'safe' cigarettes, knowing full well they were doing no such thing. This deception was ultimately revealed, leaving the public in no doubt that the tobacco industry had utterly failed in its pursuit of a so-called 'safe' combustible cigarette. With combustion, there is no such thing.

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Today, the existence of non-combustible nicotine products has created a totally different nicotine landscape. The welter of independent evidence from around the world demonstrates 'beyond any reasonable doubt' that it is possible to consume nicotine with substantially less risk to consumers and bystanders. The technology behind one of the most popular safer nicotine products, the vape, was patented by one individual, alone, with no links to the tobacco industry.

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But while the development of vapes and other safer nicotine products began outside the tobacco industry, these disruptive inventions have of course had a major impact on the world's biggest purveyors of cigarettes. Playing catch up, many have invested huge sums of money into research and development to create their own products. Some, like Altria, bought into existing companies.[36] Others, like Philip Morris, have announced their ambition for more than two-thirds of their total net revenues to come from smoke-free products by 2030.[37] The company's 2024 full-year results showed that their smoke-free business accounted for 40% of their total net revenues, but it should be noted, of course, that the other 60% still came from their combustible products.[38]

It is extremely unfortunate that, after decades of justifiable mistrust in the tobacco industry, many in public health are now as much in denial of the efficacy of safer nicotine products as the industry was in denying the health risks of smoking. But crucially, these products do exist and consumers are switching away from smoking in ever-increasing numbers, and it is now possible for people to consume nicotine without having to risk the disease and mortality associated with the combustion of tobacco.

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Images: p. 2 Healthcare Usability; p.3 Ebay listing of original advert; p. 5 Google Patents, No. 3,200,819A; other photos: depositphotos.com

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For further information about the Global State of Tobacco Harm Reduction's work, or the points raised in this **GSTHR Briefing Paper**, please contact info@gsthr.org

About us: **Knowledge•Action•Change (K•A•C)** promotes harm reduction as a key public health strategy grounded in human rights. The team has over forty years of experience of harm reduction work in drug use, HIV, smoking, sexual health, and prisons. K•A•C runs the **Global State of Tobacco Harm Reduction (GSTHR)** which maps the development of tobacco harm reduction and the use, availability and regulatory responses to safer nicotine products, as well as smoking prevalence and related mortality, in over 200 countries and regions around the world. For all publications and live data, visit https://gsthr.org

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