

Pharmaceuticalisation as the tobacco industry's endgame

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ABSTRACT

Context Declining smoking prevalence and denormalisation of tobacco in developed countries reduced transnational tobacco company (TTC) profit during 1990s and 2000s. As these companies faced increasingly restrictive policies and lawsuits, they planned to shift their business to socially acceptable reduced-harm products. We describe the internal motivations and strategies to achieve this goal.

Methods We analysed previously secret tobacco industry documents available through the Truth Tobacco Documents Library. These documents were triangulated with TTCs' investor and other professional reports, websites and public statements.

Findings Mimicking pharmaceutical business models, tobacco companies sought to refurbish their image and ensure long-term profitability by creating and selling pharmaceutical-like products as smoking declined. These products included snus, heated tobacco products, e-cigarettes, nicotine gums and inhalers. Tobacco companies created separate divisions to develop and roll out these products, and the majority developed medical research programmes to steer these products through regulatory agencies, seeking certification as reduced-harm or pharmaceutical products. These products were regarded as key to the survival of the tobacco industry in an unfriendly political and social climate.

Conclusions Pharmaceuticalisation was pursued to perpetuate the profitability of tobacco and nicotine for tobacco companies, not as a sincere search to mitigate the harms of smoking in society. Promotion of new pharmaceuticalised products has split the tobacco control community, with some public health professionals and institutions advocating for the use of 'clean' reduced-harm nicotine and tobacco products, essentially carrying out tobacco industry objectives.

INTRODUCTION

Reducing population tobacco use to near-zero levels constitutes the tobacco 'endgame' according to many tobacco control professionals.^{1–3} Despite the current dominance of cigarettes, which still comprise approximately 80% of the annual revenue of transnational tobacco companies' (TTCs)^{4–8} and will likely continue in developing markets for decades even as they are being phased out in mature markets,^{5,7} the tobacco endgame, traditionally

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Tobacco companies have been diversifying their product portfolios over the past decade with products that increasingly resemble pharmaceutical products although they are not approved for medicinal use. The internal industry reasons and rationale for these changes are not known.

WHAT THIS STUDY ADDS

⇒ This analysis of internal tobacco industry documents found that to ensure profitability and regain social acceptance, transnational tobacco companies planned to transform themselves into pharmaceutical companies to circumvent expanding tobacco control measures worldwide. Pharmaceuticalised products blur the line between pharmaceutical nicotine replacement therapy and commercial tobacco/nicotine products. Recreational products mimicking pharmaceutical nicotine therapies may lure in new generations of tobacco and nicotine addicts and undermine genuine advances in pharmaceutical smoking cessation, as they circumvent the costly regulatory hurdles and patient safety/efficacy standards required for certified pharmaceutical therapeutics.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Pharmaceuticalisation of the tobacco industry undermines public health in three ways; first, by distracting regulators from focusing on cigarette sales, which still account for the vast majority of industry profit, disease and death. Second, industry embrace of 'tobacco harm reduction' has split the scientific community, which subverts, delays, diverts and in many cases simply halts the policy-making process. Third, the industry repositioning itself as a partner producing 'harm reduced' products undermines the Framework Convention on Tobacco Control Article 5.3, which explicitly prohibits consultation or partnership between tobacco control policymakers and the tobacco industry.

framed in terms of smoking prevalence, is on a path to success.^{9–13} The US Food and Drug Administration's (FDA) exploration of substantially reducing levels of allowable nicotine in cigarettes may significantly decrease smoking addiction.¹⁴ Likewise, increased



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implementation of advertising restrictions and plain packaging worldwide deprives cigarettes of the symbolic appeal their brands have held through entrenched associations.^{15–18} Stricter clean air policies increasingly remove smoking from visibility in the public sphere, denormalising it.^{19–21} At the same time, progress has slowed.

Parallel to the tobacco control community's endgame of eradicating tobacco-related disease, the tobacco industry has its own endgame. The tobacco industry has paid close attention to the decline of cigarette sales since the 1970s, anticipating for decades the types of policies and norm changes that might lead to smoking prevalence falling below a critical threshold (~5%) at which point social acceptability collapses.^{22–24} Under the weight of constant criticism, TTCs have sought to continually reinvent themselves to continue profiting.²⁵ In response to the denormalisation of smoking, the industry has the need to evolve to keep tobacco socially and politically acceptable as well as economically profitable.

This evolution has increasingly focused on new tobacco products: the endgame of TTCs involves recentering their business around pharmaceutical nicotine products, some with government certification and others that appear similar to certified therapeutic products. Philip Morris International's stated ambitious goals include generating more than 50% of their net revenues from non-cigarette products by 2025 and completely ending sales of conventional cigarettes in the UK by 2030—contingent on 'the right regulatory encouragement'.²⁶ Putatively reduced-harm tobacco products are being rolled out *en masse*,²⁷ including nicotine pouches, electronic cigarettes (e-cigarettes), heated tobacco products, nicotine inhalers and variants of these products made with synthetic non-tobacco derived nicotine.²⁸ TTCs are aggressively applying for and receiving modified-risk authorisations from the US FDA for these products,²⁹ promoting policies to decrease their taxation,³⁰ attempting to leave behind tobacco's unwholesome past by mimicking pharmaceutical product authorisation processes. Rhetoric accompanying introduction of these products supports recreational and 'therapeutic' use of nicotine and positions alternative tobacco products as medicines to reduce smoking, or for 'neuroenhancement',^{31–32} deflecting attention from their role in instigating the next wave of the tobacco epidemic.³³

This paper examines the tobacco industry's long-term strategy to continue selling tobacco and nicotine products in an era of denormalisation, focusing on industry strategies to transform into pharmaceutical-like companies with social benefits but without the regulatory obligations. For decades, TTCs have privately self-identified as drug companies^{34–35} and around the time of the 2001 Institute of Medicine report on tobacco harm reduction³⁶ TTCs leveraged their extensive knowledge of nicotine to manufacture, market and sell non-combustible nicotine products. This analysis of internal tobacco industry documents, publicly available investors' reports, TTC acquisitions and alternative nicotine product development

identifies the overarching trends the tobacco industry has used to pharmaceuticalise its products, thus moving the goal posts in the tobacco endgame.

In the results, we discuss why tobacco companies started their product migration process and how medically-approved nicotine replacement therapy (NRT) has provided a viable model for the tobacco industry, paving their way towards new nicotine products and beyond. We analyse how this pharmaceutical turn is part of the industry's transition to 'responsible corporate citizen' to push for more favourable regulations. Finally, we examine the main features of pharmaceuticalised products through examples and discuss the implications of their 'reduced-harm' claims.

METHODS

We searched previously secret tobacco industry document archives from the University of California, San Francisco Truth (formerly Legacy) Tobacco Documents Library (<https://industrydocuments.ucsf.edu/tobacco>), from April 2016 to August 2018, with updated searches from September to December 2021. Initial search terms included: 'pharmaceutical', 'ATP' (alternative tobacco products), 'ANP' (alternative nicotine products), 'migration', 'cannibalization', 'government certification', 'harm reduction' and 'pure nicotine'. Initial searches produced thousands of documents, leading to narrowed searches using more specific keywords suggested by an initial review of the documents retrieved. These terms included references to internal strategies and initiatives, such as 'iPRIME', 'proactive migration', 'endgame', 'TARGACEPT', 'collapse', 'Adjacent products', 'OBT' and 'extinction'. Further documents were discovered using standard snowball database search techniques.^{37–39} Documents were triangulated with public documents such as news reports, TTC investor reports, press releases, industry websites, videos and other media.^{40–42} This analysis is based on a final collection of 347 tobacco documents published between 1972 and 2021. As most internal documents are from US tobacco companies, this study focuses primarily on the US context, though all companies included global strategies.

Patient and public involvement

Patients were not involved in this research.

RESULTS

The two main TTC conglomerates, Philip Morris (Philip Morris, now Altria in the USA, and Philip Morris International elsewhere, PMI) and British American Tobacco (BAT), which also acquired RJ Reynolds (RJR, now Reynolds American Incorporated, RAI), have for decades crafted and acted on plans to preserve revenue amidst changing regulation and consumer trends by refashioning their products. The results presented are mainly based on the analysis of documents related to Philip Morris and BAT. Additional evidence from other TTCs,

such as Imperial Brands (formerly Imperial Tobacco) and Japan Tobacco International (JTI), is supplemental.

As early as 1972, RJR's director of corporate research Claude E. Teague Jr opined, 'the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry'.⁴³ Teague raised the idea of operating as a nicotine company:

...why is it really necessary that allegedly harmful 'tar' accompany that nicotine? There should be some simpler, 'cleaner', more efficient and direct way to provide the desired nicotine dosage... It should then be possible, using modifications of techniques developed by the pharmaceutical and other industries, to deliver that nicotine to the user in efficient, effective, attractive dosage form...⁴³

Viewing nicotine as a drug, like any other pharmaceutical drug on the market prescribed for medical use, smokers were reframed as patients acquiring their 'individual nicotine dosage requirements' through cigarettes, an imperfect delivery device that could be improved on.⁴³ This sentiment was later repeated by influential British psychiatrist Michael Russell (who had a history of tobacco industry research funding).⁴⁴ After the US Institute of Medicine's 2001 *Clearing the Smoke* report on harm reduction included a continuum of relative risk, implicitly condoning less harmful tobacco products,⁴⁵ the barrier between medically prescribed NRT and the industry's reduced-harm tobacco products became more porous.⁴⁶

What is pharmaceuticalisation?

In medical sociology, 'pharmaceuticalisation' refers to 'the process by which social, behavioural or bodily conditions are treated, or deemed to be in need of treatment/intervention, with pharmaceuticals by doctors, patients or both'.⁴⁷ Approved NRT exists for smoking cessation and has been viewed by the industry as a competitor.^{6 24 25} However, e-cigarettes increasingly look, feel and play the role of pharmaceutical NRT and are

often marketed both as drug delivery and as cessation devices. Instead of offering nicotine as a way to wean from tobacco products completely, TTC-produced alternative nicotine products are positioned for long-term or recreational use. The compelling but dangerous argument for these nicotine products is that if the product is not as harmful as cigarettes—a low bar, to be sure—then it may be freely used and ideally exempt from cigarettes' liabilities, regulations and associated stigma. Public Health England, for example, has claimed that e-cigarettes do not fall into the 'smoking' category and thus should not be covered by pre-existing smoke-free policies.⁴⁸ This conclusion rests on the premises that (1) these products do not produce substantial negative health outcomes; (2) nicotine addiction without combustion does not sufficiently harm the individual or public; (3) use of these products does not serve as a gateway to smoking; and (4) ubiquity of these products will not recruit a new generation of tobacco users. New tobacco and nicotine products resemble pharmaceutical nicotine products, frequently deliver specific doses of nicotine and have the potential to be government certified as smoking cessation or reduced-harm products.³³ However, the FDA approval process for smoking cessation therapies at the Center for Drug Evaluation and Research is separate from regulation of e-cigarettes at the Center for Tobacco Products.⁴⁹

Conceptually, pharmaceuticalised products can be thought of as situated between FDA-approved NRT and existing tobacco products (table 1), in order to access the most advantageous aspects of both policy domains, inheriting the former ubiquity of smoking while enjoying regulatory and popular status as benign medicines. Pharmaceuticalised tobacco products are presented as offering regulators and the public health community less disease from tobacco, while positioning tobacco companies as allies in solving the tobacco epidemic.⁵⁰

Table 1 Comparison of pharmaceuticalised tobacco products with NRT and combustible tobacco products

	FDA-approved NRT	Pharmaceuticalised tobacco/nicotine products	Combustible tobacco products
Pharmaceutical status	Approved drug	Certified reduced-harm tobacco product	Tobacco product
Availability	Prescription and over-the-counter	Convenience stores, tobacco shops and pharmacies	Convenience stores and tobacco shops
Nicotine strength/dose	Low	High	High
Abuse liability	Low	High (including gateway, especially for youth/young adults)	High
Cessation is goal of use	Yes	Variable/dual use/recreational	No
Government certification	Yes	Yes/desired	No
Harm potential	Low	Low to medium	High
Length of use	Temporary (standard)	Long term	Long term

FDA, Food and Drug Administration; NRT, nicotine replacement therapy.

1600's	1700's	1800's	1900's	Future
Dry Snuff	Dry Snuff	Chewing Tobacco	Cigarettes	Modern Smoke-Free Tobacco
	Chewing Tobacco	Plug Tobacco	Moist Snuff	ANP
		Moist Snuff	Chewing Tobacco	Moist Snuff
		Pipe Tobacco	Cigars	Cigarettes (first half of century only)

Figure 1 RJ Reynolds' 'Great Migrations' plan, 2008.⁶ ('Modern smoke-free' tobacco refers to snus and other potentially reduced-risk products; 'ANP' refers to alternative nicotine products, such as e-cigarettes.)

Product 'migration' and 'cannibalisation'

As tobacco regulation and denormalisation increased, TTCs confronted the question of how to 'migrate' their future business to new reduced-harm products without losing market share in conventional cigarettes.⁵¹ The tobacco companies discussed continued development of non-cigarette tobacco products, supporting migration to potentially reduced-harm products and maintaining or strengthening existing market share, sales and profitability of conventional cigarettes; at the same time, efforts continued to expand cigarette penetration in immature markets in the developing world.^{6 52}

TTCs have made long-term plans for product migration. When introduced in 1998, PMI's early heated tobacco product Accord (called a 'potentially reduced-risk product' at the time) would play a major role in its product portfolio's 10-year plan.⁵³ In this same 2002 Departmental Game Plan, Philip Morris USA (PMUSA) indicated the need for 'development of a PMUSA business plan that fully integrates potentially reduced-risk products'.⁵³ Similarly, RJR proposed in 2008 that 'Migration strategy is the way forward but [is] unproven to date' in a planning document summarising the introduction of new tobacco products over time to illustrate that as moist snuff, cigarettes and cigars were introduced in the past, alternative nicotine products and other 'modern smoke-free' products could be successfully introduced (figure 1).⁶

Product migration could inevitably lead to market 'cannibalisation', which is the reduction in demand for a company's core product through introduction of a new and improved product that competes with it.⁵⁴ Cannibalising their core consumer base (smokers) constituted a threat for the tobacco companies, and as long as smoking was still profitable and socially acceptable, there was little reason to innovate. Business model shifts occurred in response to regulation, losing social licence, market share shrinkage, reduced sales volume and disruptive innovations from outside the industry.

'[W]e will inevitably cannibalize ourselves to some extent', admitted RJR Director of Development Richard Kampe in 1988, by introducing their heated tobacco product, Premier, which was initially promoted as a smokeless cigarette. Kampe heralded Premier as a 'technological breakthrough', justifying the product's rollout by reasoning that RJR's innovation would take a larger bite from competitors' low-tar brands than from its own.⁵⁵ Thirty years later, in 2019, Altria CEO Howard Willard would report a similar story to the *Wall Street Journal* regarding Altria's purchase of a 35% stake in JUUL: 'At a time when e-vapor is going to grow rapidly and likely cannibalize the consumers we have in our core business, if you don't invest in the new areas you potentially put your ability to deliver that financial result at risk'.⁵⁶ Such explanations for investing in new products as a hedge against changing market circumstances (such as reduced cigarette sales, increased regulation, taxes and the denormalisation of smoking) suggest that only with the increasing popularity of e-cigarettes did the industry seriously launch an offensive using the rhetoric of harm reduction to switch or migrate smokers to other tobacco and nicotine products.

TTCs actively sought favourable regulation frameworks and social acceptance for their new products with reduced-risk claims, as well as a 'seat at the table' with regulators. This objective would be difficult to achieve: the tobacco industry was prohibited from participation in tobacco control measures in the WHO's Framework Convention on Tobacco Control (FCTC) which was adopted by the World Health Assembly in 2003.⁵⁷ This quandary led to an impassioned speech titled 'External Forces: Facing the Future' by PMI's David Davies, Senior Vice President of Corporate Affairs, at the TabExpo (annual tobacco industry networking event) in 2003, during the pivotal period following the historic 1998 US\$240 billion tobacco Master Settlement Agreement (MSA) between the industry and 48 US states and when the FCTC entered into force in 2005. Intimating the

implications of FCTC's Article 5.3 which bars states from fraternising with the tobacco industry, Davies confirmed industry efforts to seek a social 'licence':

In the future societies will allow us to operate only if we maintain our social license to operate. That 'license' is dependent on our willingness to understand societal expectations and meet them...

How do we address this exclusion and how do we redress this exclusion[?] ...our reflex has been to address exclusion through confrontation that is premised on a passive acceptance of our exclusion. This never secures a seat at the table and fuels the belief that we should be denied.

I believe a case can be made that we change our mindset, that we act assertively to demand inclusion, that we relentlessly pursue renewal of our social license to operate, - by listening, understanding, and communicating. Society in turn will accept that we can insist on governments fulfilling their responsibility to consult, collaborate and co-operate. Indeed co-operation between the regulator and those being regulated becomes the key to effective policy.⁵⁸

Rather than accepting the FCTC's articles that put a firewall between industry and government, industry instead sought to position itself as the key player in developing product solutions to migrate smokers and the public to accepting a new industry-led tobacco harm reduction paradigm.

Years of focusing on gaining social licence for their new products paid off for both companies. By 2015, PMI's internal documents suggested that renormalisation of smoking no longer posed a concern when introducing e-cigarettes.⁵⁹ RJR likewise recognised the need to establish a 'scientific basis for relative risk continuum, holistic migration plan, and regulatory principles' for their new tobacco products to gain government certification as modified-risk products and to '[r]educ[e] the harm across RJR's portfolio.⁶⁰ The systematic steps RJR identified to implement this strategy constituted a major coordinated scientific and public relations enterprise that would allow them to: '[d]esign and implement studies to support migration', creating scientific evidence for the stance that instead of quitting, existing smokers would be more likely to switch to reduced-harm products; '[d]rive regulatory preparedness', getting ahead of the curve and creating mechanisms to meet expected FDA-product standards requirements, to support their new products; and '[f]acilitate credible engagement' with the public.⁶⁰

Nicotine replacement therapy (ironically) paves the way for legitimating new industry nicotine products

It is ironic that a key advance in smoking cessation treatment, pharmaceutical support (NRT), laid the ground for the tobacco industry's pharmaceutical turn. TTCs justified entering the NRT business on the assumption that nicotine is one of the less harmful components in cigarettes because it is accepted in pharmaceutical NRT.⁶¹ Because TTCs noted that smokers often take up authorised NRT but then revert to smoking, consumer research

companies contracted by multiple TTCs characterised NRT-producing pharmaceutical giants such as Johnson & Johnson as double dipping: being able to sell their cessation drugs multiple times to the same customer. This model of repeated NRT use through 'quitting-relapse-another try' was eyed as a lucrative business model by the tobacco industry. Mintel, an information gathering firm, observed in a report found in the archives for both Philip Morris and RJR that 'repeat and chronic users also prop up sales'.⁶² NRT, however, was deemed not as attractive to would-be quitting smokers as it could be, due to its '[l]ack of effectiveness and cost'.⁶² No company knew how to provide high nicotine and attractively priced products as well as the tobacco industry. During the early 2000s, the potential introduction of new and over-the-counter NRT products had potential to increase the number of chronic NRT users,⁶² presenting the tobacco industry with not only a challenge but also an opportunity. Pinney Associates, in an RJR commissioned report in 2015, noted FDA endorsement of long-term use of NRT and support for principles of tobacco harm reduction by FDA and other experts.⁶³ This new atmosphere of normalised harm reduction contributed to Philip Morris justifying their claims about minimising the harm of nicotine because '[n]icotine is used in pharmaceutical products (NRTs)'. The mere existence of NRT 'support[ed] the view that long-term use of clean nicotine by adults is safe'.⁵⁹

Philip Morris and other tobacco companies seized this opportunity to transform early on. Shortly after the MSA, Philip Morris executives realised that what they called '[t]he nicotine replacement product industry may eventually evolve into a long-term smoking cessation therapy as an approach to reduced harm', anticipating to capture a significant share of the then US\$300 billion total pharmaceutical industry.⁵⁰ Downplaying the toxic effects of nicotine and the harmful consequences of addiction fit into Michael Russell's paradigm that 'people smoke for the nicotine but die from the tar',⁶³ repeated by many pro-tobacco harm-reduction advocates.⁶⁴ While funded by RJR, Pinney Associates created a new harm reduction model called the 'Triple Continua Framework', adding the attribute of 'appeal' to argue that e-cigarettes are superior for harm reduction because they are more attractive to inveterate smokers than NRT.⁶⁵

In addition to NRT and e-cigarettes, TTCs also explored the potential of nicotine's pharmaceutical use in treating a wide range of diseases. Disease treatment would help to justify investing in and acquiring pharmaceutical companies, a necessary step for tobacco companies to obtain a better reputation and legitimacy. Philip Morris saw investing in pharmaceutical nicotine products as essential to stay competitive with RJR/RAI and JTI, which had long partnered in forays into alternative uses of nicotine such as medical inhalers.⁵⁰ Aware that critics might be sceptical of their ability to change, Philip Morris planned to 'acquire [pharmaceutical] competencies based on [their] financial resources', that is, investing in

pharmaceutical company scientists, subsidiaries and technologies.^{25 50} This new division was not meant to compete with cigarettes, but to market ‘therapeutic applications’ for treating pain and other maladies,⁶⁶ such as the ARIA pulmonary inhaler device developed by Philip Morris subsequently as part of its Chrysalis Technologies pharmaceutical subsidiary.^{67 68}

RAI also demonstrated interest in the ‘therapeutic benefits’ of nicotine since the 1980s. In 1993, RJR entered into research agreements with Japan Tobacco’s pharmaceutical division and ‘establish[ed] collaborative research programs with pharmaceutical companies to minimize [the] cost of development and therapeutics’, aiming to ‘popularize [the] positive aspects of smoking by disseminating information on the role of smoking and nicotine in ameliorating neurodegenerative diseases’.⁶⁹ Spending over US\$1 billion on this initiative in the 1990s, RJR sought to integrate pharmacology, biological chemistry and new business development.⁶⁹

RJR established Targacept in 1997—a subsidiary company designed to ‘rapidly commercialize...nicotinic pharmaceutical technologies’ for potential treatment of ulcerative colitis, hypertension and various neurological diseases (eg, Parkinson’s disease, Alzheimer’s disease, attention-deficit/hyperactivity disorder (ADHD), schizophrenia, anxiety disorders and Tourette’s syndrome).⁷⁰ Targacept’s president Donald J. deBethizy announced: ‘We are very excited about the potential to help alleviate some of the suffering experienced by millions of individuals’ with these diseases through nicotine.⁷¹ The same year, RJR announced a partnership with Rhone-Poulenc Rorer Pharmaceuticals/Aventis,⁷² a global pharmaceutical company, ‘to research and develop’ various tobacco and nicotine compounds ‘with the goal of developing new drugs to treat Alzheimer’s and Parkinson’s

diseases’. Through this partnership, RAI stated internally that nicotine-based treatments aimed to (1) ‘positively impact [the] research community’s attitude about nicotine’, (2) ‘improve public perception of nicotine through marketing of products’ and (3) ‘change [the] perception of nicotine in [the] medical community’.⁷³ Pharmaceuticalising nicotine became a potentially lucrative income stream for disease treatment as well as a rationale for the continued sale and consumption of tobacco products.

Part of RAI’s framing for therapeutic nicotine depended on their definition of nicotine as ‘not an addictive substance’.⁷⁴ In anticipation of potential public accusations regarding the self-serving aims of the ‘significant amount of research conducted (as embodied in numerous publications) on the benefits of smoking, nicotine analogues and nicotine pharmacology/physiology’, a 1994 RJR memo containing answers to public criticisms stated, ‘It is natural and appropriate for RJR to investigate nicotine’s properties—as the company does with respect to other aspects of cigarettes’. They reasoned that ‘[n]icotine research related to cigarettes is similar to caffeine research by coffee manufacturers’.⁷⁵ Similar claims likening nicotine to caffeine would be repeated decades later publicly in communications by BAT (figure 2).⁷⁶

These claims and associated public relations efforts regarding nicotine’s alleged virtues received backing through industry-funded scientific studies,⁷⁷ which highlighted the benefits of nicotine while downplaying its addictiveness and other major health risks, such as cardiovascular disease. In a 2021 BAT investor Q&A session, Director of Scientific Research David O’Reilly decontextualised the substance, repeating the mantra of safe nicotine by appealing to the authority of the WHO: ‘I mean nicotine, whilst it can be additive [sic], has a very



Figure 2 Nicotine explained. Document on BAT website in 2013.⁷⁶

good safety profile. And that's not just me saying it, it's other organisations, including the WHO'.⁷⁸

In the meantime, TTCs were moving beyond tobacco and nicotine portfolios to create a multipronged 'wellness' business model and image. For example, in 2021 BAT highlighted their products serving the purpose of 'On the Go, Wellbeing and Stimulation'.⁷⁹ PMI focused on 'botanicals' and 'respiratory drug delivery', suggesting a move towards the business of 'wellness,' as presented during its 2021 Investor Day.^{80 81} Dewhirst has also noted tobacco industry inroads into cannabis, taking advantage of cannabis's rehabilitated classification for medical use to advance to the 'well-being' industry.⁸⁰ In both cases, the move is away from framing the products as addictive drugs and associating them with lifestyle, recreation and even health. A move which spurred public health outrage worldwide, and an especially egregious example of providing a medical device with one hand while the other hurts lung health, was PMI's 2021 purchase of the asthma inhaler company Vectura, which treats a disease for which smoking is a major risk factor.^{82 83} Increasing investments in diverse wellness categories suggest that the tobacco industry may move beyond both tobacco and nicotine, buying into emerging self-prescription markets promising to allow individuals to self-medicate with medical and recreational supplements, enhancers and other alleged health-boosting or advantage-boosting products.

From 'big tobacco' to 'responsible corporate citizen'

Pharmaceuticalisation signifies a major transformation of the corporate identity of 'big tobacco'. After the 1998 US MSA, Philip Morris saw that its role as the 'leading cigarette manufacture' alone would not maintain market dominance, and did some soul searching. As part of their Management Exploration Platform (MEP), Philip Morris conducted almost 200 in-person interviews with 'business, civic and social leaders' to 'gain an understanding of current and future business, social and technology trends throughout the world'.⁸⁴ Notably, their investigations into 'business drivers, government and regulation, technology, multiculturalism, demographics, society, consumers and retailing' was neither interested in nor focused on tobacco.⁸⁴ From the results of the MEP study, showing the importance of aligning brands with social values such as environmentalism, social equity, other social and regulatory expectations, Philip Morris planned to become the 'most *responsible* cigarette manufacture' through aligning the company, parlaying its business competencies and leveraging capital to acquire nicotine and pharmaceutical companies to become a medical and recreational nicotine company (figure 3).²⁵

In one of the final presentations of Philip Morris USA's 2000 Mission Exploration Project to determine its future direction, Philip Morris schematised societal regard for corporations in three tiers: 'admired', 'responsible' and 'irresponsible' companies,²⁵ and the characteristics of irresponsible companies were that they did not change

and they denied culpability. Philip Morris's examples of irresponsible companies were Exxon, Dow and 'tobacco companies', and examples of admired companies were Apple, Coca-Cola, Disney and the pharmaceutical company Johnson & Johnson.²⁵

Initially, in the aftermath of the costly MSA, Philip Morris realised that focusing on reduced-risk products would help 'close [the] credibility gap' perceived by an incredulous public and regulators that the industry could actually be part of the solution to their self-manufactured problem.²⁵ Thus, the 'road to responsibility and respect' lay in meeting social expectations to undergo a 'transformation from 'big tobacco' to 'responsible corporate citizen'.²⁵ Philip Morris's realisation that tobacco was a 'mature, declining market' nudged them towards joining the 'pharmaceutical industry' which offered a 'competitive space' and 'sustainable growth'.²⁵

Philip Morris's senior leadership conceived a long-term plan to become the dominant pharmaceutical nicotine company, proposing a two-pronged harm-reduction and NRT approach, in order to eventually become a 'pharmaceutical company', as their 'core business tomorrow'.²⁵ Philip Morris leadership also considered if there would be opportunities to 'build brand credibility and equity by partnering with well-established pharmaceutical labs'.⁸⁵

Underlying TTCs' 'responsibility' discourse is their attempt to orchestrate a regulatory environment conducive to their transition plan. If introducing a reduced-risk category that would benefit public health would be considered a responsible move, these products, following their logic, should not be regulated as the traditional 'tobacco' products.

By introducing 'reduced-harm' products, Philip Morris aimed to be viewed as 'helping [the] public health community/regulators address tobacco issues',²⁵ acting as redeemer to the tobacco epidemic, playing down their creation of the problem.⁸⁶ According to their capacity to reorganise into a nicotine delivery business in mature tobacco markets,⁴⁶ Philip Morris argues for reduced regulation. As Philip Morris Corporate Affairs wrote in 2001, their 'objective over the plan period is to shape a political, regulatory and attitudinal environment around the world, particularly in the United States'.⁸⁷ Altria Senior Vice President of Corporate Affairs Steve Parrish wrote that the company's most important goal involved achieving what they called 'corporate normalcy... [to] be given permission by society to exist *and* to prosper'.⁸⁷ To engineer this, the company set out three aims: achieve a regulatory regime that legitimates them, 'societal alignment' with public expectations and proactively define their company to the public rather than having the public define or vilify them.

The tobacco landscape has significantly changed in the past two decades. In 2009, the passage of the Family Smoking Prevention and Tobacco Control Act gave the FDA authority to regulate tobacco products. The modern e-cigarette was introduced to the US market in 2007.⁸⁸ E-cigarettes have generated debate in the public health

Pharmaceutical Exploration

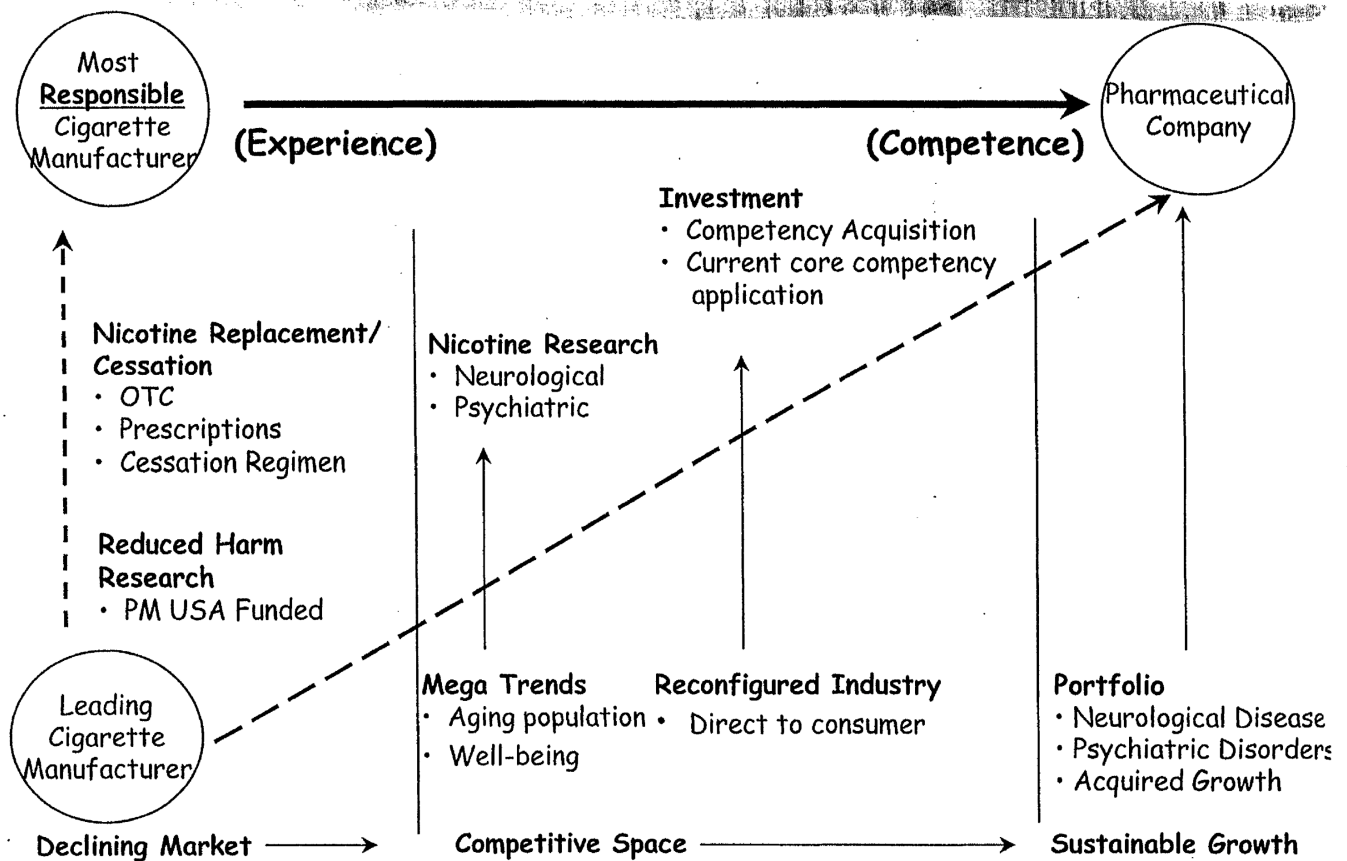


Figure 3 Philip Morris’s strategy to become a pharmaceutical company.²⁵ This 2000 document from Philip Morris’s Management Exploration Platform aimed to counteract negative public sentiment about the tobacco industry in the USA by leveraging their research into reduced-harm products and interest in entering the nicotine replacement (or cessation) market. These competencies in product design and pharmaceutical research and development would allow them to capitalise on megatrends (such as wellness) and acquire and create direct-to-consumer pharmaceutical and pharmaceutical-like products for an array of diseases, disorders and enhancement applications.

community about their potential to serve as relatively safer alternatives to combustible cigarettes or as cessation aids, and both these products and the division they created in the previously unified tobacco control community also created new opportunities for the tobacco industry. Tobacco harm reduction strategies were explicitly addressed by Pinney Associates, in work funded by Reynolds American.⁸⁹ Their 2015 report on tobacco harm reduction claimed ‘NRT have had limited success. Vapor offers a new promise and opportunity’.⁶³ Citing an FDA report, Pinney Associates stated that “there are no safety risks associated with longer-term use of nicotine replacement therapies (NRT) to avoid smoking relapse”, which opened the opportunity to consider e-cigarettes as a benign product similar to nicotine gum but much more socially attractive.⁶³

Similarly, in their 2016 United Nations Global Compact report, PMI’s CEO announced: ‘Our ambition is to lead a full-scale effort to ensure that non-combustible products ultimately replace cigarettes’,⁹⁰ which was reiterated in its 2016 Scientific Update: ‘our objective is to replace

cigarettes with RRP [reduced risk products] as soon as possible’, following a ‘scientific assessment program [...] inspired by standards and practices long adopted by the pharmaceutical industry’.⁹¹

In order to assess the risk of their products and to shepherd their products through regulatory frameworks, PMI set up an approach to the assessment similar to methods used by the pharmaceutical industry,

based on the relevant scientific literature and taking into account the US Food and Drug Administration’s draft guidance for Modified Risk Tobacco Product (MRTP) applications. This approach is similar to assessment methods used by the pharmaceutical industry. We have also used innovative systems toxicology which allows us to use non-clinical data to model the potential risk reduction impact of our RRPs in humans.⁵⁹

Similarly, in 2018, BAT marshalled their extensive scientific studies to justify an ‘abridged regulatory pathway’ to expedite the process of assessing ‘alterations to an

original new generation product'—a common practice for generic drugs in pharmaceutical industry.⁹²

In addition, PMI argued for reduced regulations for RRP, such as stressing that PMI's RRP products should not be subject to the same indoor clean air regulations as cigarettes because of the benefits in assisting quitting.⁵⁹ PMI likewise advocated for loosening restrictions on '[a]dvertising and marketing of safer products', claiming that they 'should be regulated in a balanced way but should not be subjected to the same prohibitions that apply to the marketing of cigarettes'.⁵⁹ They argued: 'Marketing of RRP should include communication about the risks and benefits substantiated by sound science' (emphasis in the original).⁵⁹

The tobacco industry's post-MSA transition to become a 'responsible corporate citizen' involves the introduction of 'reduced-risk' products. However, underneath the turn is their aim to seek for a more friendly regulatory framework that would normalise the use of such products.

One product serving two ENDS: emerging products

Over the past decade, TTCs emphasised their investment not only in 'next-generation' products, especially electronic nicotine delivery systems (ENDS), but also in nicotine pouches, synthetic nicotine technologised products and other drug applications.²⁸ Multiple tobacco companies have acquired non-tobacco subsidiaries manufacturing e-cigarettes and medical products, including more products resembling pharmaceuticals.⁶⁸ A 2019 review of TTC investments in new nicotine delivery systems found all TTCs are investing in e-cigarette products and some have sought medical licensing for products as cessation aids.⁹³

While conceding that combustibles will be the main source for the industry's profit for years,⁷ BAT nonetheless framed harm-reduced products in 2012 as 'crucial to the future of our business'.⁹⁴ According to its CEO Nicandro Durante, one of the five motivations for BAT's 2017 acquisition of RAI (they previously owned a 42% share) was to provide an opportunity to research and develop 'next-generation products' and a 'world class pipeline of vapour and tobacco heating products'.⁹⁵ Imperial tobacco company also acquired e-cigarette companies Dragonite and Lorillard's Blu in 2013 and 2014, respectively, through its subsidiary Fontem Ventures, and developed its own e-cigarette, Puritane, in 2014, which was initially marketed as a healthcare product.⁹⁶

Benefitting from the UK's National Health System approval of BAT's pharmaceutical e-cigarettes for prescription as cessation aids, in 2014 BAT subsidiary Nicovations was the first company to receive government licences for both its nicotine inhaler, Voke,^{97 98} and e-cigarette, e-Voke, in 2015.⁹⁹ This 'medically authorised nicotine replacement technology' was dropped by BAT, however, because by the time it was introduced (2015–2016), it was no longer attractive to customers, as other e-cigarettes had already received a warm welcome in the UK market, making it redundant. Later BAT admitted that consumers rejected medicalisation and being referred to as 'patient[s]', and the medical category requires

a more complicated process (prescriptions, etc) that limits the product's market accessibility.¹⁰⁰ This suggests that the medicalised technology may be valuable, not as a commercial success, but as a means to bolster BAT's reputation and positioning as a nicotine pharmaceutical company. Although BAT deprioritised this product, it remains a potent reserve innovation. BAT returned the patent to Kind Consumer, which, in a 2019 meeting with Public Health England, defined Voke as NRT, which may make a comeback through prescription.¹⁰¹

A semiotic analysis of BAT's Voke inhaler advertising clarifies certain aspects of tobacco industry pharmaceuticalisation (figure 4). The advertisement features elements that evoke a sense of medical authority and certification, stating that it possesses a 'Pharmaceutical grade formula with full analysis testing of vapour', 'Medically authorised nicotine replacement technology' and is a 'CE [*Conformité Européenne*] certified medical device'. The advertisement highlights sleek technical design features such as its 'Streamlined charging pack' and the reassuring statement that it is 'Manufactured in a controlled environment'. It includes medicalised standard dosage through phrases such as 'Measured nicotine dose' and a spec engineered 'Breath operated valve with no electronics or heat'. The advertisement also pronounces that there is 'No risk from second hand vapour'.

The medicalised features of products like the Voke inhaler coupled with cessation claims for ENDS may grant TTCs and e-cigarette companies legitimacy in marketing these products, further validated by health authority endorsement.¹⁰² Avowedly anti-industry vaping retailers¹⁰³ as well as some public health organisations^{102 104} have cast e-cigarettes as viable cessation devices and advocated for their regulation as medicines.¹⁰⁵ The UK government also announced in October 2021 that e-cigarettes can be prescribed as medicinal products and manufacturers could submit their products to go through the Medicines and Healthcare products Regulatory Agency approval, under the same regulatory process as medicines that are covered by the National Health Service.¹⁰⁶

Even when new nicotine products lack explicit sanction by medical authorities, the public may perceive these products as pharmaceutical.¹⁰⁷ While many industry nicotine products can neither be legally advertised as cessation devices nor certified as reduced-harm products, they may be advertised and perceived as de facto NRT analogues.¹⁰⁸ In this way, the industry may assume the mantle of medical legitimacy without having legally earned it.

Whatever specific label these new products are referred to in the companies' business strategies ('next generation', 'reduced risk/harm', etc), they are accompanied by the key message that the tobacco companies are making innovations to satisfy a variety of customer preferences. These products can be represented within a four-platform space according to PMI's 2014 internal document on its objectives for developing products with reduced-risk potential (figure 5).¹⁰⁹ As shown in the diagram labels, the x-axis 'conservative/discrete–progressive' indicates social (not political) categories of consumer tobacco product use, with the former representing consumers wishing to be seen as smoking

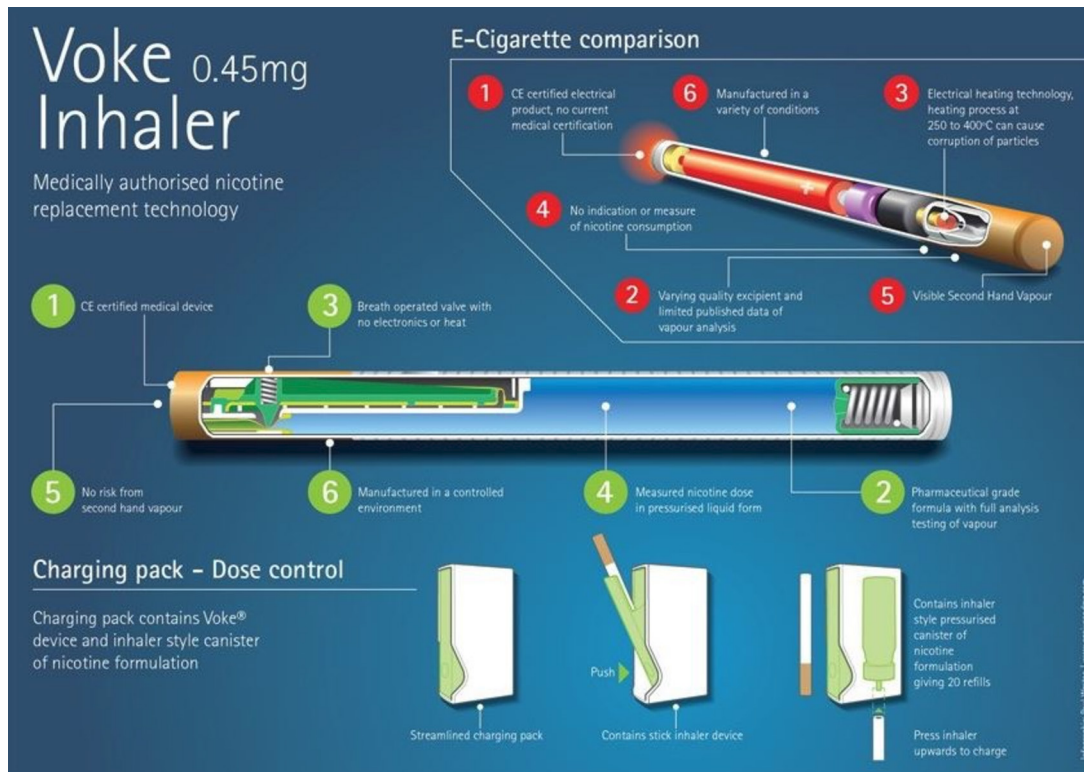


Figure 4 Advertisement deconstructing the components of the UK insurance-licensed Voke inhaler, which was approved by the UK National Health Service but has not yet been brought to market.⁹⁹

4 platform spaces available

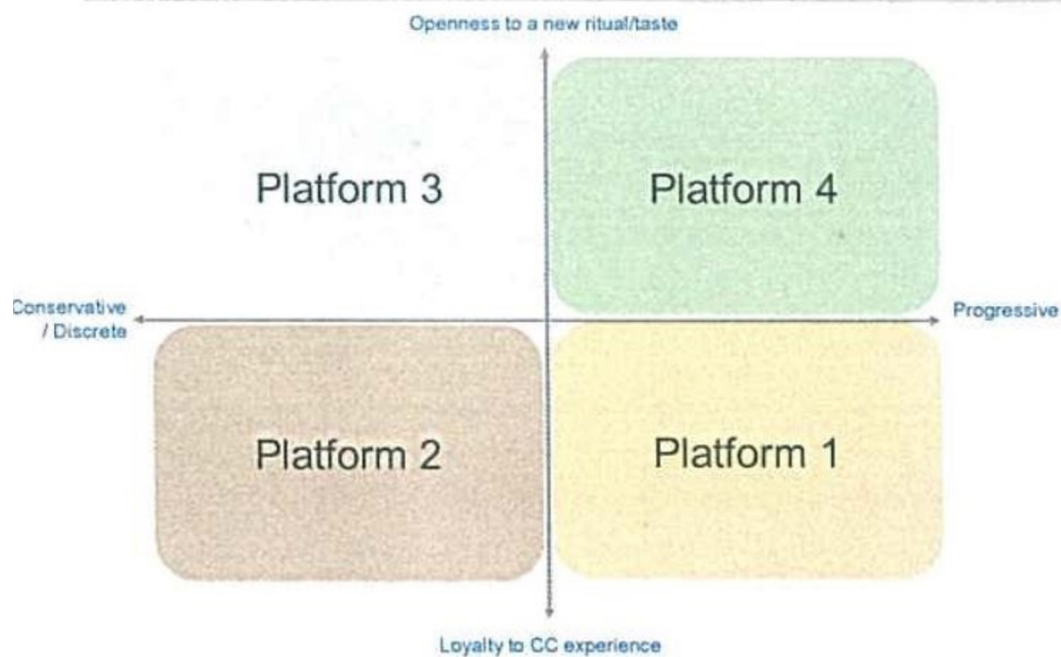


Figure 5 PMI's four 'platforms'. Platform 1 is IQOS; platform 2 is a pressed carbon modified conventional cigarette (under development) similar to RJR's Eclipse; platform 3 encompasses nicotine inhalers (nicotine salt aerosol); and platform 4 includes all e-cigarette products.¹⁰⁹ CC, conventional cigarette; PMI, Philip Morris International; RJR, RJ Reynolds.

cigarettes (socially), while the latter category wishing to avoid a product that resembles a conventional cigarette. The y-axis represents consumers' attitude, either 'open[] to a new [nicotine] ritual/taste' to maintain their addiction or '[I]oyalty to [the] CC [conventional cigarette] experience', preferring products mimicking smoking or that resemble modified cigarettes.¹⁰⁹

As of today, platforms 1, 3 and 4 have products that Philip Morris and BAT are rapidly developing and promoting. PMI's platform model provides possibilities for further conceptualising products with different combinations of user needs, including going beyond tobacco and nicotine. These different product platforms chart the future waves of the tobacco epidemic. Depending on the status of mature cigarette markets and regulations, PMI can offer products from their various platforms, from most cigarette-like (2—modified lower heat 'safer' cigarettes and 1—IQOS) to more pharmaceuticalised devices (4—e-cigarettes followed by platform 3—non-electric nicotine inhalers like the Voke inhaler above).

DISCUSSION

As smoking rates decline, pharmaceuticalisation provides the TTCs a path to regain social acceptability and normalcy, paving the way for continued tobacco product use and government certification of safety, while avoiding the extensive pharmaceutical trials and testing, product warnings and bureaucratic process required to get an investigative new drug to market. While PMI announced bold public claims to end the sale of cigarettes in some countries,²⁶ the industry version of 'endgame' aims to sustain the use of nicotine and 'reduced-risk' tobacco products for a new generation.¹¹⁰ Instead of ending the commercial sale of tobacco—the traditional definition of the tobacco control endgame for most public health professionals¹¹¹—harm reduction and risk modification have become the lowered goalposts. PMI aims to redirect the endgame from a tobacco-free future to one free of cigarettes but replete with sanctioned reduced-risk tobacco and nicotine products. In the process, they exonerate the role of the tobacco industry in inflicting the tobacco epidemic and portray the industry as a partner in tobacco control.^{112 113}

Pharmaceuticalisation and harm reduction provide a rationale for sympathetic regulators, public health policy-makers and scientists to work with TTCs. By repositioning tobacco alongside science-backed reduced-harm products, the TTCs attempted to rewrite the rules and social mores governing them. Highlighting their willingness to meet regulatory requirements, scientific due diligence and alacrity to adopt practices used in pharmaceutical companies and medical fields, PMI and BAT sought to maintain profitability with nominally reduced-risk products, which carried the additional benefit of improving their corporate image and providing a rationale to weaken tobacco control regulations and marketing restrictions on new products. In addition, TTCs have promoted themselves as legitimate advisors on science and related health issues on their websites (eg, PMI

highlights their 511 scientific publications on 'smoke-free products and related science' as well as their cache of '1180 scientists, engineers, technicians and support staff')¹¹⁴ and on social media, where BAT has tweeted, 'World-class science is at the core of everything we do'.¹¹⁵

Pharmaceuticalisation activities differ substantially from the tobacco industry's historical diversified portfolios, including Altria's ownership of Miller Beer or Kraft Foods, where tobacco's reputation was sometimes a liability to their non-tobacco brands.¹¹⁶ In contrast, pharmaceuticalisation embraces and extends the industry's core business marketing nicotine and applies it to other substances. Philip Morris International's CEO, Jacek Olczak, remarked in his 2023 Investor Day presentation that, 'We still believe that this business provides the very sizable [sic] but long-term potential, and applies especially in the territory of pharmaceutical, medical and consumer wellness segments'.¹¹⁷

BAT and PMI initiatives embracing pharmaceuticalisation have been facilitated by public health professionals' calls. Longstanding supporters of the Public Health England position, Britton and McNeill, for example, wrote in 2001 that 'we also need legislation that explicitly encourages the development of alternative products that can deliver uncontaminated nicotine at a dose and rate comparable with cigarettes and in a way that is commercially and socially acceptable'.¹¹⁸ Public Health England's more recent guidelines to distinguish between smoking and vaping for differential application of smoke-free policies highlighted the fundamental differences between smoking and vaping, and insufficient evidence suggesting vaping harms bystanders, emphasizing potential to help cessation and denormalise smoking.⁴⁸ Such regulatory considerations could pave the way to revoke the smoke-free norms public health long fought to achieve. Granting exceptions to e-cigarettes under smoke-free policies is also framed as an equity issue, as Public Health England's recent report on e-cigarettes argues that disadvantaged groups with higher smoking prevalence need access to e-cigarettes as cessation tools.¹⁰⁵ It is one thing to claim that e-cigarettes can be one tool among many in helping people quit. It is quite another to reframe quitting conventional cigarettes as dependent on lifting the policy restrictions surrounding e-cigarette manufacture, advertising and use.^{105 119} Public health advocacy to reintroduce pharmaceuticalised tobacco product use into denormalised spaces¹²⁰ may not help public health, but it definitely benefits the tobacco industry.

Pharmaceuticalisation undermines traditional tobacco control for three main reasons. First, the focus on the parade of new products could distract regulators and scientists from paying attention to cigarettes, still the largest source of industry profit and source of deaths.¹²¹ TTCs are still very actively marketing cigarettes in developing markets, but their activities have been overshadowed by excessive attention to new products.²⁸ Pharmaceuticalisation efforts concentrate in mature markets, exacerbating disparities in which developing markets are suffering the most. While introducing technically advanced and expensive new products in mature industrialised markets, tobacco companies continue to introduce new types of cigarettes in developing markets, as

Philip Morris International has done in Indonesia. There, PMI launched in 2007 Marlboro Mix 9 kretek cigarettes, which boast the highest levels of tar of any cigarette they have developed in decades (1.8 mg of nicotine and 30 mg of tar, twice as much as any other Marlboros sold in other countries).^{122 123} Those countries still enduring the cigarette wave of the tobacco epidemic and not yet saturated have not been prioritised for introduction of ‘clean nicotine’ pharmaceuticalised products, for the simple reason that there is still money to be made in conventional cigarettes. As some tobacco harm reduction advocates claim, this lack of equal access to reduced-harm products in developing countries is a social injustice.¹²⁴ If the tobacco industry was serious about harm reduction, they would promote the products they deem to be reduced harm and phase out their aggressive marketing of cigarettes in developing countries.

Second, tobacco harm reduction as the rationale for pharmaceuticalisation has split the tobacco control community. The creation of controversy and splitting opposition is a longtime tobacco industry strategy.¹²⁵ Scientific and public perceptions of tobacco harm reduction have changed markedly in the past two decades. In 2004, a major consensus by Hatsukami *et al*²¹ on the topic found that ‘public policy approaches to harm reduction are considered more dependable than strategies that involve pharmaceutical treatment or rely on the tobacco industry, such as product modification’.¹²⁶ One study found that smoke-free policies led to increased quitting at a rate roughly ten times what cessation products and interventions accomplished on their own.¹²⁷ In recent years, however, with the rise of nicotine reductionism and normalisation, tobacco control policy has been undervalued and product replacement has become the holy grail of smoking cessation, enhanced by a plethora of new products.¹²⁸

Funding research is a particularly effective way to split the scientific community. The Foundation for a Smoke-Free World, funded by PMI, institutionalises the research funding mechanisms for promoting reduced-risk products and shifting public health goals from abstinence to reduced-harm products. The availability of a promised US\$1 billion in research funding for reduced-harm products attracts previously non-industry aligned scientists to engage with and support industry aims.¹²⁸ This provides scientists a justification for working with the tobacco industry to develop ‘reduced-harm’ products with the aim of reducing tobacco-related mortality,¹²⁹ which in turn recreates social licence. Because the tobacco industry created the problem, their logic goes, they are best situated to help alleviate the smoking epidemic—for a price.¹³⁰ Harm reduction, as promoted by the tobacco industry, thus becomes a disease vector,¹³¹ spreading the notion that taking up attractive substitute nicotine products is the path to social acceptability and health benefits. These ideas have been taken up by influential tobacco control researchers and practitioners,^{64 129} doing the tobacco industry’s work for them. In addition, third party consultants, such as Pinney Associates or organisations such as Knowledge-Action-Change,¹³² both directly and indirectly funded by the tobacco industry, also serve to

amplify and normalise commercialised tobacco harm reduction messaging.¹³³

Third, pharmaceuticalised novel nicotine products have been used to undermine Article 5.3 of the WHO’s FCTC⁵⁷ by encouraging partnership with the tobacco industry to produce reduced-harm products.¹³⁴ The implications for public health are grave. By inviting BAT to partner with their public health system to provide tax-payer funded cessation devices, for example, the UK violates FCTC Article 5.3, which explicitly prohibits consultation or partnership between tobacco control policymakers and the TTCs.⁵⁷ Such partnerships have resulted in certain public health organisations, like Public Health England, working with ostensibly non-industry pro-nicotine associations which are in fact funded by TTCs.¹³⁵

Tobacco control and public health communities can benefit from understanding pharmaceuticalisation as a larger trend taking place within the tobacco industry. Using pharmaceuticalisation as a framework to appreciate the bigger picture of the product landscape facilitates understanding the different and emerging tobacco, nicotine and related products entering the market, rather than narrowly focusing on individual product characteristics and their effects.

Limitations

Industry documents are an inherently incomplete data source, and while triangulation with other sources is beneficial, not all pharmaceuticalisation strategies and tobacco companies were addressed. This analysis focuses on the US and UK contexts, as the primary data sources are from companies based in these countries. However, these documented efforts to pharmaceuticalise companies and products for renormalisation, and roll back health policies on nicotine, have occurred throughout developed markets worldwide and will likely take place in developing markets as they denormalise smoking and enact policies to decrease smoking prevalence, if they fail to regulate emerging nicotine and tobacco products.¹³⁶

CONCLUSION

Parallel to the tobacco control endgame that public health professionals have pursued to eradicate smoking-related disease, the tobacco industry’s *own* endgame involves pharmaceuticalisation—the transition to continuing the tobacco epidemic in declining mature markets using pharmaceutical-style nicotine products to sustain nicotine addiction, sanctioning partnership with scientists and regulators and distracting from ongoing cigarette sales in developing markets. As TTCs increasingly insert themselves into the lucrative business of cessation and long-term nicotine maintenance, public health professionals and regulators must decide whether the industry should be allowed to profit from ‘treating’ the very problem it perpetuates.

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