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Invisible smoke: third-party endorsement and the resurrection of heat-not-burn tobacco products

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ABSTRACT

Background Tobacco companies are introducing new 'heat-not-burn' cigarettes in dozens of countries. Historically, these products failed commercially, and independent researchers contested their health claims. The most prominent early heat-not-burn cigarette was RJ Reynolds's (RJR's) Premier, introduced in the USA in 1988. Curiously, *The Lancet* endorsed Premier as a 'near-perfect low tar cigarette' in a 1991 editorial, 2 years after Premier had been removed from the market. We examined the context of this endorsement.

Methods To ascertain what RJR knew about this endorsement, we systematically searched and analysed previously secret RJR documents in public archives and triangulated the industry document data with other published work.

Results RJR had a long-standing interest in collaborating with outside scientists to endorse potentially reduced harm cigarettes. The author of *The Lancet* editorial had previously corresponded with RJR regarding Premier's health effects and market potential. Internally, RJR regarded *The Lancet's* editorial, its stance on novel tobacco products, and its endorsement of Premier as major successes. While the editorial came too late to save Premier, RJR saw future business opportunities for novel products if endorsed by health authorities.

Conclusions Endorsement by high-impact medical journals and health authorities may be critical in helping heat-not-burn' products succeed where previous attempts have failed. Conflicts of interest influenced these endorsements in the past. Health leaders and academic journals should consider both conflicts of interest and the ethics of endorsing tobacco product substitution, as tobacco companies simultaneously work to promote cigarette smoking and undermine tobacco control globally.

BACKGROUND

Since the 1960s, the tobacco industry has developed 'safer' products to attract health-conscious smokers and improve its public image.¹ Major tobacco companies have recently expanded their product portfolios to include alternative nicotine products, such as electronic cigarettes (e-cigarettes) and 'heat-not-burn' cigarettes.² In 2015, Philip Morris International (PMI), British American Tobacco (BAT), RJ Reynolds (RJR; now owned by BAT) and Japan Tobacco International (JTI) all launched heat-not-burn products in dozens of countries.

Heat-not-burn cigarettes have a near 30-year record of dismal market performance.^{3,4} RJR introduced the first heat-not-burn product—Premier 'smokeless' cigarettes—in the USA in 1988. RJR

internally hoped Premier would 'address the growing pressures cigarette smokers face on the subjects of smoking and health, environmental tobacco smoke, and other issues related to the social acceptability of smoking'.⁵ In an internal memo to employees, RJR's President of Development Richard Kempe described Premier as 'one of the most important projects any of us will be involved in during our professional lives...because the success of this project could easily result in a tremendous long-term competitive advantage to RJR and would clearly have a substantial impact on the industry as we know it'.⁶ Smokers nonetheless widely rejected the product's taste, smell and difficulty of use. Having invested \$300 million (\$635 million inflation-adjusted to 2018), RJR removed Premier from test markets after only 6 months.

In 1991, 2 years after Premier's failure, *The Lancet* published an editorial praising Premier's ability to deliver nicotine with fewer carcinogens.⁷ The editorial called for health authorities, particularly in the UK, to promote cigarettes that delivered nicotine with as little accompanying tar as possible. As one of the earliest examples of an influential journal promoting a novel tobacco product, *The Lancet's* endorsement of Premier provides important context for the tobacco industry's current pursuit of health authority endorsements for its new products.⁸ Though the 1991 editorial appeared after Premier's demise, RJR viewed *The Lancet's* position as promising evidence that some health authorities would support novel tobacco products, and that with such endorsements, consumers might accept future products.

METHODS

We analysed previously secret internal tobacco industry documents available through the Truth Tobacco Industry Document Library (<https://industrydocuments.library.ucsf.edu/tobacco/>) between January 2016 and February 2017. In seeking to identify why *The Lancet* endorsed Premier in 1991, we combined qualitative analytical methods with iterative search strategies.^{9–11} Initial keyword searches included: 'Lancet' AND 'Premier'; 'Nicotine use after the year 2000'; 'editorial' AND 'Premier' and 'Chemical and Biological Studies of a Cigarette that Heats Rather than Burns Tobacco'. On learning that two historians attributed the anonymous editorial to Michael Russell,^{2,12} we conducted further searches with keywords including: 'Michael Russell', 'MAH Russell' and 'Russell' AND 'Premier'. We conducted snowball searches to locate related documents using reference (Bates) numbers, file locations, dates and individuals mentioned in pertinent documents. Triangulation with online search engines and



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news coverage (eg, Google News) generated data that helped resolve and contextualise questions raised by the documents. We repeated iterative searches until keywords and documents yielded only previously viewed documents, suggesting saturation. This analysis is based on a final set of 196 documents.

RESULTS

In a 1988 internal memo, RJR insisted that in its marketing of Premier, the company was:

[N]ot claim[ing] that the cigarette is 'safe' or 'safer'... [instead] we have used the word 'cleaner'... This is not a therapeutic claim... Premier's tobacco-heating technology is a breakthrough that 'changes the very composition of the smoke – substantially reducing many of the controversial compounds found in smoke of tobacco-burning cigarettes'.¹³

RJR President and CEO for West Germany, Peter Fischer, stressed that, when meeting with policy makers, RJR's scientific representatives should 'concentrate on "tar"/condensate related scientific aspects of [Premier] thereby avoiding to address [sic] the remaining nicotine and CO issues'¹⁴ which, if independently interrogated, might lead scientists to refute Premier's implicit health claims as 'cleaner'.

Legally restricted from making health claims, RJR depended on the scientific community and media to make those claims on its behalf. Proctor notes that Premier's marketing campaign included 'one-on-one briefings with university presidents, medical school deans, science writers, and medical organizations, along with politicians and "opinion leaders" throughout the world'.¹⁴ In a confidential 1987 planning document, Fischer discussed strategy to 'insure [sic] a successful product launch' for Premier, recommending RJR 'build strong support for the product concept among scientific, regulatory and political constituencies'.¹⁴

In 1990, to garner scientific and public support for Premier, Donald deBethizy, a senior toxicologist and Vice President of Research and Development at RJR, published a paper with nine other RJR scientists that compared the nicotine absorption, urine mutagenicity and carcinogens in mainstream smoke from Premier to a conventional cigarette.¹⁵ According to the paper—entitled "Chemical and Biological Studies of a Cigarette that Heats Rather than Burns Tobacco"—all chemical and carcinogen levels, save formaldehyde, were lower among Premier smokers.¹⁶ The authors attributed these reductions to Premier's smoke, reported as consisting of more than 90% water, glycerol and propylene glycol.¹⁵

The Lancet endorses Premier

Before its publication in the *Journal of Clinical Pharmacology*, deBethizy's paper was rejected by the *Journal of the American Medical Association*¹⁷ and the *New England Journal of Medicine*.¹⁸ In October 1989, deBethizy submitted the paper to *The Lancet*, hoping for 'better luck in England',¹⁹ despite the product already having been pulled from US shelves 8 months earlier.²⁰ *The Lancet* also rejected the paper on the grounds that its printing in the journal was 'not justifiable'.²¹ In the rejection letter, *The Lancet* editor David Sharp nonetheless called the paper 'a substantial study... [that] deserves to be published in full'.²¹ Sharp proposed a future editorial about Premier should a different journal publish the article.²¹ Over a year later, deBethizy notified *The Lancet* of the paper's publication in the *Journal of Clinical Pharmacology* and requested the editorial.¹⁶

In this follow-up letter, deBethizy argued that Premier 'speak[s] directly to the call by the Froggett (sic) Committee in

Great Britain for reduced "tar" to nicotine ratio cigarettes'¹⁶ The Froggett Committee was, since Peter Froggett's appointment as chair, the informal name of the Independent Scientific Committee on Smoking and Health (ISCSH; earlier known as the Hunter Committee). The ISCSH served as the UK government's chief scientific advisory body on the issue of smoking and health through the 1970s and 1980s and was openly advised by major British tobacco manufacturers.²² Effectively, deBethizy, an RJR scientist, used the authority of the ISCSH, which was under industry influence, to stress to *The Lancet* the importance of RJR-funded findings on Premier (an RJR product). In his letter, deBethizy set Premier in a framework promoting tobacco product substitution:

The public health community in the US has not been receptive to these prototypes, taking the position that prohibition of smoking is the only avenue that should be pursued. We believe that this is a short-sighted approach which ignores the projections that by the year 2000, forty million Americans and an even greater number worldwide will choose to smoke.... We feel that cigarettes that heat tobacco will provide an alternative to smokers who choose to smoke despite warnings that adverse health effects may arise from smoking.¹⁶

While we found no return correspondence from *The Lancet*, the journal published the editorial 6 months later.⁷ Historians Virginia Berridge and Mark Elam^{2 12} attribute this editorial's authorship to Michael Russell, one of Britain's most prominent tobacco scientists during the second half of the 20th century. We found no evidence of collaboration between RJR and Michael Russell regarding the content of this editorial.

Michael Russell

Michael Russell is oft-quoted as stating, 'people smoke for nicotine but they die from the tar'.²³ A psychiatrist by training, Russell is today widely regarded^{24 25} as influential in British health organisations^{26–28} and authorities^{29 30} promotion of e-cigarettes for long-term nicotine maintenance and cessation purposes. One of the first researchers to identify nicotine as the primary reason for which smokers became addicted, Russell was an early developer of and advocate for nicotine replacement therapy.³¹ Among other proposals, Russell promoted medium and high nicotine, low tar cigarettes so as to avoid smokers' 'compensation', a phenomenon in which low-tar cigarette smokers inhale more deeply to obtain nicotine, thereby ingesting as much, if not more tar and negating any 'health' benefits of low-tar cigarettes.²³

In the late 1970s, Russell collaborated with BAT on two 'safer' cigarette studies³² and received £55,000 (£300,850 inflation adjusted to 2018) in funding to conduct a third joint study, testing medium nicotine, low tar cigarettes.^{33–36} Russell acknowledged this 'strong relationship with BAT' and their 'help with some funding' in a 2004 interview with *Addiction*, commenting that maintaining relationships with tobacco companies was common practice among researchers at the time.³⁷ Russell also engaged extensively with RJR about Premier's 'positive aspects',³⁸ both prior to the product's release and following its failure (box 1).

In August 1988, Russell requested 3000 Premier cigarettes from RJR to conduct a study measuring 'nicotine, cotinine and carboxyhemoglobin levels in persons smoking Premier'.³⁹ On RJR's approval of his study in October 1988, Russell stated that the 'publication of results in an English Medical Journal', showing Premier to have fewer carcinogens than regular cigarettes, 'could go a long way to raising interest here [i.e. in the UK] and casting a favorable light on things'.⁴⁰ The first time RJR attempted to send Premier cigarettes to Russell, however, British customs

Box 1 Events prior to *The Lancet* editorial favouring Premier

August 1988: Michael Russell writes to RJ Reynolds (RJR) requesting 3000 Premier cigarettes for 'a week-long study with 10–12 male smokers... [to] monitor plasma, nicotine, cotinine and carboxyhemoglobin levels in persons smoking Premier'.³⁹ Jack Blanchard, Director of Scientific Relations at RJ Reynolds, saw this correspondence as a 'result of discussions that Dr. Russell had with several of us on this topic...last month'.⁴¹ Blanchard suggests to Wallace Hayes, Vice President of Research at RJR, that research scientist Donald J. deBethizy interact with Russell to facilitate these studies.⁴¹

October 1988: On RJR's approval of his study, Russell states that the 'publication of results in an English Medical Journal', showing Premier to be healthier than regular cigarettes, 'could go a long way to raising interest here and casting a favorable light on things'.⁴⁰

November 1988: Premier introduced to American test markets.

February 1989: Premier withdrawn from American test markets.

February 1989: deBethizy *et al* manuscript sent to Martin Cline at UCLA for comment; Cline suggests RJR to submit the paper to the *New England Journal of Medicine*, and failing that the *Journal of the American Medical Association (JAMA)*.⁷¹

February 1989: deBethizy paper submitted to the *JAMA*, which rejects it.¹⁷

July 1989: deBethizy paper submitted to *New England Journal of Medicine*, which rejects it.¹⁸

August 1989: Wallace Hayes, coauthor and Vice President of Research at RJR, sends a copy of the paper and recent articles on Premier to Michael Russell, whom he thanks in a letter for his 'encouragement regarding Premier'.⁷²

October 1989: deBethizy submits paper to *The Lancet*.¹⁹

November 1989: *The Lancet* rejects the paper, but editor David Sharp proposes a future editorial on Premier should the article be published elsewhere.²¹

January 1990: deBethizy submits paper to *Journal of Clinical Pharmacology*, on recommendation by Eliot Vessel.⁷³

August 1990: deBethizy paper published in *Journal of Clinical Pharmacology*.⁷³

December 1990: deBethizy alerts *The Lancet* to the article's publication, hoping the journal will follow up on its initial interest in writing an editorial about Premier.¹⁶

January 1991: Russell writes to RJR proposing future tests on Premier that he could lead were funding from RJR granted.^{42 74}

May 1991: Editorial praising Premier (attributed to Russell) appears in *The Lancet*.⁷

detained them. Russell consequently proposed to Wallace Hayes, RJR Vice President of Research and Development that RJR send the cigarettes to Russell directly, the associated fees for which Russell could pay, and for which RJR could later reimburse him. Russell suggested he could then 'lose' records of this [reimbursement] such that no 'note would be kept in the Heathrow customs that could eventually be traced to your company'.⁴⁰ We were unable to determine if Russell ever received the cigarettes or conducted the study. While RJR internally planned to coordinate discussions between Russell and deBethizy,⁴¹ we found no evidence of subsequent discussions between the two.

In January 1991, Russell met with RJR executives again, to whom he proposed additional studies on Premier, which 'would of course need to be funded, and we [i.e. Russell's research team]

would be interested to consider this when the time is ripe from your [i.e. RJR's] point of view'.⁴² Russell noted that it would not even be necessary for these studies to demonstrate 'that harmfulness is reduced in any direct way' but that it would be 'sufficient initially to simply show that when people switched [to Premier] their blood nicotine levels are if anything lower'.⁴² In that letter, Russell also mentioned having done a 'preliminary study with [Premier] cigarettes that we purchased ourselves'.⁴² This preliminary study may have been the basis for a 1993 paper that Russell coauthored in *Thorax*, showing lower average nicotine, carbon monoxide and tar intake among Premier smokers.⁴³

Four months after this January 1991 correspondence, the anonymous editorial, 'Nicotine Use After the Year 2000', appeared in *The Lancet*, praising Premier as a 'near-perfect low tar cigarette'.⁷ In the tradition of newspapers, *The Lancet* publishes unsigned editorials, occasionally from outside authors whose opinion reflects the journal's editorial board and represents the position of *The Lancet*. Russell's editorial urged the British government to promote the long-term, recreational and even addictive use of nicotine as a cessation therapy provided the nicotine could be delivered alongside as little tar as consumers found acceptable.⁷ Such products should then be made 'as acceptable and palatable as possible, advertised, actively promoted with health authority endorsement, and given tax advantages over tobacco'.⁷ In the same month, Russell published an article in the *British Journal of Addiction*, in which he promoted a nasal nicotine spray and nicotine lozenge as potential 'long-term alternatives to tobacco that makes the virtual elimination of tobacco a realistic target'.⁴⁴ Using near-identical wording to that employed in *The Lancet* editorial, Russell argued that such products should be made as palatable and acceptable as possible and actively promoted on the open market to enable competition with conventional cigarettes. He stated the products would also need health authority endorsement, tax advantages and support from the anti-smoking movement if tobacco use is to be gradually phased out altogether.⁴⁴

Russell also advised RJR in correspondence to seek advice about introducing Premier into the UK market from Peter Froggatt, Chairman of the ISCSH.⁴² Initially receptive, Froggatt ultimately decided to neither endorse Premier nor lobby for its entrance into the UK market.⁴⁵ Premier was never marketed in the UK.

RJR reacts

A month after *The Lancet* editorial appeared, deBethizy sent an interoffice memo stressing to colleagues that:

[T]he position on nicotine advocated in this editorial is a major departure from the position taken by the public health community in the US...[indicating] a willingness on the part of some prominent physicians to propose tobacco product modification as an essential component to a realistic public health policy on smoking and health.⁴⁶

deBethizy saw this difference between American and British attitudes towards potentially reduced harm tobacco products as a major business opportunity. In September 1991, deBethizy and one of his coauthors, David Doolittle, cited *The Lancet*'s endorsement of Premier in a letter to RJR President James Johnston. deBethizy and Doolittle advocated that the company should continue to market products that specifically respond to consumers' increasing 'health consciousness,' in order to 'stabiliz[e] or revers[e] market decline'.⁴⁷ As health concerns around smoking intensified, the two scientists argued that the 'long-term vitality' of RJR would depend on repositioning cigarettes to

address these concerns. The letter stated, 'one can only imagine the market share' that such products, 'uniquely perceived...as less hazardous', stood to secure.⁴⁷

RJR executives again acknowledged the importance of third-party endorsements after Premier was removed from the market. In 1993, Russell wrote to Carl Ehmann, RJR's Research Director, arguing that RJR should not abandon Premier or similar potentially reduced harm products.⁴⁸ Ehmann responded that RJR was confident it could redress Premier's shortcomings and introduce a similar product that smokers would accept.⁴⁹ Nonetheless, Ehmann stated that the company's

ability to market such a product [in the future] will be dependent upon more rational scientists, like yourself, speaking up and encouraging such concepts. Otherwise, we will be at the mercy of anti-smoking zealots who mistakenly believe they can engineer a smoke-free society and therefore have no interest in products which address the very issues about which they are concerned.⁴⁹

DISCUSSION

A major UK medical journal's endorsement of a defunct American tobacco product was aided by an enthusiastic scientist's cooperation with RJR tobacco company. This scientist's conflict of interest with the maker of Premier should have been, at the very least, disclosed by both Russell and *The Lancet*. Russell's conduct (eg, soliciting funding from RJR and stating *a priori* that publication of the study results in an English journal could go a long way to 'casting a favorable light on things';⁴⁰ offering to 'lose' records' of reimbursement from RJR,⁴⁰ and suggesting RJR pay him to undertake research on a product he later anonymously endorsed while representing *The Lancet*⁴²) raises serious questions of integrity. It is unclear whether these conflicts of interest were disclosed to the journal, or why the journal offered to write the editorial for a paper they deemed 'not justifiable' for publication in *The Lancet*. Current industry communications attribute new products' public health impact to consumer acceptance,⁵⁰ framed publicly more simplistically than their internal research,⁵¹ as the product of nicotine, taste and the user's associated 'ritual'.⁵² Our analysis, however, suggests that health-authority backing will also be central in determining whether the next generation of heat-not-burn devices succeeds where previous attempts have failed.

The industry document database consists mainly of documents produced during litigation and is not a complete archive. As such, we may have missed relevant information, particularly information contained in documents that the industry has withheld on the grounds of trade secrets or client/lawyer privilege.⁵³ Nonetheless, the documents we have analysed provide a window into prominent RJR scientists' and executives' candid discussions of a potentially reduced harm product. These insights may help public health professionals craft policy that anticipates reiterations of the tobacco industry's promotional strategies for its newest crop of products.

While Premier was a commercial failure, the industry has continued to pursue potentially reduced risk tobacco products.⁵⁴ The major tobacco companies have adopted 'harm reduction' language to promote their product portfolios.⁵⁵ In 2014, PMI introduced its heat-not-burn product IQOS in Italy and Japan, before expanding to 30 other markets within 2 years. In 2015, BAT and JTI launched heat-not-burn products in Japan. In December 2016, PMI filed an application to the Food and Drug Administration so that it may market IQOS as a modified risk tobacco product in the USA.⁵⁶ PMI now claims that its 'vision... is that these [reduced-harm] products will one day replace

cigarettes',⁵⁷ and in September 2017 announced it would commit \$1 billion to the establishment of the 'Foundation for a Smoke-Free World'.⁵⁸ Wells Fargo analyst Bonnie Herzog has predicted that heat-not-burn products could displace 'up to 30 percent of the combustible cigarette industry in developed markets by 2025',⁵⁹ although sales for IQOS, the current industry leader, began to plateau in the first quarter of 2018.⁶⁰

The industry has also continued courting public health endorsement of its new products. PMI's 'Foundation for a Smoke-Free World' claims to want to combat cigarette smoking via public health partnerships and the promotion of new products.⁵⁸ Part of the foundation's launch included publication of an article in *The Lancet*,⁸ penned by Derek Yach, a former WHO official who previously worked in tobacco control. While many oppose the Foundation,⁶¹ and *The Lancet* also published a comment by public health advocates voicing concerns,⁶² *The Lancet* editorial board failed to support the WHO's strong stance against industry cooperation in their accompanying editorial.⁶³

Nearly 1000 peer-reviewed papers based on tobacco industry documents, as well as the US District Court's ruling that the tobacco companies violated the Racketeer Influenced Corrupt Organizations Act⁶⁴ demonstrate the folly of partnership with the tobacco industry. August public health organisations, authorities and journals that believe 'the best science must lead to better lives'⁶⁵ should consider the ethics of endorsing tobacco industry attempts to preserve profits⁶⁶ with products claimed to be, but not yet demonstrated as reduced risk,⁶⁷ while simultaneously continuing to both aggressively promote cigarettes and undermine tobacco control worldwide.⁶⁸ Public health practitioners should also bear in mind past experience with industry-backed 'safer' cigarettes (eg, filtered and low-tar) that served to undermine and delay tobacco control efforts.^{69 70} Endorsements from health leaders and regulatory authorities may be the key factor in determining current heat-not-burn products' commercial

What this paper adds

What is already known on this subject

- ▶ The tobacco industry has long viewed the endorsement of external authorities as necessary to the success of its potentially reduced harm products.
- ▶ In 1991, *The Lancet* endorsed RJ Reynolds' (RJR) heat-not-burn cigarette, Premier, as a safer alternative to traditional cigarettes.
- ▶ While Premier failed commercially, the support of potentially reduced harm tobacco products as substitutes continues among some public health organisations and authorities, and is aggressively promoted by tobacco and electronic cigarette manufacturers.

What this paper adds

- ▶ The author of *The Lancet*'s editorial had previously collaborated with and advised RJR on Premier.
- ▶ While the editorial appeared after Premier was removed from the market, RJR internally regarded *The Lancet*'s stance on Premier as both opening a critical business opportunity for harm-reduced products and as an important departure from health authorities in the USA.
- ▶ Endorsements by respected health leaders are likely to play a critical role in determining new heat-not-burn tobacco products' commercial fate and may help the newest crop of modified tobacco products succeed where previous attempts have failed.

success, as well as the tobacco industry's future legitimacy as it promotes new products.

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