

PRESCRIPTION FOR CONFLICT: WHY THE ALLIANCE BETWEEN THE PHARMACEUTICAL INDUSTRY AND THE ANTI-TOBACCO MOVEMENT IS NOT IN THE BEST INTERESTS OF SMOKERS

Patrick Basham and John C. Luik

Large pharmaceutical companies are major funders of anti-smoking lobby groups. The same firms manufacture the products used in Nicotine Replacement Therapy (NRT) and stand to gain when governments recommend this approach to smoking cessation. There is growing evidence, however, that NRT is less effective than 'cold turkey' methods, and, indeed, that it has a number of harmful side effects. Its continued promotion, together with counterproductive anti-smoking measures, raises serious questions about the influence of special interests over tobacco policy.

Keywords: anti-smoking groups, Big Pharma, Nicotine Replacement Therapy, smoking cessation, tobacco control.

Introduction

This paper examines the nature and implications for tobacco control policy of the close links between the anti-tobacco movement and certain parts of the pharmaceutical industry. At a time in which the connections between the pharmaceutical industry and the medical profession are increasingly questioned, the pharmaceutical industry-anti-tobacco link receives scant attention, despite its many problematic features. Indeed, as outlined below, such a connection raises at the most fundamental level the question of whether the tobacco control proposals pursued by anti-tobacco activists, particularly around smoking cessation, and served up as policies by various governments, including those of the UK and the USA, really do work for smokers as opposed to simply enhancing the profitability of those drug firms manufacturing NRT (Nicotine Replacement Therapy). Four claims are advanced: that the anti-tobacco movement is strongly committed to the use

of NRT for smoking cessation; that the anti-tobacco movement receives very substantial financial support from the makers of NRT; that the scientific evidence does not support NRT as the most effective form of smoking cessation; and that pushing NRT for smoking cessation is not in the best interests of smokers.

In June 2011 a group of spine specialists used the pages of the *Spine Journal* to challenge the research of colleagues on Medtronic's bone growth product, Infuse, calling the research misleading and biased (Meier and Wilson, 2011). Such questioning of experts' research capabilities and integrity, and the effectiveness of medical devices and therapies themselves, is increasingly common, in large part because of the revelation of an on-going pattern of 'science for hire' in which researchers' objectivity appears to have been compromised by the fact that their work has been commissioned and funded and in some cases even written up by the drug industry and its consultants.

Instead of disinterested science, the pharmaceutical industry may be willing to stack the deck in its favour in order to win regulatory approval, and with it billions of dollars in potential sales, for its products.

In a sense this represents a substantial departure from what was expected of science in general and bio medical and pharmaceutical research in particular. Indeed, such bias and misrepresentation was something that was allegedly found, for instance, only in 'rogue industries' such as the tobacco industry, which supposedly regularly distorted all science to do with smoking and smoking prevention and then routinely lied about having done so. The tobacco industry supposedly behaved differently from the legitimate scientific community, the public health and the pharmaceutical industry because it was engaged in self-interested activities of questionable morality and made products designed not to help and heal but ultimately to kill its customers. The tobacco industry by its very nature as a business was self-interested and produced dubious if not corrupted science, while the pharmaceutical industry in conjunction with the public health community worked tirelessly for the public good through producing reputable and reliable science that resulted in demonstrable beneficial outcomes for its customers.

The scandals of recent years involving the pharmaceutical industry have changed this tidy picture. It has become increasingly clear that Big Pharma – as it is often called by its detractors – and its public health partners have their own commercial interests, and with such interests comes the same incentive to distort science as alleged for the tobacco industry.

Over the last quarter century the pharmaceutical industry has increasingly entered what was previously the sole preserve of Big Tobacco – the nicotine business – through the development and marketing of nicotine replacement therapies (NRT), which include gums, patches, nasal sprays, inhalers, lozenges and varenicline. The efforts have been brilliantly successful, not only as a billions-of-dollars-a-year business (\$1.7 billion in 2006, (Euromonitor, 2007)), but more fundamentally in convincing policymakers that 'cold turkey' quitting is ineffective since stopping smoking is something that needs to be 'medicalised'. Both Big Pharma's products and its business strategy have, however, largely escaped any significant critical evaluation.¹

In this paper we attempt to fill this critical void by looking at two aspects of the pharmaceutical industry's nicotine business – its NRT and its justifications for its pre-eminence in smoking cessation, and the substantial financial support for the anti-tobacco movement, which has made switching smokers away from tobacco products to NRT a major pillar of its smoking cessation campaigns.

As we shall see, there is a close connection between the two. More disturbingly, it is not clear that Big Pharma's intervention in the nicotine business has significantly helped smokers stop smoking.

The effectiveness of NRT

Over the last twenty-five years, both the public health community and the anti-smoking movement have come to support NRT as the most effective way to stop smoking. For

instance, the UK government in its tobacco strategy claimed that 'Those who are most successful in quitting use a combination of behavioural and medicinal support' (HM Government, 2010 p. 11). This follows a similar claim in the Department of Health's 2006 consultation on the future of tobacco control which noted that 'smokers from the routine and manual groups . . . frequently opt for a "cold turkey" approach to quitting, which is much less successful than quitting with support' (p. 46).

In the USA in June 2000 the government issued its Clinical Practice Guideline for Treating Tobacco Use and Dependence which advocated NRT for all quitters. The clear belief is that planned quitting using 'medicinal support' is more likely to bring about success in stopping smoking than cold turkey, unplanned smoking cessation. Big Pharma has thus succeeded brilliantly in establishing the medicinal paradigm in which smokers wishing to stop need to use some form of NRT in order to be successful. The problem with this position is that it fails the most basic test of evidence-based medicine – namely, it is contradicted by much of the published literature which suggests that NRT has a very low rate of success compared with unassisted, cold turkey quitting. Indeed, in real world situations, NRT often performs well below the levels reported during Food and Drug Administration (FDA) approval studies.

So just what does the scientific evidence about the effectiveness of NRT suggest? Below we examine 13 of the most important studies on the effectiveness of NRT in relation to unassisted, cold-turkey cessation, including two published in the first month of this year.

Lee and Kahende (2007), using data from the National Health Interview Survey 2000, reported that 75.7% of successful quitters (abstinent for 7–24 months) stopped by using the cold turkey method without pharmaceutical assistance, compared with 12.4% who used nicotine patches or gum. Pierce *et al.* (2002), in a study of Californian smokers, noted that pharmaceutical aids 'were not associated with a clinically meaningful long term improvement in successful cessation. . . .' They noted that 'only about half of California aid users managed to discontinue smoking even for a day after they stopped using the aid' (*ibid.*). The authors concluded that the effectiveness of NRT in clinical trials does not appear to be replicated in general populations of smokers in real world situations.

Moreover, in a recently published study, Pierce *et al.* (2012) find that 'while public health initiatives on smoking cessation have increased substantially . . . and quit attempts have increased, widespread dissemination of these aids has not improved population success rates' (p. 12-1). Indeed, as they note, 'Some policies actively discourage unassisted smoking cessation despite the documented high success rates of this approach' (*ibid.*). In effect pharmaceutical cessation drugs have not increased the number of smokers who have been able to quit smoking over the long term. This suggests that the US Clinical Practice Guideline on smoking cessation and the government recommendations about quitting in the UK are *not* based on sound clinical evidence. For example, Pierce *et al.* found that the 90-day quitting success rate with NRT was only 19% for light smokers compared with 26% for smokers who quit unaided (*ibid.*), a clear contradiction of the UK advice. Indeed, as Pierce *et al.* note, in recent years there has been a

levelling off of successful quitting. Smoking prevalence in the UK has also stabilised.

Despite this, governments have continued to recommend that NRT is used in all quit attempts, even though 'there is no evidence that such policies lead to an increase in successful cessation in the population' (ibid., p. 12).

Ferguson *et al.* (2009) found that most of those who quit smoking without planning used neither behavioural nor medicinal support and, most significantly, unplanned attempts to quit were twice as successful as planned attempts using NRT. Schnoll *et al.* (2010) found that the one year abstinence rate for those using patches was only 0.8% of the sample. This compares with unaided quit attempts which yield one year abstinence rates of between 3 and 11% according to Gritz *et al.* (1989).

In a comprehensive review of the effectiveness of NRT in cessation in the US, Cummings and Hyland (2005) concluded that 'Time series analyses of national cigarette consumption and NRT sales from 1976–1998 suggest that sales of NRT were associated with a modest decrease in cigarette consumption immediately following the introduction of the prescription nicotine patch in 1992. However, no statistically significant effect was observed after 1996 . . .'

Fiore *et al.* (1990), using data from the 1986 Adult Use of Tobacco Survey, reported that 'among smokers who had attempted cessation within the previous 10 years, 47.5% of persons who tried to quit on their own were successful whereas only 23.6% of persons who used cessation programs succeeded.' Nor has this situation markedly changed since their study.

Walsh (2008) found that 'despite optimistic predictions when nicotine replacement therapy . . . was switched to over-the-counter availability, population surveys have failed to demonstrate a positive impact on long term smoking cessation . . . the superiority of OTCNRT over unaided smoking cessation has not been demonstrated convincingly'. And Larabie (2005) finds that in his sample a majority of quit attempts were reported as unplanned and unaided. West and Sohal (2006) provide similar results in a study which found that almost half of a group of British smokers' quit attempts were unplanned and that unplanned attempts were more likely to be successful at the six month mark. Wakefield *et al.* (2008), examining smoking prevalence in Australia, reported that NRT had no statistically significant effect on smoking prevalence.

Finally, in a just-published study of the effectiveness of NRT, Alpert *et al.* (2012) followed 787 Massachusetts adult smokers who had quit smoking. These smokers were surveyed over three time periods and were asked whether they had used NRT in order to help them quit smoking. In each time period about one-third of the quitters relapsed and started smoking. Alpert *et al.* found no difference in relapse rate among those who used NRT for more than six weeks, nor was there a difference in success depending on smoking status. According to Alpert *et al.* the study showed 'that using NRT is no more effective in helping people stop smoking cigarettes in the long-term than trying to quit on one's own' (quoted in Siegel, 2012).

Commenting on the public policy implications of their findings, they write that 'The findings of this study cast doubt

on the relative effectiveness of NRT as a population strategy and on the expectations of the effects on smoking prevalence of providing cessation services to individuals. . . . Funding ineffective services that aim to change individual behaviour may be resulting in the loss of scarce resources from public health programmes that have proven to be effective in changing social norms and reducing smoking . . .' (Alpert *et al.*, 2012, p. 4).

As Chapman and MacKenzie (2010) note 'unassisted cessation continues to lead the next most successful method (nicotine replacement therapy) . . . by a wide margin'. Moreover, they write that 'population level analyses of the impact of the proliferation, deregulation, and widespread promotion of NRT and other pharmacotherapies have failed to show any significant, sustained impact on smoking prevalence, despite the conclusions of clinical trials.'

Why NRT instead of unassisted cold turkey

Given the fact that unassisted smoking cessation is the 'most successful' way to quit smoking and given the poor success rate at six and twelve months for over the counter NRT (generally 5–7%), why do governments and the anti-smoking movement continue to push NRT as the approved way to quit smoking? Let us examine four reasons.

Firstly, research on smoking cessation is dominated by the medical model in which NRT is portrayed as the only way to quit successfully. Indeed, the vast majority of cessation studies concentrate on assisted as opposed to unaided quitting. Chapman and MacKenzie (ibid.) report that 91.3% of recent intervention studies focused on assisted cessation. The pharmaceutical industry's deep research pockets provide enormous funding for NRT research, and this funding itself tends to blur the question of effectiveness. As Chapman and MacKenzie note, 'This greater availability of funding for certain sorts of research produces a distorted research emphasis on pharmacotherapy that . . . concentrates both scientific and public discourse on cessation around assisted pharmacotherapy' (ibid.).

In their 2009 analysis of cessation research they report that 'of the 84 papers for which competing interest information was available, . . . 48% of pharmacotherapy intervention studies, . . . 10.3% of non-pharmacotherapy intervention studies and 0% of unassisted cessation studies had at least one author declaring support from a company manufacturing cessation products and/or research funding from such a company . . .' (ibid.).

Furthermore, there is also the question of whether the source of cessation research funding influences the outcomes of NRT trials and research. Etter *et al.* (2007) looked at all the randomised controlled trials for nicotine gum and patches that were included in the comprehensive Cochrane review of nicotine replacement therapy. They found that 'compared with independent trials, industry-supported trials were more likely to produce statistically significant results and larger odds ratios'.

Secondly, NRT continues to dominate smoking cessation because it is sold to policymakers and to a lesser extent the general public on the basis of clinical trials rather than on real-world situations. But there is a significant difference

between the success of participants in clinical trials and smokers trying to quit smoking outside of such trials. As Alpert commented on his own trial, 'Our study essentially shows that what happens in the real world is very different from what happens in clinical trials' (quoted in Carey, 2012). The most significant difference is the amount of resources provided to participants of such trials in the form of counselling, phone calls etc. For example, one well-known smoking cessation medication was approved by the FDA partly on the basis of clinical trials which reported six month abstinence rates that in some cases reached 33.5%. However, more recent studies reported only a 14% six month abstinence rate (Hughes *et al.*, 2011). Indeed, as Michael Siegel notes, one wonders what the abstinence rate would be if *no* counselling sessions were provided (Siegel, 2011a). Siegel writes 'This research suggests that as the number of support sessions falls and the intervention approaches a real-world situation, the effectiveness of the medication falls quite drastically . . . The rest of the story is that tobacco control advocates and researchers are grossly over-estimating the effectiveness of existing, FDA-approved pharmaceutical smoking cessation aids . . . because the clinical trial setting . . . does not simulate the real-life situation in which most of the population is using these drugs'.

Thirdly, there is the difficult question of money. It is not simply that the pharmaceutical industry provides enormous support for research on NRT and that this research shows a much higher rate of NRT cessation success than non-industry funded research (see Etter *et al.* (2007), who found that only 22% of non-industry clinical trials of NRT reported statistically significant results compared with 51% of trials funded by the industry), but also that the industry provides significant amounts of money directly to the anti-smoking movement. This raises the question of whether such support leads the public health community and the anti-smoking movement to trumpet the benefits of NRT to the exclusion of unassisted smoking cessation.

This connection between the pharmaceutical industry and the anti-smoking and public health communities is hardly a secret, though its disturbing implications are little discussed. For instance, in 1999 the World Health Organization launched a partnership with the pharmaceutical industry on smoking cessation. The partnership involved many of the world's leading pharmaceutical firms. Major health charities have also entered partnerships with Big Pharma, allowing, for example, charity logos to be used in adverts for smoking cessation products. And as anti-smoking activist and Boston University professor Michael Siegel has pointed out, several well-known US charities that campaign against tobacco have or have had financial associations with the makers of NRT products (Siegel, 2011b).

Nor has the largesse of Big Pharma been confined to the United States. Millions of dollars have been dispersed to support anti-smoking groups and initiatives abroad. For instance, it is obviously in the interest of all three makers of NRT to support the FCTC (Framework Agreement on Tobacco Control, the international anti-tobacco treaty), as it is essentially an export of the developed world's tobacco control policies – with their built-in support for NRT provisioned

smoking cessation – to the huge tobacco market represented by the developing world.

The usefulness of tobacco control measures for the fortunes of NRT can be seen in a number of areas. Take, for example, public smoking bans which provide but one example of how the commercial interests of the industry and the public policy objectives of the anti-smoking movement neatly intersect. By restricting smoking in public places, smokers are pushed to stop smoking or find alternatives – both of which options are conveniently available through NRT. Public smoking bans and indeed a host of other anti-smoking measures such as higher taxes on cigarettes serve to disrupt the current nicotine market and move it from one dominated by Big Tobacco to one more open to alternative suppliers of nicotine through NRT. As a strategic objective, it therefore makes eminent sense for Big Pharma to support not only such bans but also the anti-tobacco organisations pushing for them. As Chris Snowdon puts it ' . . . what could be better for a seller of nicotine drugs than smoking bans, the demonization of the tobacco industry and higher cigarette prices?' (Snowdon, 2010).

In return for their enormous investment in the anti-smoking movement, Big Pharma receives a handsome payback and prominent individuals within the movement use its considerable advocacy resources to champion tobacco control policies that ultimately support Big Pharma's commercial objectives. This can be seen in any number of policy proposals pushed by the anti-smoking movement and the public health community.

Indeed, it appears that this agenda now has support at supranational level. For example, Gro Brundtland, former Director General of the World Health Organization, in a speech at the 11th Global Conference on Tobacco or Health (2000), noted that 'the best way to help people stop using tobacco is to raise its price, to make nicotine replacement therapy available, to control smuggling and avoid tobacco advertising', thereby establishing NRT as one of the four pillars of the organisation's tobacco control strategy.

A comprehensive proposal for a nicotine policy put forward in 2005 by some of the leading lights of the anti-smoking movement reflects how neatly the interests of Big Pharma are advanced by the anti-smoking movement (Gray *et al.*, 2005). According to Gray *et al.*, the primary goal of nicotine policy in the short term is a liberalisation of the market for clean nicotine (read NRT), while in the medium term 'clean nicotine' would overtake cigarettes as the primary source of nicotine. In the longer term, the move to clean nicotine would be facilitated by the 'progressive reduction in the nicotine content of cigarettes, with clean nicotine freely available to take the place of tobacco as society's main nicotine source'. In effect, here we have Big Pharma's strategic goal of capturing for NRT the nicotine market currently held by cigarettes brazenly pushed as public policy by the anti-smoking movement. Indeed, the competing interest statement at the end of the paper makes clear not only how deeply connected with Big Pharma but also how deeply conflicted and non-objective the interests of these anti-smoking activists can be. Of the eight authors, five have some current or past connection with not just the pharmaceutical industry, but the NRT end of the industry.

Thus, instead of pushing tobacco control policies that will benefit their commercial interests themselves, the three makers of NRT can leave the advocacy of such policies to the supposedly neutral, objective and disinterested anti-smoking movement. If this were Big Tobacco one might be tempted to say that the industry was using a 'front group' to push its agenda, but of course this is something that one would never dare say about Big Pharma and the anti-smoking movement.

In the USA, the FDA's Tobacco Products Scientific Advisory Committee, which provides crucial advice on tobacco policy, including new products and cessation, has four members, including the Committee chair, with substantial financial interests in the pharmaceutical industry and its smoking cessation products (Siegel, 2010). This is further evidence of Big Pharma's disproportionate influence.

A further important point is that NRT continues to dominate smoking cessation because of the pernicious effect of the addiction model of smoking. Because smokers are continually told that tobacco use is addictive, indeed, more addictive than hard drugs such as heroin and cocaine, they are encouraged to believe that the only effective way in which to stop smoking is through a professionally administered pharmaceutical intervention. By convincing smokers that they are addicted (read powerless on their own to stop smoking), the move to NRT as the only way to combat this addiction is seen as normative. Unassisted smoking cessation is seen as ineffective since smokers' confidence in their ability to succeed is undermined by their belief that they are addicted. As Chapman and MacKenzie (2010) note "The persistent messaging that nicotine addiction is refractory and stopping unaided will be futile deflects attention away from what is by far the most common story of cessation: people doing it without professional or therapeutic help".

The unwelcome consequences of the dominance of NRT in smoking cessation

There are several extremely unwelcome consequences of the Big Pharma engineered dominance of the smoking cessation field by NRT. Firstly, and most obviously, are the dangers that some NRT products represent. For instance, in a recently published study by Singh *et al.* (2011) which examined 14 randomised controlled trials of one well-known drug involving 8216 participants, the authors reported that 'Varenicline was associated with a significantly increased risk of serious adverse cardiovascular events compared with placebo'. Indeed, in June 2011 the FDA issued a warning, based on an analysis of a small clinical trial, which noted that the drug appeared to be associated with an increase in heart attacks in patients with an existing cardiovascular disease.

Secondly, given that the most successful quitting method is unassisted cessation, the dominance of NRT in the smoking cessation market and its endorsement by the public health community and the anti-smoking movement, does not serve the interest of smokers who wish to quit so much as those of Big Pharma who as Chapman (2009) notes are focused, at least in part, on 'prolonging cessation and in repeat attempts after relapse'. To put the matter bluntly, the dominance of NRT is not supported by the research data: it effectively pushes smokers away from the most successful way to quit and

thus reduces their chances of successfully quitting. By pushing smokers who wish to quit to NRT, the public health community and the anti-smoking movement paradoxically reduce their chances of stopping smoking and thereby increase their chances of dying from smoking. In an uncharitable reading, smokers are quite literally sacrificed to the interests of the pharmaceutical industry and its anti-smoking partners.

Thirdly, given the fact that NRT is not supported by the best and most complete scientific evidence and given the fact that the close and deeply conflicted connection between Big Pharma and the public health community and the anti-smoking movement is for the most part little known and critically unanalysed, the triumph of NRT and the commercial interests of its makers represents to some extent a corruption of an evidence-based and transparent public policy process.

Not only smokers but the public in general are being told something that is scientifically untrue – i.e. the superiority of NRT over unassisted quitting – and the reason for this misrepresentation is not apparent. Smokers deserve to have unbiased and accurate information about something that quite literally could save their lives. And the rest of us need to be confident that public policies serve our interests and not just those of commercial interests such as the pharmaceutical industry.

Finally, the ill effects of the 'bargain' between the drug industry and the anti-smoking movement and the public health community go beyond the question of smoking cessation and NRT. By considering tobacco control policies only through the lens of self-interest, Big Pharma ends up championing and funding anti-smoking policies that have little proven effectiveness, for example advertising bans and public smoking bans, while ignoring policies that might genuinely prevent and reduce tobacco use. Instead of pushing the anti-smoking movement to examine critically their entire idea of tobacco control, Big Pharma's big cheques permit them to continue business as usual, something that is a tragedy for smokers and non-smokers alike.

Statement of interests

Neither Basham and Luik nor the Democracy Institute own any pharmaceutical or tobacco stock. Their primary employer is the Democracy Institute and they have never been employees of the pharmaceutical or tobacco industries. Both have provided consulting services to the tobacco industry.

1. An exception to this is a fine article by Chapman and MacKenzie (2010).

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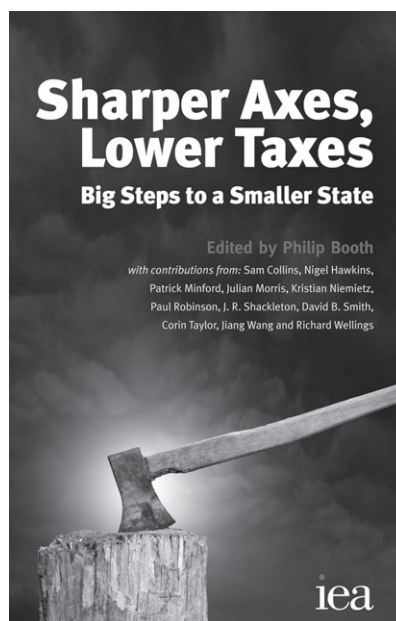
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