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FREE MARKET SOLUTIONS IN HEALTH

The case of nicotine

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About the author

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Summary

- Many campaigners working in the field of public health believe that good health and free market capitalism are irreconcilable. They regard advertising, competition and the pursuit of profit as major causes of unhealthy consumption and view disfavoured industries as 'disease vectors'. Accordingly, they support political action which limits commercial speech and restricts product development.

- One consequence of this 'neo-prohibitionist' approach is that innovative products are banned under the precautionary principle. The sale of the two least hazardous recreational nicotine products - e-cigarettes and Swedish snus - are banned in many countries despite growing evidence that they can play an important role in reducing the smoking rate.

- The public health movement is divided between those who support the 'neo-prohibitionist' approach and those who support 'harm reduction'. Opponents of harm reduction claim that safer nicotine products act as a 'gateway' to smoking and deter smokers from quitting. However, most evidence suggests that nicotine products have little appeal to nonsmokers and are overwhelmingly used as a gateway *from* smoking.

- Arguments made against tobacco harm reduction on health grounds are not compelling. Opposition to e-cigarettes and snus can only be properly understood in the context of longstanding moral objections and anti-industry sentiment.

- There is evidence that orthodox tobacco control policies are having only a limited effect on smoking rates in Europe. Countries that follow the model of smoking bans, high tobacco taxes and graphic warnings do not have lower smoking rates than other countries. Evidence from Sweden strongly suggests that the harm reduction approach has more to offer than the neo-prohibitionist model.

- Smokers should not be discouraged or forbidden from switching to vastly less hazardous forms of nicotine use. Unless alternative nicotine products pose significant risks to health, or act as a gateway to smoking, there is no justification for them being heavily regulated or banned. The main beneficiaries of the neo-prohibitionist approach are the incumbent cigarette industry and the pharmaceutical industry. If health is the goal, governments should step back and allow free market solutions to gain popularity. In practice, this means taxing and regulating e-cigarettes as ordinary consumer products and allowing snus to be sold with appropriate and accurate labelling to inform customers of its risk profile relative to cigarettes.

- The prohibition of safer tobacco products has led to unnecessary deaths in the European Union and elsewhere. It is highly likely that the prohibition and excessive regulation of e-cigarettes will also lead to unnecessary premature deaths. The neo-prohibitionist approach is unjustifiable from the perspective of both personal liberty and population health.

- Recent developments in the fragmented nicotine industry show that private enterprise can correct market failure long before government failure is even acknowledged, let alone rectified. The interests of consumers are better advanced by the provision of accurate information and free choice than by prohibitions and restrictions on commercial speech.

Free markets versus health?

Epidemics of infectious diseases are largely a thing of the past in wealthy societies today. The traditional public health approach of education, vaccination and sanitation has eradicated many of the lethal diseases of the past and those which remain are often treatable with modern medicine. Life expectancy in the UK has risen from 47 years in 1900 to 79 years today. The major causes of death are no longer contagious killers such as influenza, tuberculosis and gastrointestinal infection, but non-communicable diseases such as cancer and heart disease which most often affect the elderly.

Since some of the risk factors for these diseases of old age are rooted in private behaviour such as eating, drinking, smoking and physical inactivity, the focus of the modern 'public health' movement has shifted from protecting people from diseases carried by others to attempting to protect people from themselves. Initially, this meant raising awareness and offering information about healthy living. Today, with the population generally well informed about the risks of smoking, drinking and overeating, the inclination of millions of people to turn a blind eye to medical advice cannot be attributed to ignorance alone. As the limits of education as a means of encouraging the public to mend their ways became evident, the public health lobby turned to a more intrusive and forceful approach than had traditionally been within the remit of government-led health campaigns.

The stark difference between tackling infectious diseases with collective action and tackling non-communicable diseases by regulating personal behaviour has been partially masked by changing terminology. The concept of 'public health' is now defined so broadly

that gambling and gender equality are seen as no lesser 'public health issues' than malaria and water fluoridation (Korn and Shaffer, 1999). The word 'epidemic' has been almost entirely divorced from its original meaning of being an outbreak of infectious disease and is instead used to describe endemic behaviour such as drinking, or non-contagious diseases such as cancer, or physical conditions such as obesity which are neither diseases nor activities.[1] Although it amounts to little more than euphemism, such terminology helps to maintain the conceit that governments have the same rights and responsibility to police the 'bad habits' of its citizens as they do to ensure that drinking water is uncontaminated.

In practice, there are many insurmountable obstacles in the field of 'lifestyle regulation' (to use a more candid term for 'public health'). It may be desirable to eat five pieces of fruit or veg a day, or to take 30 minutes vigorous exercise, but such behaviour cannot be mandated outside of an army barracks, school or totalitarian state. With compulsion of this sort largely unavailable to them, the public health lobby instead favours legislative action which target products in the marketplace which are deemed to be unhealthy (Callard, 2013). Regardless of whether these products are hazardous *per se* (eg. cigarettes) or are merely hazardous when consumed in excess (eg. salt, alcohol), the objective is to reduce their consumption at the population level.

It is a short step from demonising 'demerit goods' to vilifying the industries that produce them, especially when the targeted businesses generally oppose regulations which curtail their ability to communicate with their customers and compete with their rivals. In keeping with the terminology that portrays consumer products as the source of 'epidemics', the relevant industries are viewed as 'disease vectors'. This analogy has been made explicitly by Anna Gilmore of Bath University, who views public health issues as a chain in which there is 'the host (the consumer), agent (the product, e.g. cigarettes, alcohol), environment and, crucially, the disease vector (the corporation).' (Gilmore, 2011: 2)

[1] 'Labeling obesity a disease may be expedient but it is not a necessary step in a campaign to combat obesity and it may be interpreted as self-serving advocacy without a sound scientific basis.' (Heshka and Allison, 2001)

The depiction of the consumer as a passive, unwilling 'host' is apt. There is no expectation on the part of public health that individuals should take any measure of responsibility for their habits and health; to do so would be 'victim blaming' since ordinary citizens cannot be expected to resist 'corporate power' (Hastings, 2012).

Nor is there any suggestion that businesses sell products because people want to buy them. The relationship is always viewed from the other end of the telescope - people buy products because businesses market and sell them. When campaigners disapprove of a product, it is not merely advertised, it is 'aggressively marketed'. Customers do not voluntarily exchange money for goods, but are 'recruited' by corporations. Often these recruits have been 'lured' by 'glitzy' packaging or 'seductive' advertising. Food is not cooked to make it tasty, it is 'manipulated' to keep us coming back for more. Companies do not work hard to persuade the fickle public to keep buying its product, they 'control' x per cent of the market - another expression of their supposed power over the consumer. Industries are not made up of competing firms but are monolithic giants (Big Tobacco, Big Alcohol, Big Food) engaged in a conspiracy against the public. While public health lobbyists are 'advocates', commercial lobbyists are 'hucksters', 'mouthpieces', 'shills' and 'hired guns'. The root causes of 'unhealthy consumption', says Gerard Hastings of Stirling University, are 'evocative promotion, ubiquitous distribution, perpetual new product development, and seductive pricing strategies' (Hastings, 2012b).

Although these views are not universal in the field of public health, they have become increasingly dominant. As public health historian Virginia Berridge writes: 'Hostility to industrial interests now pervades the public health field: campaigners on obesity attack the food industry, and the drinks industry and its influence within the government is reviled by some sections of the alcohol research community.' (Berridge, 2007: 82) As the following recommendation from a group of 'civil society' actors makes clear, it is assumed that private profit and public health are irreconcilable:

> 'The policy development stage should be free from industry involvement to ensure a 'health in all policies' approach, which is not compromised by the obvious conflicts of interests associated with the food alcohol, beverage and other industries, that are primarily answerable to shareholders.' (Eurocare, 2011)

This distrust of private enterprise extends to advocates of free markets who are, by definition, opponents of prohibition and excessive regulation. ‘Public health doctors have unanimously hated Thatcher and her legacy’, writes Richard Smith, the former editor of the *British Medical Association,* because ‘her ideological commitment to individualism’ sat uneasily with the collectivist sensibilities of the public health lobby (Smith, 2013). Although there is no evidence that people are more healthy in countries where markets are less free - and ample evidence that economic growth leads better health outcomes - many in public health believe that good health and free market capitalism are irreconcilable.

The hazards of groupthink

In the new public health discourse, non-communicable diseases are largely caused by the production and sale of unhealthy products, which campaigners view as a market failure (Gilmore et al., 2010). Industry and the free market are therefore both culpable for lethal illnesses and must be brought to heel by the state. In practice, this involves using demand-side and supply-side measures, up to and including prohibition, to control commercial activity through tight regulation of the existing product, the prohibition of new variants of the product, higher excise taxes and the elimination of marketing. This approach requires political will rather than medical know-how and has been termed ‘neo-prohibitionism’ (Mindus, 2003; Studlar, 2013).

Tackling perceived market failure by transferring power from the market to the state increases the chance of government failure. Whilst companies are vilified for making money out of demerit goods, their customers are dismissed as irrational addicts/victims. Both of these stakeholders are therefore excluded from the policy-making process, leaving only a narrow elite of public health advocates to dictate the nature of legislation. Echo chambers such as this carry their own risks. The most obvious problem is that they might simply be wrong. The further they stray from their area of formal expertise, the more likely they are to be in error - and the smaller the elite, the less likely it is that mistakes will be rectified. What they call ‘health policy’ often involves profound questions of economics, law, ethics, intellectual property, constitutional rights and political philosophy

which fall far outside the remit of a medic or scientist. What they see as the ‘public interest’ is often no more than a narrow interest of risk management and lifestyle regulation that has never won the battle of ideas, let alone ever stood for election.

The damage that can be wrought by groupthink is limited so long as it is confined to mere advice. It is more dangerous when it becomes enshrined in binding legislation from which there is no escape. This paper looks at how neo-prohibitionist regulation and anti-free market legislation can harm health by stifling innovation, raising barriers to entry and misinforming the public. We use the example of tobacco and nicotine where anti-industry sentiment is most firmly entrenched. We argue that where there is strong demand for healthier options, the free market is often able to provide them without hampering personal liberty. A policy of state intervention and anti-industry ideology, on the other hand, can jeopardise both liberty and health.

The search for a safer cigarette

In the twentieth century, efforts to reduce the hazards of cigarette smoking were led by the tobacco industry and involved modifying conventional cigarettes. Cellulose filters were added to cigarettes as early as the 1930s and tobacco companies experimented with other filters once the hazards of smoking became common knowledge. Innovations included the selective filter on Brown & Williamson's short-lived *Fact* brand (launched 1975), the charcoal filter on Liggett & Myers' *Lark* brand (launched 1962) and the infamous 'micronite' filter on Lorillard's *Kent* brand (launched 1952) which contained asbestos.

Formal acceptance of the link between smoking and lung cancer by the Royal College of Physicians and the US Surgeon General in the early 1960s made the search for a safer cigarette all the more urgent. Incentivised by the enormous profits that would follow from the invention of a safer cigarette, tobacco companies employed various creative methods but to no avail. Industry and public health scientists initially believed that it would be possible to identify and remove carcinogenic compounds from tobacco, although these hopes faded as they began to grasp the enormity of the challenge (Berridge, 2007: 92-93). Neutering the harms of smoking requires much more than isolating and expelling one chemical culprit. Burnt tobacco contains too many carcinogens for all to be removed and even if that were possible, carbon monoxide would remain.

Nevertheless, twentieth century tobacco research left some tantalising 'what ifs?' Liggett & Myers developed a new cigarette in the 1970s by adding the rare metallic element palladium into the tobacco. Skin painting experiments on mice suggested that the new brand, set to be called *Epic,* led to 95-100 per cent fewer tumours than ordinary cigarettes. Ultimately, internal pressure from the rest of the industry (which had not yet publicly accepted that smoking caused cancer) as well as external pressure from the tobacco control movement led to the company withholding it from the market. *Epic* was held back by the same factors that would hinder every attempt to reduce the harms of cigarette smoking in the twentieth century: advertising bans which prevented companies from informing the public about putative health benefits, opposition from anti-smoking campaigners who feared that safer products would deter smokers from quitting, and the industry's own reluctance to implicate conventional cigarette as unsafe for fear of accepting liability. As one Liggett and Myers' executive later said, *Epic* 'would have been attacked from all sides - the government, health authorities, antismoking groups, and especially our competitors.' (Kluger: 461)

Until circa 1980, many of the attempts to modify cigarettes were collaborative efforts between industry and government agencies. The US National Cancer Institute set up the Tobacco Working Group in 1968 and spent $6 million a year in the search for a safer cigarette (Fairchild and Colgrove, 2004). In Britain, the government formed the Independent Scientific Committee on Smoking and Health in 1973 to oversee efforts to reconstitute cigarettes in a less damaging form.

One promising avenue was reducing tar yields. Cigarettes typically have ten times as much tar as they do nicotine (eg. 10mg tar and 1mg nicotine) and since the ratio is fixed, there is a limit to how far tar yields can be reduced without making cigarettes unsatisfying, but epidemiological evidence had shown that smokers of high tar cigarettes were at greater risk than smokers of low tar cigarettes. In the USA, Dr Gio Gori led an industry-government collaboration to reduce tar yields to the point at which cigarettes would pose what he called a 'tolerable risk' (Kluger, 1996: 448-449). Assuming a linear relationship between tar yields and disease, Gori made some rather simplistic calculations and concluded that 'it is reasonable to expect that the current epidemic proportions of smoking-related

diseases could be reduced to minimal levels in slightly over a decade' if smokers shifted *en masse* to very low tar ('ultra-light') cigarettes (Gori, 1976).

The most concerted British initiative was the development of 'tobacco substitutes' in the 1970s. The idea was to replace some of the tobacco in cigarettes with less toxic cellulose. Like the industry, the government had a financial motive for developing a less hazardous cigarette on British shores. A successful product, if exported, 'had the potential of saving foreign currency and ... improving the balance of payments' (Berridge, 2007: 143). The industry invested tens of millions of pounds in tobacco substitutes and the new products were cleared for sale in April 1977 after the Independent Scientific Committee on Smoking and Health concluded that 'there is no doubt that they are a contribution to safety.' (Van Rossum, 1978: 3) Three months later, on a date picked by the government, eleven new cigarette brands containing up to 50 per cent tobacco substitutes were put on the market. It was a commercial disaster. A year after the launch of the new brands, their combined sales made up less than one per cent of the market. The most successful of them, *Peer*, was finally taken off the shelves in 1984.

Smokers were given little reason to switch to the new brands. Advertising restrictions forbid any claim that one cigarette was less hazardous than another and the government decided to levy the same rate of tax on both traditional and modified risk products. The industry had expected 'some form of qualified public support' from the government for the new cigarettes but instead found itself on the end of a 'campaign of vilification' (Van Rossum: 3-4). Action on Smoking and Health and the Health Education Council opposed the 'safer smoking' initiative, with the latter declaring that shifting from traditional to modified cigarettes was akin to jumping out of the thirty-sixth rather than the thirty-ninth floor of a building. Roland Moyle, the Minister for Health, told the public that 'cigarettes with or without substitutes can be debilitating and ultimately lethal' and reaffirmed his commitment to 'the ultimate objective of a smoke-free society'' (ibid.: 4).

These sudden denunciations stood in contrast to more encouraging noises from the Ministry of Health and the Royal College of Physicians a few years earlier but, by 1977, attitudes were beginning

to harden and total abstinence was increasingly seen as the only option in tobacco control. As Berridge notes of the tobacco substitutes debacle, 'product modification and "safer" smoking had fallen foul of a major shift in health policy.' (Berridge, 2007: 155)

Gio Gori's work on low-yield cigarettes fell victim to the same attitudinal sea-change in the USA, although the ambitious scientist's hubris also played its part. In 1978, Gori published an article in the *Journal of the American Medical Association* in which he asserted that cigarettes were virtually harmless below a certain tar level and went on to name existing brands which could be smoked in large quantities 'without exceeding tolerable levels' (Gori and Lynch, 1978). Sales of the supposedly least hazardous brand soared by 50 per cent after the paper was published and Gori's naïve assumptions drew a hail of criticism from health authorities who feared that Americans were being given *carte blanche* to carry on smoking (Kluger, 452). The government's interest in developing safer smoking alternatives subsided thereafter.

Nicotine delivery devices

By the end of the decade, the tobacco industry's hopes of modifying conventional cigarettes had turned from 'a gallant acceptance of the challenge to a cynical acceptance of an inevitably harmful product' (Glantz, 1996: 169). Subsequent efforts at harm reduction focused on non-combustible tobacco products and alternative nicotine delivery devices. The American tobacco giant R.J. Reynolds spent hundreds of millions of dollars on its near-smokeless *Premier* brand and launched it in a few US states in 1988, but smokers were indifferent. Based on the principle of 'heat, not burn' *Premier* was almost certainly less hazardous to health, but it had so little in common with conventional cigarettes that it required its own instruction manual and those who tried it in the test-cities of St Louis and Phoenix found it unsatisfying, perplexing and smelly. It was swiftly abandoned.

Philip Morris made similar efforts with brands called *Next* and *Accord*, and R.J. Reynolds relaunched a heavily modified version of *Premier* in 1996 under the name *Eclipse*. *Eclipse* was closer to a conventional cigarette but released much less 'secondhand' smoke and delivered

fewer potentially harmful chemicals to the user (R.J. Reynolds, 2000). Even ardent opponents of the tobacco industry, such as Senator Henry Waxman, accepted that *Eclipse* was 'safer, relatively speaking' (Fairfield, 2004) but all the major US health organisations - bar the Institute of Medicine - rejected it without trial and the American Cancer Society fought for it to be taken off the market, claiming that it 'may be more lethal than other low-tar cigarettes' and pointed to the tobacco industry's 'long history of deception.' (American Cancer Society, 2000) The product is still available in the USA, albeit with a very niche customer base.

Pharmaceutical nicotine

By the end of the millennium, despite billions of dollars spent on research and hundreds of patents acquired, a saleable reduced harm cigarette still eluded the tobacco industry. Manufacturing a known carcinogen continued to be a more viable business proposition than producing and marketing a less hazardous tobacco product. The only safer nicotine products that had gained the support of public health campaigners were pharmaceutical products such as patches and gums. Licensed as smoking-cessation aids, 'nicotine replacement therapy' (NRT) has a relatively modest success rate when it comes to helping smokers quit. It is widely accepted that its use increases the chances of successful quitting by 50 to 70 per cent (Stead, 2008: 2), but the number of successful quitters remains low. As noted in the definitive Cochrane review, at least 95 per cent of unaided attempts to stop smoking end in failure, so even those who use the most effective forms of NRT have less than a ten per cent chance of being a nonsmoker after six months (ibid: 13).

Some recent studies have questioned the efficacy of NRT in bringing about longterm abstinence. A study in *Tobacco Control* found that relapse rates were no different for people taking NRT than for those who quit 'cold turkey' (Alpert et al., 2012) and a study in *Archives of Internal Medicine* found no difference in successful quit attempts between NRT users and controls (Carpenter et al., 2011). Although some smokers find NRT helpful, its widespread use over three decades has not had a dramatic effect on the smoking rate. A recent study in the *Annual Review of Public Health* found no correlation

between NRT use and smoking cessation rates at the national level and concluded: ‘To date, there is no evidence that such policies [ie. recommending that ‘pharmaceutical aids be used in all quit attempts’] lead to an increase in successful cessation in the population... That successful smoking cessation has not increased ... despite the increased efforts focused on it suggests that there is an urgent need to revisit current tobacco control policy.’ (Pierce et al., 2012)

The new wave of smoking alternatives

Two products dominate the tobacco harm reduction debate in the twenty-first century. Neither of them were developed by 'Big Tobacco', if that term refers to multi-national cigarette companies, and both of them entered the field of harm reduction out of the blue. They are electronic cigarettes (e-cigarettes) and Swedish-style oral tobacco (snus).

E-cigarettes

Writing in 2001, the public health doctor John Britton suggested that it was 'necessary to develop nicotine delivery products that can provide the nicotine that the addict wants, and with the speed of delivery achieved by the cigarette, but without the harmful products of tobacco combustion.' (Britton et al., 2001: 15) Unbeknownst to him, the Beijing pharmacist Hon Lik had invented just such a product a year earlier. The electronic cigarette (e-cigarette) uses a battery and atomiser to vaporize a liquid combination of nicotine, water and propylene glycol which is absorbed into the bloodstream via the lungs. Much of its potential as a harm reduction product stems from the way it closely mimics the smoking experience, including the 'throat hit' and the rapid nicotine absorption. The vapour itself is almost entirely odourless and contains no burnt matter, no tar, and no carbon monoxide.

The e-cigarette is the kind of product the tobacco industry contemplated for many decades but never brought to market. British American Tobacco (BAT) experimented with non-tobacco nicotine delivery devices as early as 1960 when it embarked on 'Project Ariel', an effort to create a cigarette without tobacco, based on the then-radical hypothesis that people smoked for the nicotine only. Despite numerous prototypes and several patents, all BAT's efforts were stillborn, including a non-combustible device called *Favor* which was found to be 'extremely irritating' on the throat and was never brought to market (Proctor, 2003: 90). In the late 1990s, BAT formed BAT Cigatronics Ltd. to develop a 'non-combustible completely "smoke-free" electronic cigarette shaped and sized device designed to create and control nicotine vapour for delivery, via the lungs' (BAT, 1998: 3). A prototype for a disposable device containing the nicotine equivalent of a packet of cigarettes was developed but, again, the product was never launched.

Today, the e-cigarette market is growing rapidly. There are more than 650,000 e-cigarette users in the UK, according to Action on Smoking and Health (ASH, 2013). The UK's Electronic Cigarette Consumer Association estimates that there will be a million owners by the end of 2013, up from just a thousand in 2007 (ECCA, n.d.). The Electronic Cigarette Industry Trade Association estimates that the e-cigarette market is growing at the extraordinary rate of thirty per cent per month (Matrix Insight, 2012: 49).

Since e-cigarettes are a relatively new product, much of the evidence of their efficacy as a substitute for smoking remains anecdotal, but early empirical evidence is encouraging. A 2011 clinical trial found that e-cigarette use led to sustained smoking abstinence for 22.5 per cent of smokers who were not motivated to quit, and there was a large reduction in cigarette consumption for a further 32.5 per cent (Polosa et al., 2011). As for their safety, a study in the *Journal of Public Health Policy* reported that e-cigarettes are 'comparable in toxicity to conventional nicotine replacement products' with trace levels of tobacco-specific nitrosamines detected at 0.07-0.02 per cent of the level found in conventional cigarettes (Cahn and Siegel, 2010: 18). 'Thus far,' write Cahn and Siegel, 'none of the more than 10,000 chemicals present in tobacco smoke, including over 40 known carcinogens, has been shown to be present in the cartridges or vapour of electronic cigarettes in anything greater than trace

quantities.' (ibid: 26) A 2013 study in *Tobacco Control* found that 'levels of toxicants [in e-cigarettes] were 9-450 times lower than in cigarette smoke' (Goniewicz et al., 2013). The National Institute for Health and Clinical Excellence notes that there are 'no firm cases of harm that are directly attributable to e-cigarette use.' (NICE, 2012: 64)

Swedish snus

Snus (rhymes with 'juice') is finely cut moist tobacco in a teabag-like pouch which is placed under the top lip thereby allowing the nicotine to absorb through the gum. It has been used in Sweden for more than two hundred years but fell out of favour during the cigarette age of the mid-twentieth century. In the 1970s, snus was associated with old men and appeared to be moribund as a consumer product, but growing acceptance of the dangers of cigarette smoking led to a dramatic revival in its fortunes. The unprompted mass switchover of the last four decades has had a dramatic impact on rates of smoking and smoking-related disease. In 1976, Sweden's male smoking rate was an unexceptional 40 per cent. Thereafter, snus consumption more than doubled and, by the end of the century, Sweden's smoking rate was the lowest in Europe. In 2000, a third of male ex-smokers had used snus as a cessation aid and Sweden was almost unique in having a smoking rate that was higher for women than for men (snus has traditionally been used mainly by men).

Today, only 13 per cent of Swedish men and 15 per cent of Swedish women are daily smokers (Haagensen, 2012: 57), much lower than the EU average of 29 per cent and 18 per cent for men and women respectively (OECD, 2012).[2] Unsurprisingly, Sweden has the lowest rate of tobacco-related mortality - including lung cancer mortality - in Europe, despite consuming the same quantity of tobacco (by weight) as other countries (Rodu and Cole, 2004).

[2] Alternative smoking prevalence figures issued by Eurobarometer are similar, with an EU average of 28 per cent

Empirical evidence from Sweden and Norway strongly suggests that switching to snus is an effective cessation technique for a significant number of smokers (Gilljam and Galanti, 2003). A study of Norwegians found that 48 per cent of smokers who used snus to quit remained abstinent, compared to only 26 per cent of those who used NRT (Scheffels et al., 2012). A small but growing evidence base from countries which have no tradition of using snus also shows that it is an acceptable substitute for many smokers (Joksić et al., 2011).

At one time, snus was assumed to increase the risk of oral cancer, but the weight of epidemiological evidence shows no such association (Rosenquist et al. 2005). More recently, it has been claimed that snus increases the risk of pancreatic cancer and heart attacks, but rigorous epidemiological research has again failed to support this (Bertuccio et al., 2011; Hansson, 2012). Sweden has a relatively low incidence of both oral and pancreatic cancer by European standards and, in 2001, the EU took the unprecedented step of removing the cancer warning from a tobacco product when it changed its regulations for Swedish snus products (European Commission, 1999: 43-51).

Snus is little known outside Scandinavia and there is widespread ignorance about its low risk profile. Its potential as an alternative to smoking, though clearly demonstrated in Sweden, is constrained by a lack of consumer knowledge. A study in the US found that 51 per cent of 'highly educated professionals' believe that the health risks of snus use and cigarette smoking are similar (Peiper et al., 2010). Even in Norway, where snus consumption is common, only 23 per cent of smokers believe that snus has a 'far lower' risk profile than cigarettes, while 40 per cent believe the risks from snus use are 'equal or higher' (Lund, 2012). Perceptions amongst health professionals are also mixed. Only 36 per cent of Norwegian general practitioners believe that snus is 'much less harmful' than cigarettes, while 15 per cent believe it to be as harmful or more harmful (Lund and Scheffels, 2012).

There is, however, a more profound hindrance to tobacco harm reduction than mere ignorance. The legal status of e-cigarettes and snus in many jurisdictions is the very opposite of what might be expected from a calm assessment of their risk profiles. Many

countries have outright prohibitions on snus, e-cigarettes and/or nicotine-containing liquid. The sale of oral tobacco, including snus, has been prohibited in the EU since 1992 on the basis that the Common Market needed to be harmonised after Ireland and the UK banned the sale of *Skoal Bandits*, an American brand of snus, in the 1980s. The public health justification for the EU-wide ban was the presumed association between snus and oral cancer. Sweden negotiated an exemption from the ban when it joined the EU in 1995. This exemption undermined the EU's ostensible commitment to market harmonisation, and the EU's subsequent acknowledgement that snus is not carcinogenic undermines the public health justification for the ban. In light of the 'Swedish experience' of widespread snus consumption, low smoking rates and low rates of cancer, the EU ban appears arbitrary and counter-productive. In spite of this, public health groups are pressing the government of Norway, the only non-EU country in Scandinavia, to ban snus by 2017.

Likewise, there are *de facto* or *de jure* prohibitions on e-cigarettes in several countries, including Greece, Singapore, Israel, Lithuania, Brazil, Norway and Panama. Nicotine-containing liquid is banned in Canada and Australia on grounds of safety. In Denmark, e-cigarettes are classed as medicinal products and have not yet been authorised for sale. In New Zealand, e-cigarettes can only be sold in pharmacies as medicinal devices. Anyone found in possession of an e-cigarette in Hong Kong can be given a two year prison sentence. Meanwhile, cigarettes are widely available in almost every country in the world and are by far the most commonly used - and most lethal - nicotine product.

Harm reduction and its opponents

The arguments for and against harm reduction in the field of nicotine are much the same as those in the field of illegal drugs where governments have increasingly adopted needle exchanges, methadone programmes and safe consumption rooms to reduce drug-related mortality. In the field of drugs, harm reduction is widely considered to be a healthier and more humane approach than rigid prohibition. The biggest difference between harm reduction for narcotics and harm reduction for nicotine is that many more people die each year as a result of smoking than die as a result of drug use, albeit usually at an older age.

The other key difference is that narcotics are illegal whereas cigarettes are not. Accusations of institutional hypocrisy made against governments which facilitate the consumption of illicit drugs carry less weight in the case of tobacco harm reduction since cigarette smoking is legal. Advocates of e-cigarettes and snus cannot be accused of condoning smoking since both products are alternatives to smoking and the former does not even contain tobacco. At worst, they can be accused of condoning nicotine use, but nicotine does not cause disease and, as a drug, it is much closer to caffeine than to opiates. Tobacco harm reduction therefore forces campaigners to ask themselves if it disease they are fighting or if addictive pleasures and corporate profits are a greater concern.

The economist Thomas Sowell divides people into those who have the ‘tragic vision’ and those who have the ‘vision of the anointed’ (Sowell, 1995). The latter believe that the problems of mankind are

created by institutions and that, through legislation, solutions can be found - in this instance, total worldwide abstinence. The former see mankind as inherently flawed and believe that there are rarely 'solutions', only trade-offs. There are those who believe that legislation, denormalisation and NRT can reduce the prevalence of tobacco use to less than 0.5 percent of the population within twenty years (Thomson, 2012: 294). Others look at the failure of similar efforts to suppress alcohol and drugs in the past and view the neo-prohibitionist approach as utopian, unrealistic and ultimately damaging to health.

Back of the envelope calculations of how many premature deaths could be prevented by a shift to alternative nicotine products are easy to produce. 'If all the smokers in Britain stopped smoking cigarettes and started smoking e-cigarettes,' writes John Britton of the Royal College of Physicians' Tobacco Advisory Group, 'we would save 5 million deaths in people who are alive today. It's a massive potential public health prize.' (BBC, 2013) This assumes that every smoker will be happy to shift to the electronic devices, an unrealistic scenario, but significant health gains can be predicted whatever the level of uptake.

In a private letter written in 1984 when harm reduction was out of fashion and total abstinence was the order of the day, the renowned epidemiologist Richard Peto pondered the question of 'how many cancer deaths would be likely to be caused each year if one-third of the British population become habitual tobacco suckers.' (Peto, 1984) This was a reference to snus, which was becoming the subject of controversy in Britain as a result of the *Skoal Bandits* furore. Peto acknowledged that the health risks associated with snus, if any, were unknown and would take many years to identify. He cautioned that 'no matter what epidemiological studies you mount, you probably won't get even a preliminary answer this century, so as a practical basis for action I suggest you assume that the adoption of *Skoal Bandit*-like products by a quarter or a half of the British population will cause about 1000 cancer deaths a year. In contrast, tobacco smoking currently causes about 100,000 British deaths a year!' (emphasis in the original). Peto based his prediction of a thousand cancer deaths on the assumption that snus had a similar risk profile to the kind of loose oral snuff used earlier in the century in the USA. It took many years before the

epidemiological evidence showed no association between Swedish snus and mouth cancer. He was, however, correct in his basic assumptions which he outlined as follows:

> ‘
> - The risks are not zero
> - The risks can probably be reduced by immediately commissionable laboratory research;
> - The risks are much, much less than those of cigarette use.’ (Peto, 1984)

Writing about *Skoal Bandits* in the *Lancet* the following year, the addiction specialist Michael Russell came to a similar conclusion:

> ‘Our results suggest that this new product could help people trying to give up smoking. It might be cheaper than nicotine chewing gum and would not require a prescription. If all smokers in Britain switched to sachets about 50,000 premature deaths per year might eventually be saved at an annual cost of less than 1,000 deaths from mouth cancer.’ (Russell et al., 1985: 1370)

Speaking to Virginia Berridge in 1995, Russell recalled that such messages fell on stony ground in the 1980s. ‘I gave a talk fifteen years ago at a respectable conference in Edinburgh - if you could get people to switch to snuff you could prevent lung cancer and bronchitis - all for a small risk. People don’t like it if you raise these issues.’ Such arguments ‘carried little weight with a public health lobby which still regarded safer smoking (in whatever form) as a discredited strategy and abstention as the only aim,’ writes Berridge (2007: 271). ‘The scientific message might have been right, but it was coming from the wrong messengers at the wrong time.’[3]

In the USA, the oral pathologist Brad Rodu was roundly condemned by anti-smoking campaigners when he published his book *For Smokers Only: How Smokeless Tobacco Can Save Your Life* (1995).

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[3] In 1984, the British Medical Association began to abandon its ‘fusty’ image as an old-fashioned trade union for doctors and became more politically active. Harm reduction had no place in its newly militant agenda and its first major campaign was directed against Skoal Bandits (Berridge, 2007: 233).

Like Peto, he based his calculations on the risk profiles of the most carcinogenic smokeless products but nevertheless concluded that 'if all 46 million smokers used smokeless tobacco instead, the United States would see, at worst, 6,000 deaths from smoking-related cancers, heart problems, and lung disease.' (Rodu, 1995: 131) Despite the book's title clearly indicating that Rodu was not condoning the use of smokeless tobacco by nonsmokers, he was accused of being 'irresponsible' and 'naïve' by public health activists who have ostracised him in the years since (Sullum: 78-80).

Arguments against safer products

Opposition to harm reduction is by no means universal in public health circles. A number of organisations, including the American Association of Public Health Physicians, Action on Smoking and Health, the American Council on Science and Health and the Royal College of Physicians have recommended that snus be re-legalised and e-cigarettes be encouraged. For others, however, stated concerns include the possibility that alternative nicotine products act as a 'gateway' to cigarette smoking, that some people will use less harmful products *as well as* cigarettes, and that snus and e-cigarettes allow smokers to 'get around' smoking bans.

Taking the objectives of modern public health at face value, one can consider the following theoretical process by which a less harmful product could negatively affect population health. It is possible that individuals who would not have taken up smoking because they think it is too dangerous might take up the less harmful product. If Product A is half as hazardous as Product B and the entire market shifts from B to A, then net harm will fall by half. If, however, Product A attracts so many new customers that the entire market doubles, the net effect would be zero. And if the market increases threefold, net harm would increase by 50 per cent.

How likely is it that a shift to safer nicotine products will increase net harm? Further research will quantify exactly how much safer e-cigarettes and snus are in comparison to conventional cigarettes, but there is little doubt that they are at least 90 per cent less hazardous and are probably in the region of 98-99.9 per cent less hazardous (Rodu, 2011; Cahn and Siegel, 2011). If so, the risk

posed by these products is of a similar order to that of eating red meat, drinking alcohol in moderation, driving a car, sun-bathing or any of the other run-of-the-mill lifestyle choice.

Approximately twenty per cent of the UK population currently use nicotine, of whom the vast majority smoke cigarettes. The nicotine market cannot, therefore, increase by more than fivefold (100 per cent). If snus and e-cigarettes are 95 per cent less hazardous than cigarettes (a very conservative estimate), then there would have to be a more than twentyfold increase in the size of the nicotine market for net harm to rise above the current level. This is a mathematical impossibility.

Alternatively, it is possible that individuals might take up the less harmful nicotine product and then move on to cigarettes - the 'gateway' effect. There is, however, very little evidence that reduced harm products appeal to nonsmokers in the first place. In the case of e-cigarettes, ASH (2012) notes that 'there is little evidence of use by those who have never smoked.' Based on survey data, ASH found that 'regular use of e-cigarettes is extremely rare' amongst children. Only one per cent of 16-18 year olds - and *zero* per cent of 11-15 year olds - use an e-cigarette more than once a week and this tiny minority is made up of smokers and ex-smokers. ASH found no regular users of e-cigarettes amongst non-smoking teenagers:

> 'Among young people who have never smoked 1% have "tried e- cigarettes once or twice", 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon... Frequent (more than weekly) use of e-cigarettes was confined almost entirely to ex-smokers and daily smokers.'

Far from acting as a gateway to smoking, all the evidence indicates that e-cigarettes are a gateway *from* smoking. Switching from vaping to smoking would require a conscious decision to take up a habit that is ten times more expensive and one hundred times worse for your health. The prohibition or over-regulation of these devices will close off a hypothetical gateway from e-cigarettes to tobacco, but it will also close off a very real gateway for people who want to go from tobacco to e-cigarettes, and that is the path most travelled.

Some have complained that e-cigarettes 'normalise' smoking. 'We are especially concerned that e-cigarettes might reinforce the smoking habit as they are designed to closely mimic smoking actions', says the British Medical Association (2013). For this reason, the BMA has called for the smoking ban to be expanded to include e-cigarettes despite it being almost inconceivable that 'passive vaping' could pose any risk to bystanders. On the campus of the University of California, San Francisco, it is against the rules to carry, let alone use, an e-cigarette, even outdoors.

For all the talk of 'denormalising' tobacco use, smoking prevalence in most countries exceeds twenty per cent of the adult population. Smoking may not be universal, but it can hardly be described as abnormal or unusual. In 2010, cigarettes and rolling tobacco made up 94.9 per cent of the EU's nicotine market. E-cigarettes and NRT held just 0.4 per cent each while smokeless tobacco held 0.6 per cent (Matrix Insight, 2012: 20). Whilst there is evidence that the 'denormalisation' approach can lead to lower smoking rates (Hammond et al., 2006), it remains doubtful whether e-cigarettes 'normalise' smoking in any meaningful way. As a device that has spread rapidly by word-of-mouth in recent years, it would be more accurate to say that e-cigarettes normalise harm reduction and smoking cessation. Moreover, there are social costs incurred by the denormalisation/stigmatisation approach which can be avoided by the more liberal harm reduction approach (Bayer and Stuber, 2006).

Once bitten, twice shy?

A further objection sometimes raised is that harm reduction has been tried before and failed. Low tar cigarettes and filter tips are now widely portrayed as tobacco industry ruses to trick consumers and delay tougher regulation. This 'once bitten, twice shy' argument requires some rewriting of history. Lowering tar yields and investigating the 'safer cigarette' had the support of many public health scientists, including some of those who first identified the link between cigarette smoking and disease, as well as successive Surgeon Generals and several Ministers for Health. The Federal Trade Commission recommended that tar yields be printed on cigarette packs in 1969 (Sullum: 69) and many governments officially advised smokers to switch to low tar brands in the 1980s and 1990s.

Moreover, the harm reduction efforts were not complete failures. There is ample evidence that the unfiltered high-tar cigarettes of the 1950s posed more of a health hazard than the filtered low-tar cigarettes of later decades (Hammond et al., 1976; Tang et al., 1995; Blizzard and Dwyer, 2001; Harris et al., 2004). The European Union has progressively lowered the maximum permissible levels of tar and nicotine in cigarettes, presumably because it believes lower yields to be less dangerous. Although the 'safer smoking' initiative of the twentieth century was a more collaborative effort between the tobacco industry and government than is often recognised, the industry was guilty of keeping its misgivings about 'light' cigarettes to itself and it clearly failed to produce a 'tolerable risk' cigarette. None of this has any bearing on the safety or efficacy of snus and e-cigarettes, however. 'Once bitten, twice shy' is fallacious reasoning.

Arguments made against tobacco harm reduction on health grounds are not compelling. Opposition to e-cigarettes and snus can only be properly understood in the context of the public health lobby's longstanding goals of eradicating recreational nicotine use and destroying the tobacco industry. An underlying objection of anti-smoking campaigners to these products is that cigarette companies could survive and thrive by selling them. Several tobacco firms have started selling snus and Lorillard became the first tobacco company to acquire an e-cigarette firm in April 2012. British American Tobacco has created a startup company called Nicoventures to create products for 'smokers who may not want to quit smoking but who want a safer alternative to cigarettes' while Philip Morris has patented a nicotine aerosol product (Matrix Insight, 2012: 52) Many anti-smoking veterans would find it intolerable if 'Big Tobacco' became a player in harm reduction since they have long since cast the industry as a consummate enemy with whom they are engaged in a war of annihilation.

Meanwhile the pharmaceutical industry has an incentive to lobby against non-medicinal nicotine products and national governments have a financial incentive to perpetuate the smoking of highly-taxed cigarettes. The novelist Lionel Shriver, who kicked her smoking habit thanks to e-cigarettes, blames opposition to the devices on 'kneejerk cultural prejudice, puritanical vindictiveness, corporate collusion, and the unconscionable greed of tax authorities that won't

be able to heap the same punitive, confiscatory, opportunistic duties on a product that doesn't hurt anyone.' (Shriver, 2013)

Resistance to e-cigarettes - which contain no tobacco and are, for the most part, not made by 'Big Tobacco' - is consistent with the puritanism and prejudice Shriver alludes to. Moral indignation towards pleasure-giving 'vices' may well be a motivation for some of those working in the tobacco control industry. Bell and Keane (2012) note that objections to e-cigarettes have a moral dimension and that 'it is not clear that further research into e-cigarettes will substantially alter current opinion. This is because their dangers stem not merely from the constituents of the products themselves, but the ideological challenge they pose to the binary categorisation of nicotine into not only remedial and harmful forms, but morally "good" and "bad" ones.'

As smokeless products, e-cigarettes and snus do not violate the anti-smoking lobby's vision of a 'smoke-free society' - indeed, they are likely to bring it closer to fruition - but recreational nicotine use of this sort remains morally suspect to some of its members and was never part of the plan. The question now is whether 'it is better to aim for complete exclusion or prohibition of nicotine use, or to accept the place of nicotine in society but to regulate to make nicotine products safe.' (Britton et al., 2001: 14-15) It remains to be seen whether that plan is flexible enough to adapt to changing circumstances or if the abstinence-only ideology is too big a juggernaut to be turned around.

Harm reduction versus neo-prohibition

As previously noted, anti-smoking campaigners since the late 1970s have been wedded to a policy of incremental prohibition with the ultimate aim of an 'endgame' in which there is a *de facto* or *de jure* ban on the sale of cigarettes and/or tobacco (Proctor, 2013; Wilson et al., 2013). In common with earlier prohibitionist crusades, campaigners portray this as a battle against industry rather than against consumers.

The cornerstones of tobacco control orthodoxy in developed countries are (1) comprehensive smoking bans, (2) progressively larger (graphic) health warnings, (3) bans on advertising and promotion, (4) progressively higher tobacco taxes, and (5) distribution of pharmaceutical nicotine products for smoking/nicotine cessation. The European 'Tobacco Control Scale' (TCS) scorecard provides a check-list of anti-smoking best practice. The scorecard was devised in 2006 'to measure the implementation of tobacco control policies systematically at country level.' (Joossens and Raw, 2006) Produced by the Association of European Cancer Leagues, it awards points for the following criteria:

- High tobacco prices
- Extensiveness of smoking bans
- Spending on public anti-smoking campaigns
- Extensiveness of advertising bans
- Size of health warning labels and inclusion of graphic images
- Smoking cessation services, including state-funded pharmaceuticals

With these policies assumed to be paramount, the UK and Ireland have come top of the TCS rankings in the two editions produced to date (2007 and 2010). Sweden came an unimpressive ninth, sandwiched between Belgium and Malta.

Ireland is, in many respects, the poster boy for tobacco control. It was the first European country to ban snus in the 1980s and the first country in the world to ban smoking in enclosed public places. It has the highest cigarette prices in the EU and its government partially funds the sale of NRT and other stop-smoking drugs. The UK has taken much the same path but achieves a higher ranking on the TCS because it introduced graphic warnings earlier and has a larger budget for tobacco control.

Sweden, by contrast, has exemptions to its smoking ban, allows point-of-sale advertising for some tobacco products, has no graphic warnings, does not subsidise NRT and has significantly cheaper cigarettes than both the UK and Ireland.[4] The TCS report's authors lament the fact that: 'Surprisingly, Sweden is often NOT in support of strong tobacco control measures at European and international level.' (Joosens and Raw, 2011) Above all, it allows the sale of snus.

One critical indicator of progress is not included in the scorecard - the smoking rate. Despite failing to adopt 'strong tobacco control measures', Sweden has by far the lowest smoking rate - and the lowest rate of lung cancer - of any EU country. Figures from the OECD show that Sweden had a smoking rate of 14 per cent in 2010, less than half of the rate in Ireland (29 per cent) and a full four percentage points lower than the country with the second lowest smoking rate, Luxembourg (Luxembourg comes a miserable 29th out of 31 in the TCS) (OECD, 2012: 59).

[4] Sweden allows closed, ventilated, designated smoking rooms. Interestingly, the Appendix of the report shows that Sweden has the highest percentage of residents who are 'never or almost never exposed to tobacco smoke' at work (96 per cent). Exposure to smoke is, however, not regarded as a criterion of success and so Sweden scores below Spain, which has more restrictive legislation but where only 58 per cent of residents report little or no exposure.

Meanwhile, Ireland and the UK - exemplars of the orthodox tobacco control model - have unimpressive smoking and lung cancer rates, as well as being home to Western Europe's largest black markets in tobacco (KPMG, 2013: 15).

Charting the smoking rate against the Tobacco Control Scorecard using the most recent data (TCS, 2010 and OECD, 2012), Figure 1 shows that there is no association between TCS scores and smoking prevalence (r^2=0.03). Countries which ignore the neo-prohibitionist model fare no better and no worse than those which follow it to the letter. This is confirmed by Figure 2 which charts the scorecard against the change in smoking prevalence in each country between 1990 and 2010 (OECD, 2013: 239). The data points appear to be scattered at random, with Ireland reducing its smoking rate by less than any other country (r^2=0.04). Interestingly, the three countries that have seen the largest declines in smoking prevalence are all Scandinavian nations with a strong tradition of using smokeless tobacco.[5]

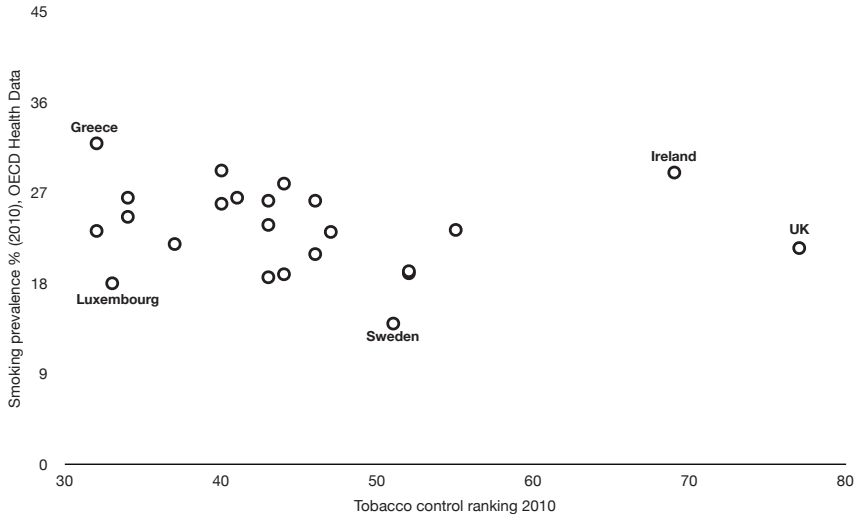

Figure 1: Smoking prevalence/TCS score

[5] Norway is not in the EU and snus is therefore legal. EU law allows the sale of snus in Sweden only, but loose snus (ie. not contained in a pouch) is legal in Denmark. Sales of smokeless tobacco rose by 255 per cent in Denmark between 2000 and 2010 (from 4 to 14.2 tonnes per annum) (European Commission, 2012b: 6)

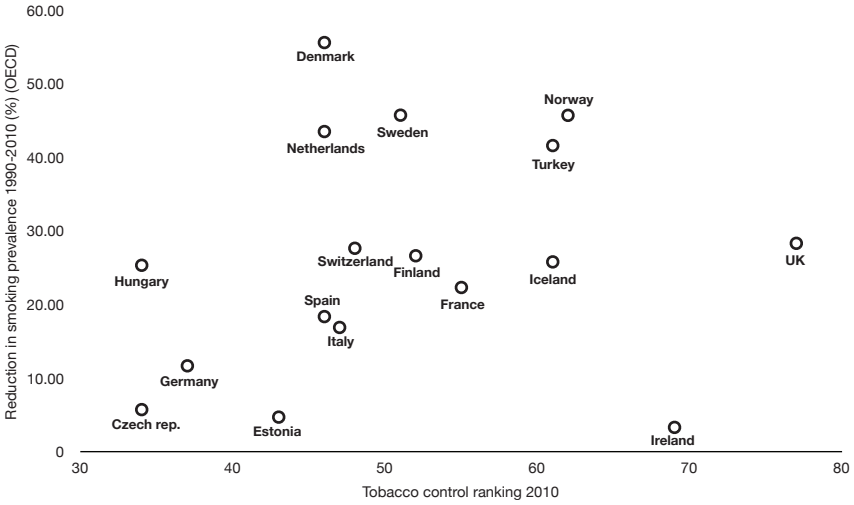

Figure 2: Change in smoking prevalence 1990-2010/TCS score

It should not be inferred from these graphs that anti-smoking policies have no impact on smoking rates. On the contrary, the tobacco control movement has succeeded in changing social norms about smoking and there is strong evidence that tax rises, for example, have reduced smoking prevalence in the past. Some policies work better than others, however, while some may be ineffective or even counterproductive. If the TCS is any guide, it appears that a relatively high smoking rate and a significant problem with the illicit trade does not disqualify a nation from being regarded as a model of best practice. If policy was truly evidence-based, one might expect best practice to be derived from the countries with the lowest smoking rates. Instead, the world-beating Swedish model is ignored in favour of nations which have followed the neo-prohibitionist blueprint despite a conspicuous lack of success in reducing the number of smokers.

The lack of relationship between TCS scores and smoking prevalence can be explained by the waning power of tax rises to deter Europeans from buying cigarettes and the marginal, if not counter-productive, impact of smoking bans, graphic warnings, display bans and nicotine replacement therapy in discouraging smoking.

The experience of Britain and Ireland in recent years supports the hypothesis that the neo-prohibitionist approach to tobacco control is producing diminishing returns at best. A report commissioned by three British anti-smoking groups in 2011 concluded that 'whilst there has been a downward trend in smoking prevalence over several decades, this appears to have stagnated since 2007.' (Trueman et al., 2011: 5) The authors did not dwell on the uncomfortable fact that this stagnation coincided with an unprecedented wave of neo-prohibitionist policies including a comprehensive smoking ban, steep tax rises, graphic warnings and raising the age at which tobacco could be purchased, in addition to gory advertising campaigns such as those showing the faces of smokers severed with fish hooks. In the four years before the English smoking ban was introduced in 2007, the smoking rate dropped by five percentage points. In the four years after, the rate dropped by just one percentage point.

When the tobacco control scorecard was first devised, its creators noted that: 'There is already vigorous discussion in the tobacco control field of the role smokeless tobacco in Sweden (snus) has played in the decline in smoking prevalence.' (Joossens and Raw, 2006) A recent opinion piece in *Tobacco Control* noted that 'a global natural experiment is underway where data from some nations which have banned or restricted access to harm-reduction products might be compared with those which have embraced them.' (Chapman and Wakefield, 2013: i35) It is doubtful whether any ethics committee would approve an experiment in which one group is denied access to the least hazardous forms of a product but, for better or worse, these natural experiments are indeed underway. It is too early to reach firm conclusions about the effect of the e-cigarette revolution on aggregate smoking rates, but the evidence from Sweden strongly suggests that the harm reduction approach has more to offer than the neo-prohibitionist model.

The regulatory threat

This paper has not addressed the question of whether cigarettes should be legal. Most surveys find that only a minority of the public would support prohibition and we agree that appropriately informed adults should be free to smoke (Saad, 1998; BBC, 2003). Whatever the arguments, the fact remains that cigarettes *are* legal and will remain so for many years. It is therefore neither consistent nor ethical to prevent smokers from switching to much safer alternatives.

Ongoing efforts to prohibit or medicalise e-cigarettes and snus are a far greater threat to public health than the products themselves. The EU's revised Tobacco Products Directive, due to come into force in 2015-16, will introduce a *de facto* ban on e-cigarettes by limiting the nicotine content of e-cigarette liquid to a level at which most users would find unsatisfying. Stronger e-cigarette liquid will only be available as a licensed medicinal product sold with a health warning (European Commission, 2012: 9). If the directive becomes EU law, e-cigarette liquid as it is known today would be taken off the shelves until it can prove its safety and efficacy as a medical treatment for nicotine addiction. This could take years and may not happen at all (no amount of subsequent evidence has been enough to re-legalise snus). Even if e-cigarettes secure authorisation as medicinal products, they would be more difficult to obtain than conventional cigarettes and would arguably have less appeal to smokers who do not consider themselves in need of medical treatment.

The EU's position has been supported in Britain by the Medicines and Healthcare products Regulatory Agency (MHRA, 2013). Both the European Commission and the MHRA support placing not only

e-cigarettes, but all ‘nicotine containing products’ under medical regulation. This category includes all existing innovations in the nicotine market as well as any nicotine product that is invented in the future. Only tobacco is excluded. This will have profound implications for future developments. It will leave the next generation of recreational nicotine products in the hands of a public health establishment that is instinctively drawn to precautionary bans and the doctrine of total abstinence.

The medicalisation of e-cigarettes has been portrayed as a way of putting them ‘on an equal footing’ with NRT (Erbach, 2013), but this ignores the pertinent fact that the pharmaceutical industry *wanted* their nicotine products to be authorised as medicines so that they could be marketed as drugs and sold to state-run health agencies. There is no other precedent for ‘nicotine delivery devices’ being viewed as medicines and there are no calls for the most widely sold ‘nicotine delivery devices’ - tobacco products - to undergo medical authorisation. The e-cigarette industry maintains that its products are *not* medicinal drugs, but are recreational consumer products which can be used an alternative to smoking. There is no compelling reason why products containing nicotine should be medicalised when products containing caffeine, alcohol or sugar are not. Normal consumer protection laws should suffice.

Like other governments that have dealt with e-cigarettes in a heavy-handed manner, the EU is endorsing the same neo-prohibitionist approach that led to the disastrous missed opportunity with Swedish snus. Other proposed regulations in the directive are *reductio ad absurdum* variants of orthodox tobacco control measures which, as the previous chapter showed, have little or no impact on smoking rates. These include mandating still larger graphic warnings, standardising the exact length and diameter of cigarettes and banning ‘characterising flavourings’. By tying itself up with such trivial issues, the EU is living up to its stereotype as a bureaucratic machine that produces unnecessary and petty regulation.

The most visible effect of a ban on ‘characterising flavourings’ will be to prohibit the sale of menthol cigarettes, but it will also result in a *de facto* ban on a wide range of snus brands in Sweden (which are usually flavoured) as well as most e-cigarette fluids. Here, as elsewhere, the Tobacco Products Directive is stacking the deck

against harm reduction while introducing arbitrary regulations for the cigarette industry. The directive will require medical authorisation for most ‘nicotine-containing products’ and will require pre-authorisation for any new tobacco product. Moreover, it will prohibit any labelling that might suggest that one product is less harmful than another. In short, it will not only kill off the two most promising reduced harm products, but will prevent any new innovations from hitting the shelves in the future. The effect will be to slice up the European nicotine market, dividing the spoils between cigarette companies and the pharmaceutical industry.

Conclusion

Harm reduction for smokers would save many more lives than harm reduction for drug addicts and it would not require a penny of government spending. It only requires the government to step back and allow free market solutions to gain popularity. In practice, this means taxing and regulating e-cigarettes as ordinary consumer products to ensure basic standards of quality while allowing snus to be sold with appropriate and accurate labelling to inform customers of its risk profile relative to cigarettes.

The neo-prohibitionist approach to public health has raised barriers to entry and excluded new entrants, thereby making the nicotine market less competitive and less innovative. Meanwhile, the cigarette industry continues to be highly profitable as a heavily regulated oligopoly, as Dr Robert Branston, Deputy Director of the University's Centre for Governance and Regulation, acknowledges: 'The market has failed to curb cigarette manufacturers in terms of pricing power and profit, and tobacco control policies have unintentionally exacerbated the problem.' (Bath University, 2013)

Consumers suffer in uncompetitive markets from higher prices and limited choice. Neither of these are seen as problematic by anti-smoking campaigners who view higher cigarette prices as desirable, but a more serious problem arises when safer products are preemptively banned under the precautionary principle or cannot be brought to market due to advertising restrictions and heavy bureaucracy. As former ASH director Clive Bates puts it, 'if you over-regulate a new, disruptive, low-risk alternative to the dominant

and deadly cigarette, you simply protect the worst products from competition.' (Bates, 2013) Whether by accident or design, the beneficiary is the incumbent industry, rather than the consumer.

We argue that the interests of consumers are nearly always better advanced by the provision of accurate information and free choice than by prohibitions and restrictions on commercial speech. Markets can correct themselves more quickly than governments. Market failures can be corrected by free enterprise long before government failures are even acknowledged, let alone rectified. Transforming a free market into a 'dark market' carries significant risks which are well understood by students of Prohibition and the War on Drugs. Restrictions on product development and marketing in the nicotine industry have led to information failures which have led, in turn, to further failures of both government and the market. Buttressed by political grandstanding, corporate rent-seeking, rigid ideology and old-fashioned puritanism, the result has been a disaster for the only group of people whose interests are of direct relevance: smokers.

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