Thesis
The place for harm reduction and product regulation in UK tobacco control policy

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ABSTRACT

Tobacco use remains the leading cause of preventable death in this country and more needs to be done to reduce smoking rates. Harm reduction is one policy option. Smokers smoke for the nicotine, but die from the other toxins in cigarette smoke. Harm reduction in tobacco control aims to reduce the harm arising from nicotine use by shifting smokers, who are unable to quit, to using far less hazardous sources of nicotine, notably medicinal nicotine, in place of cigarettes. This article argues that for harm reduction to work in the UK, a nicotine product regulation authority is first needed. This would regulate nicotine products in proportion to harm to ensure that, contrary to the current paradoxical arrangements, the most harmful source of nicotine, the cigarette, becomes the most highly regulated (and thus the least easily accessible, available and attractive). It goes on to explore how a harm reduction strategy might be further developed, exploring controversies and potential pitfalls. It argues that the public health community needs to own and drive this debate because failure to do so would let the tobacco industry gain the upper hand and see thousands of more unnecessary deaths from tobacco use.

Keywords smoking

The need for a new approach

As a result of its high cigarette prices and the recent introduction of a comprehensive tobacco advertising ban and smoke-free legislation, the UK was recently ranked as having the strongest tobacco control policies in Europe.¹ With pictorial warnings on packs due to be introduced later this year,² conventional tobacco control policies are now well implemented in the UK. However, with 10 million people still smoking and the prevalence of smoking reducing only slowly, tobacco remains the leading cause of death, disease and health inequalities.² More needs to be done. Although the effectiveness of conventional policies must continue to be maximized and new policies introduced—(media campaigns including those that delegitimize the industry)—other more radical policies must also be considered.

Harm reduction is one option. Harm reduction in public health is not new, but has not yet been formally applied in tobacco control. Harm reduction is intended to reduce the harm to self and others arising from a behaviour. People smoke because they are addicted to nicotine and seek a nicotine ‘hit’, but it is the constituents of tobacco smoke other than nicotine that cause most of the harm. As nicotine can be obtained from various products, which vary in their level of harm and addictiveness from smoked tobacco at the top end of the harm/addiction spectrum to medicinal nicotine (MN) at the bottom end, harm reduction in tobacco control would work by encouraging smokers to shift to using nicotine in a less harmful form, and importantly and ideally, would ultimately result in them quitting nicotine use altogether.

This seems straightforward, yet harm reduction in tobacco control has been controversial and divisive for a number of reasons. First, both proponents and opponents
starting from the big picture and moving on to the detail

nicotine product regulation

A market in nicotine products effectively exists and includes three main types of products—smoked tobacco (predominantly cigarettes), ST and MN. Cigarettes are the most harmful, killing one in two of their users. A large variety of ST products are available, which vary widely in toxin content and risk profile although all are substantially less hazardous than smoking, as it is largely the combustion process that makes smoking so deadly. At the lower end of the risk scale is MN, a relatively safe drug and many magnitudes safer than smoking.

The dependence potential of nicotine products appears to be a function of both the dose and speed of delivery. Although ST products deliver similar quantities of nicotine to cigarettes, cigarettes differ in delivering the dose more rapidly with an arterial ‘bolus’. Cigarettes are therefore considered the most highly addictive, ST somewhat less so, with MN, which gives both lower and slower nicotine absorption, having low potential for abuse. Paradoxically, however, the current UK regulatory system strongly favours the most dangerous and addictive nicotine products (smoked tobacco) over the least hazardous (MN), thereby encouraging smoking as the easiest and most affordable nicotine habit. Smoked tobacco is virtually unregulated, largely as a result of its introduction decades before its health risks were understood. By contrast, as a medicine, MN comes under the control of the Medicines and Healthcare products Regulatory Agency (MHRA), and is tightly controlled. This regulatory imbalance means that smoked tobacco is easily accessible at any time of day or night from a vast array of outlets, whereas MN is far less available, some formulations being available only on prescription, and those available over the counter (OTC) typically being sold in pharmacies with limited opening hours. Packs of MN tend to be much more expensive than cigarettes at the point of sale; they also contain extensive literature on the potential risks and side effects of nicotine use, whereas cigarette packs carry none, perpetuating the misperception among smokers and health professionals that the MN is harmful. Tobacco companies can bring new brands of tobacco products onto the market without reporting to any regulatory authority, simply supplying the Secretary of State with the name of the brand, its tar, nicotine and carbon monoxide machine-based yields (which bear little resemblance to actual yields) and providing a product sample. In contrast, new MN products have to go through extensive licensing requirements and post-marketing surveillance.

Anomalies in the regulation of ST products also favour more harmful ST products over less harmful ones. ST products can be broadly divided into those that are chewed and those that are sucked. The former includes products such as gutkha and pan masala, which are widely used by the South Asian community in the UK and have a significant hazard profile, being an important cause of oral cancer. Like smoked tobacco, these products are virtually unregulated and can be sold freely. By contrast, the sale of ST that is intended to be sucked, notably the Swedish moist snuff (known as snus—see Box 1), which appears to have the lowest risk profile of any oral tobacco, is prohibited in the UK under European Union (EU) legislation.

It would seem imperative therefore that these regulatory imbalances and anomalies are resolved. A regulatory system in which regulation, and consequently access and availability (as detailed further below), is afforded in proportion to the hazard of the product would be in the interests of public health.

A number of other issues underlie the need for better regulation of nicotine products. First, the lack of regulation...
has enabled the tobacco industry’s longstanding and well-documented manipulation of cigarette chemistry, engineering and testing to encourage uptake and discourage cessation; the ‘light’ and ‘mild’ debacle being the best example. Second, the

Box 1 What is Swedish snus and the ‘Swedish experience’?

Snus is a relatively high nicotine delivery, low nitrosamine moist snuff that can be rolled by the user or bought in soft porous packs (like tiny tea bags) and placed under the upper lip. Its tobacco content, manufacture and storage differs from that of other ST products and it is thought that this accounts for its low carcinogen content and mutagenic activity compared with other ST products. For example, rather than fermentation, it is processed by steam treatment, thought to prevent microbial fermentation and consequent nitrosamine formation, and is refrigerated immediately after production and throughout the retail chain, a factor thought to maintain the low levels of tobacco-specific nitrosamines. In addition, the largest manufacturer of Swedish snus has a manufacturing standard that specifies maximum limits for toxins.

Snus has traditionally been widely used by Swedish men and Sweden has the highest rate of per capita snuff consumption in the world. The high rates of snus use among Swedish men, combined with the fact that male smoking and tobacco-related mortality rates in Sweden are the lowest in the world has led to a growing interest in the role that it could play in smoking cessation and harm reduction. This ‘Swedish experience’ provides proof of concept that substitution of ST for smoked tobacco can be effective as a harm reduction strategy.

Although snus appears to have lower health risks than other STs and certainly than smoked tobacco, it is not risk free. Reviews of the evidence suggest that it increases the risk of pancreatic cancer and death from, although not incidence of, myocardial infarction and has adverse effects in pregnancy. However, isolating the risks of snus from those of other STs in studies where wide varieties of products are often grouped together is complex, and limitations in the evidence base have been identified. Thus although reviews suggest that there is no clear increased risk of oral cancer from snus, and Sweden’s rate of oral cancer is no different from that in comparable developed countries, a recent prospective cohort study found a significant increase in incidence of oral cancer and a slight increase in overall mortality in snus users.

nicotine market has recently been further complicated by the introduction of various new cigarette or cigarette-like products as well as new ST products. The former include so-called potentially reduced exposure products or PREPS, some of which are conventional cigarettes with minor changes to carcinogen content or filter structure, and more novel products such as Eclipse and Accord which heat rather than burn tobacco. Electronic cigarettes which vapourize nicotine are currently being marketed in the UK for use in smoke-free public places. As long as no health claims are made for such products, they remain unregulated. Yet health claims are often implicitly or explicitly made (see for example http://www.amazinghealth.co.uk/e-cigarette.htm or http://www.youtube.com/watch?v=E18jmMNUBdM). Third, the current regulatory structure discourages the development of more innovative and effective MN products. Not only is it expensive to develop, evaluate and bring new medicinal products to the market, especially in comparison with cigarettes, but should newer MN products be produced, any able to effectively compete with cigarettes would almost certainly be addictive, and under current regulations would face strict restrictions on promotion and use.

Harm reduction

It has been argued that a harm reduction strategy offers a major opportunity to reduce the health impacts of smoking. By shifting smokers from the most harmful nicotine delivery device, the cigarette, to a less harmful alternative, the harm caused by nicotine addiction could be significantly reduced. In addition, by shifting smokers to smoke-free nicotine products, involuntary exposure of others to tobacco smoke would be reduced and smoking would be further denu-

What should be part of a harm reduction strategy?

So harm reduction is theoretically plausible and feasible, but key questions remain. What is the evidence that it would work? What products should be promoted as part of a harm reduction strategy and notably, should ST products form part of the harm reduction model?

MN is in fact already used for harm reduction in the UK, and more so here than elsewhere given the strength of our cessation services. There is sufficient evidence of the safety of MN and its effectiveness in aiding cessation that moving towards a position in which MN is more widely and easily available and its long-term use in place of smoking is promoted should cause little controversy. It would simply strengthen current policies. However, even with best practice behavioural support, only one in five smokers succeeds in quitting for 6 months or more, so the population impacts of such an approach are limited.
A key issue appears to be that MN in its current formulation fails to give smokers the nicotine 'hit' they seek. Newer MN formulations that give more of a 'hit' might be more effective, but there is no incentive to develop them under the current regulatory structure outlined earlier.

ST products such as snus, with a far lower risk profile than smoking, but a more similar nicotine delivery, might provide a more attractive alternative to smokers. Harm reduction with ST is, however, far more complicated—snus is an addictive tobacco product with established health risks, sold by tobacco companies. The 'Swedish experience' (Box 1) suggests that snus has the potential to substitute for smoking and has served to reduce harm at a population level.\textsuperscript{4,5,10,11} It also suggests that male snus users are more likely to quit smoking than non-users although many go on to then use snus longterm.\textsuperscript{5} Unsurprisingly however, evidence for snus as a quit product is far more limited than for MN\textsuperscript{5} and data from prospective studies on the impacts of snus on smoking habits are limited.\textsuperscript{12} This has led some, including a European expert committee, to conclude that at present there is insufficient evidence to draw conclusions as to the effectiveness of ST as a quit product.\textsuperscript{5,13}

In addition to its effectiveness in smoking cessation, a further issue is whether snus acts as a gateway to or deterrent from taking up smoking. Although there is some evidence, particularly from the USA,\textsuperscript{14} that adolescents using ST may progress to cigarettes, the use of both products may simply be markers for risk-taking behaviours generally, and most Swedish studies suggest there is no gateway effect.\textsuperscript{5,9,11,15} Conversely, ST may offer an alternative to adolescents who would otherwise take up smoking; although the evidence here again remains uncertain.

Other limitations to the evidence also need to be considered. First, it is largely limited to men and other factors in Sweden, including effective tobacco control policies, have clearly also played a role in determining current smoking patterns.\textsuperscript{5,13,16} Second, the Swedish experience may be culturally specific—questions remain over whether experiences in a country where snus has been used for generations are transferable.\textsuperscript{5} Ultimately, population impacts elsewhere would depend on the extent to which snus is taken up by smokers who would otherwise have continued smoking relative to the extent to which snus might be taken up by non-smokers and snus users might go on to use cigarettes. The first is largely unknown, but we are able to exert some control over the last two by carefully regulating the availability and promotion of nicotine products.

Despite these limitations, the evidence suggests that there is potential for benefit. Using the best available data and expert reviews, it was estimated that the introduction of snus was likely to produce a net benefit to population health within Australia and that things would have to go pretty seriously awry for this not to occur.\textsuperscript{17}

Finally, the ethical issues must not be overlooked. Although it may be considered unethical for public health experts to promote or condone the use of a tobacco product, others argue that we have a duty to inform smokers about less hazardous alternatives and give them the right to choose.\textsuperscript{4,18} The case has been clearly made that making alternative products available would offer the best balance of ethical considerations.\textsuperscript{4}

Whatever one takes on this, the reality is that at present the practical likelihood of snus becoming available for use in the UK is extremely low: legalization of snus in the EU, and thus UK, in the near future is most unlikely, despite the tobacco industry’s best efforts.\textsuperscript{19} Thus any harm reduction strategy could not, in the immediate future, encompass ST. Therefore, we would argue that the snus issue is a distraction that is serving largely to split the public health community, much to the tobacco industry’s advantage.

**The practicalities: how might nicotine product regulation be achieved?**

The regulation of all nicotine products could be brought under the control of a single authority tasked to provide a unified, consistent regulatory framework, which regulates in direct proportion to harm, as recently outlined by the Royal College of Physicians.\textsuperscript{20} The aim of such an authority would be to reduce the harm from tobacco by encouraging as many smokers as possible to quit, and to shift those that cannot quit onto less harmful forms of nicotine.

Regulation would ideally cover the product itself, its price, promotion and placement (the latter including access and availability). The primary objective of regulation of smoked tobacco should be to make smoking and smoked tobacco products unappealing, unattractive, unaffordable and inaccessible as quickly as possible.\textsuperscript{20} Achieving this would require a combination of traditional tobacco control measures (tax increases, controlling cigarette smuggling, controls on advertising), as well as less traditional ones (plain packaging) and those that fit more obviously within the harm reduction model (Box 2).

For MN products the objective would be to develop a regulatory system that would make current products as available and attractive to smokers as possible, encourage their use as a cessation aid or as an alternative to smoking in those unable to quit; the ultimate aim being to quit all nicotine use.\textsuperscript{20} A regulatory system could also encourage the development of new MN products that would provide more acceptable alternatives to smoking than current products. Potential functions in this regard are also outlined in Box 2.
Box 2 Potential functions for a nicotine regulatory authority

Reduce the retail availability of smoked tobacco
- License all existing retail tobacco outlets
- Prosecute and revoke the retail licence of anyone who sells tobacco illegally
- Use license fees or levies on sales to discourage existing retailers from selling tobacco and set a high start-up fee to discourage new tobacco outlets, thus progressively reducing the number of licensed retailers
- Prohibit internet purchase of smoked tobacco
- Restrict the number of hours each day in which tobacco products can be sold
- Prohibit tobacco company incentives to retailers to increase promotion or sale
- Prohibit vending machine sales

Inform the public
- Deliver a sustained and varied programme of media campaigns, covering for example, the benefits of quitting smoking, options for quitting smoking, harm reduction strategies, tobacco industry tactics
- Replace the current listing of tar and nicotine contents of smoke on cigarette packs with more accessible and effective communications on the content of harmful substances
- Increase the size of pictorial health warnings on cigarette packs, put warnings on all sides of the pack and continue to improve and vary the warning messages and images
- Use the pack and media campaigns to promote stop smoking services
- Work with retailers to encourage promotion of harm reduction and cessation

Reduce the retail purchase cost and increase availability of and incentives to try MN
- Permanently exempt all MN products from Value Added Tax
- Assess the current pricing structure and profit margins of existing MN products, and if possible act to reduce the cost to the consumer
- Provide incentives to promote price competition in OTC sales
- Encourage innovative design, promotion of single-day packs at competitive prices
- Provide MN free for all smokers using NHS services
- Make all MN products available for OTC general sale in any retail outlet
- Require MN to be displayed prominently for sale wherever tobacco is on sale
- Allow MN to be sold from vending machines
- Replace the current extensive list of contraindications and cautions in MN packs with simple consumer information outlining the potential risks of MN and comparing these with smoking
- Provide better information to the public and health providers on the safety and optimal use of MN

Implement a permissive licensing system for new medicinal products
- Define acceptable limits for dose delivery equivalent to those delivered by tobacco smoking
- Establish fast-track licensing for new MN products that deliver doses up to these limits for marketing as harm reduction products
- Revoke the current requirement to demonstrate efficacy as smoking cessation therapy as a pre-requisite for licensing
- Allow products that deliver MN within the above criteria to support cessation and/or abstinence to be sold OTC
- Monitor use of new products to ensure that harm reduction is being achieved, and act to prevent adverse use or effects

Promote the development of fast acting MN products
- Encourage development of new, more effective MN products
- Require safety data in addition to that already available for MN products only for products using new routes of delivery (e.g. inhalation) or delivering total doses in excess of those provided by smoking, and assess any risks of such products in relation to the risk of smoking
- In the absence of significant safety concerns arising from the above, permit market access as proposed for other MN products
- Require evidence of efficacy in cessation or temporary abstinence for products provided free through the NHS
- Safeguard against irresponsible promotion through market monitoring

Source: Adapted from Ending tobacco smoking in Britain: Radical strategies for prevention and harm reduction in nicotine addiction.

Controversies and issues to address

The role of industry
Without wishing to overlook concerns about the conduct of the pharmaceutical industry, understanding the tobacco industry’s attitude to harm reduction is a more immediate priority if serious pitfalls in policy development are to be avoided. Contrary to suggestions that allowing competition between cigarettes and ST products would benefit public health, there would be no real competition between cigarettes and ST products when both are being manufactured by the same companies. And with the major cigarette companies buying up existing ST manufacturers, there are now relatively few companies that solely manufacture ST. No cigarette manufacturer
would seriously promote a new ST product (which would require considerable marketing spend particularly in markets where ST use is not widespread) to compete with and potentially cannibalize its existing cigarette market share; not least because cigarettes are more profitable and require little marketing. Moreover, companies solely manufacturing ST do not have an interest in marketing only to smokers.

Selling ST does, however, offer other benefits to cigarette companies. First, it provides an addictive form of nicotine for use in venues where smoking is forbidden. This dual use would help smokers maintain their nicotine addiction, continuing to smoke and maintain tobacco industry profits when smoke-free policies are introduced. Is it a coincidence that test launches for new ST products in the USA appear to target cities with smoke-free policies? Second, selling ST products that match their existing cigarette brands enables the industry to promote cigarette smoking in ways that might otherwise be restricted. For these reasons, as it has long done with cigarettes, it appears that the tobacco industry is manipulating its new ST products to suit its own purposes: it is suggested that Philip Morris deliberately marketed low nicotine Marlboro snus in the hope that it would provide a temporary, but not permanent, alternative to cigarettes. Third, engaging in the harm reduction debate is key to the tobacco industry’s reputation management agenda enabling it to restore its tarnished reputation and open doors to regulators that had previously been firmly shut. Finally, harm reduction has been dividing the tobacco control community, something the tobacco industry has long sought to achieve.

It is for these very reasons that we would argue that the public health community needs to be involved in and lead the debates on production regulation and harm reduction. Like it or not, these issues are on the agenda, and our failure to seize the reins would leave the tobacco industry in the driving seat.

### Other concerns

A few other issues warrant consideration, although most could probably be overcome through careful regulation, a step-by-step approach with an initial focus on the existing MN products and regular monitoring. These include the fact that the very characteristics of new MN or ST products that would make them attractive to smokers and successful as part of a harm reducing model, would also make them open to abuse, which would have to be safeguarded against. Other issues include the danger that public health messages about the harmfulness of tobacco products get confused, particularly if industry influence was not adequately controlled, that a resource intensive focus on product regulation and harm reduction could detract from other tobacco control policies and that a focus on new MN products could jeopardize the development of innovative non-nicotine-based quit products. Finally, although careful evaluation and monitoring show that existing MN is safe, new evidence suggests that nicotine may inhibit apoptosis (a form of cell death), stimulate cellular proliferation, angiogenesis, tumour growth and atherosclerosis. While most of this work has been undertaken in animal models and its implications for long-term nicotine use in humans are not yet fully understood, this requires careful monitoring.

### Conclusions

(i) Tobacco use remains the leading cause of preventable disease and death in this country and more needs to be done to reduce its toll.

(ii) It is not the nicotine that smokers seek that kills them, but the other toxins in tobacco smoke. Cigarettes are the most dangerous nicotine delivery device, but nicotine can be delivered in less harmful ways, most notably as MN.

(iii) Nicotine product regulation is needed. Even if nothing else changes and no new nicotine products are introduced, an evidence-based system of nicotine regulation would be a major step forward. It would complement and improve on existing tobacco control policies by improving access to and availability of MN products while reducing the availability of cigarettes.

(iv) Harm reduction, within an appropriate regulatory framework, has the potential, at least in theory, to lead to major public health benefits.

(v) Harm reduction with existing MN products is not controversial or new. It would build on the existing smoking cessation structures and should be formalized now. The ultimate goal should be to reduce both harm and addiction, and to help nicotine users quit all nicotine use. But if smokers cannot quit, they would be far better off using MN products long term than cigarettes.

(vi) Consideration can then be given to facilitating the development and introduction of new MN products that, in order to be more effective, would almost certainly have to be more addictive, and would therefore have to be carefully monitored.

(vii) In the longer term, consideration could be given to the use of snus as part of harm reduction strategy depending on emerging evidence and progress in reducing smoking. It is important to stress, however, that harm reduction does not have to entail the legalization of snus, which is most unlikely in the near
future and should not be contemplated without the introduction of an appropriate regulatory framework. Most importantly, we must not let the snus issue divide the public health community.

(viii) We need to take ownership of this debate and drive it forwards. Failure to do so would let the tobacco industry gain the upper hand and see thousands more unnecessary deaths from tobacco use.

Conflicts of interest

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References
25 Gilmore A, Collin J. World leader or also-ran, paragon or pariah? The future of BAT. 4th European Conference on Tobacco or Health, Basel, 2007.


