Supping with the Devil? The role of law in promoting tobacco harm reduction using low nitrosamine smokeless tobacco products

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S U M M A R Y
In Sweden, male cigarette smoking has declined as snus, a smokeless tobacco product which is low in carcinogenic nitrosamines, has gained popularity among male tobacco users. Epidemiological modelling based on the Swedish experience indicates that there would be major public health gains if a substantial number of current smokers in other countries could also be persuaded to switch to this product. This form of ‘tobacco harm reduction’ is very controversial in the public health community for many reasons. These include: objections in principle to the use of less harmful but still addictive nicotine products; uncertainties about the long-term effects of these products on health; doubts about the likely interest in and uptake of these products among existing smokers; concerns that increasing the availability of these products will increase the number of new tobacco users and eventually the number of smokers in the population; and anxiety about how the tobacco industry may use these products to undermine current tobacco control policies. This paper concludes with suggestions for a graduated series of policies that may allow exploration of the public health costs and benefits of encouraging smokers to switch to snus.

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Introduction

When the harm of cigarette smoking first became apparent in the 1950s, it seemed sensible to both the tobacco industry (TI) and many health professionals in the USA and the UK to design less harmful cigarettes.2,3 However, attempts over half a century to develop a safer cigarette failed.2,3 First, filtered cigarettes, and later, so-called light, low-tar and low-nicotine cigarettes proved very attractive to smokers, but these failed to reduce the hazards of smoking due to compensatory smoking.3 These modified cigarettes were a deceptive ploy by the TI to reassure health conscious smokers that they could keep on smoking while reducing their risks.4 This experience has understandably made many tobacco control advocates sceptical of the value of all attempts at tobacco harm reduction (THR).

The World Health Organization’s Study Group of Tobacco Product Regulation aims to reduce tobacco-related harm through mandated maximum permissible levels of a range of key toxicants in mainstream cigarette smoke.5 However, based on past experience, efforts to modify cigarettes to make them less harmful or to find other ways ofcombusting tobacco are unlikely to reduce tobacco-related harm substantially.3,6 In any case, the time frame required to evaluate the validity of any claims for reduced exposure from combusted tobacco products is so long (given the 40–50 year latency for many cancers)3 that this approach to reducing tobacco-related harm should arguably be abandoned.

A much more promising approach to harm reduction involves adopting non-smoked methods of nicotine delivery. Among the most promising options are pharmaceutical or ‘clean’ nicotine products (PN) and low-nitrosamine smokeless tobacco (LNSLT) products (e.g. Swedish snus). The major disadvantage of PN is that it has not been taken up by smokers as an alternative to smoking despite its wide availability in many developed countries. This seems to be because the PN products that have been approved by the regulatory authorities have been engineered for smoking cessation and with the aim of minimizing their potential for abuse. In addition, they are not marketed in a way that would make them attractive long-term alternatives to tobacco smoking. For these products to gain popularity, the regulation of PN products would need to be liberalized to allow them to be re-engineered in ways that made them more attractive to inveterate smokers. In the shorter term, given the regulatory obstacles to producing more attractive PN products, encouraging a private market in LNSLT looks to be a more promising approach based on Sweden’s experience with snus. There, the increased use of snus among men has been accompanied by a steep decline in both the prevalence of cigarette smoking and the incidence of tobacco-related diseases in men.7,8

THR using LNSLT has been opposed by many in the tobacco control
community for a variety of reasons, and these are outlined and discussed briefly below.

**Should the goal of tobacco policy be the elimination of all tobacco use?**

Some opponents of THR reject the strategy on principle because they reject any tobacco control policy goal other than the elimination of all forms of tobacco use. Some do so on moral grounds, arguing that even if LNSLT use reduced tobacco-related disease, it should be opposed because its use would perpetuate nicotine dependence. Many of these opponents want to pursue zero tobacco use as a policy goal, but without any clear strategy for achieving this. Legal prohibition that bans all tobacco sales has been introduced in Bhutan and proposed in Korea, but its imminent introduction is unlikely in any developed country. If a ban was introduced, the likely consequences could be counterproductive for reasons discussed elsewhere.

Most tobacco control professionals do not support legal prohibition of tobacco, but the Institute of Medicine's recent report described a de-facto prohibition policy as one of the most promising policy options that could reduce the prevalence of tobacco smoking to less than 10% of the population over 20 years. Along with intensifying existing tobacco control strategies, the Committee identified the formation of a wholesale tobacco monopoly and legislation to reduce the nicotine content of all cigarettes over 10 years to a level that would not sustain addiction as promising 'frontiers' of tobacco control.

**Does LNSLT use reduce harm to users?**

Those who do not object to THR in principle may have doubts about the health benefits of LNSLT use for individual users or public health. These critics are often sceptical about the connection between increased snus use in Swedish men and declining tobacco smoking and tobacco-related disease in Sweden. They often cite the experience with light cigarettes which presents strong reasons for opposing cigarette-like nicotine delivery devices to be promoted as THR products. However, these arguments do not apply to PN and LNSLT. The safety of PN is well established in the short to medium term, with users having been followed for up to 5 years. PN may carry some residual health risks, such as an increased risk of cardiovascular disease arising from chronic nicotine intake, but these risks are trivial in comparison with those of continuing to smoke cigarettes.

The health risks of SLT are probably greater than those for PN because they may include an increased risk of oral and pancreatic cancers. The risks are higher for traditional SLT products but probably lower for snus and some new products (e.g. Ariva) that have been treated to reduce levels of carcinogenic nitrosamines. Many of these opponents want to pursue zero tobacco use as a policy goal, but without any clear strategy for achieving this. Legal prohibition that bans all tobacco sales has been introduced in Bhutan and proposed in Korea, but its imminent introduction is unlikely in any developed country. If a ban was introduced, the likely consequences could be counterproductive for reasons discussed elsewhere.

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For the following reasons, these are not compelling objections to THR using PN or LNSLT. First, Kozlowski et al. showed that there would still be a net population health gain from the use of these products, even if one makes the most pessimistic assumptions about their residual health risks and assumes that these products were used by the whole adult population. Second, PN products are less likely to initiate new nicotine users than cigarettes because they deliver nicotine at a much slower rate, produce a steadier blood level of nicotine, and hence are less rewarding than tobacco smoking in nicotine-naive users. Third, the Swedish experience with snus contradicts the pessimistic view about the population impact of THR.

The uptake of snus among Swedish men increased over the past 20 years, with as many Swedish men now using snus as smoke cigarettes. The increase in snus use was accompanied by a greater decline in cigarette smoking than occurred in similar societies that did not allow snus use (from 40% in 1976 to 15% in 2002). Contrary to the gateway hypothesis, there have been no increases in smoking prevalence among adolescent males, who were the heaviest users of snus. Instead, snus use appears to be protective against smoking initiation. It is more common for smokers to switch to snus than for snus users to switch to smoking, and snus is a commonly used cessation aid for Swedish male smokers. Some studies have found similar patterns of SLT use and cigarette smoking among American males, but some sceptics cite other evidence to support the claim that SLT products have been a gateway to smoking in the USA.

Most critically, in Sweden, the increase in snus use was accompanied by a decline in lung cancer mortality and the absence of an increase in either cardiovascular mortality or head and neck cancers. The plausibility of a causal relationship between increased snus use and these good health outcomes from reduced smoking was strengthened by the absence of similar reductions in smoking prevalence or lung cancer mortality in Swedish women, who did not adopt snus at the same rate as men.

Estimates of the effect of LNSLT on aggregate tobacco-related harm from modelling suggest that there is little difference in health-adjusted life expectancy between smokers who quit all tobacco and smokers who switch to LNSLT. Men who switched to LNSLT would lose only 1.2–3.6 months of health-adjusted life expectancy compared with men who quit all tobacco, and women who switched would lose 1.2–4.8 months.

All the evidence on the health benefits of cigarette smokers switching to LNSLT comes from observational studies, which some critics of THR claim is inherently weak evidence. In doing so, they use double standards in the evaluation of evidence. They ignore the fact that the public health case for a causal role of tobacco in many chronic diseases in the late 1950s depended upon exactly the same sort of observational evidence, namely: (1) ecological correlations between a rising smoking prevalence and (after a long latency period) increased mortality and morbidity from lung cancer, heart disease and chronic obstructive pulmonary disease, and later, a decline in smoking prevalence followed by a decline in tobacco-related mortality and morbidity; and (2) cohort studies showing that rates of these diseases increased in a dose–response way with smoking and declined in smokers who quit smoking.

**How transportable is the Swedish experience to other cultures?**

Some critics of THR concede that Sweden’s experience with snus has been positive, but express doubts about the likelihood that it can be reproduced in other cultural settings. Some note, for example, that in the USA, only a minority of tobacco users have used SLT despite its long-term availability and promotion, and there

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is not the same evidence in the USA that SLT use has reduced cigarette smoking. Indeed, they claim, there is some evidence that SLT may have served as a gateway to smoking among US adolescents. If these critics are right, there would be little uptake of LNSLT among existing smokers and hence no public health gain (and very little public health harm) arising from allowing it to be sold. However, some critics want to argue for the worst-case scenario that makes two arguably less plausible claims about the likely population health impact of LNSLT namely that LNSLT will not be attractive to current smokers but it will be adopted by current non-smokers, a substantial proportion of whom will later become cigarette smokers. In any case, there is no evidence of this conjunction of health impacts in Sweden.

Ultimately, the impact that increased LNSLT use has on cigarette smoking and tobacco-related harm is an empirical question. It may well be answered over the next decade by the current marketing of snus in the USA and Canada by cigarette companies in response to increased restrictions on smoking in public places. Empirical tests of the effect of LNSLT on smoking cannot be conducted in Australia, Britain, most of Europe and New Zealand because of legislation enacted in the 1980s and 1990s that banned the manufacture and sale of oral snuff, and chewing tobacco in the case of Australia and New Zealand.

The risks of tobacco industry subversion

Some critics who accept that LNSLT may be a genuine THR product and that Swedish use has reduced tobacco-related harm are nonetheless concerned that the TI will use the promotion of LNSLT to subvert tobacco control policies, and thereby continue to promote cigarette smoking, reduce quitting among existing smokers or both. There are good reasons to fear the subversive use of THR by the TI. The US TI has been convicted of engaging in racketeering behaviour over the past 50 years. This has included misleading smokers, politicians and the public about the addictiveness and health risks of their products, and delaying and subverting policies to reduce smoking and smoking-related disease. The past and present misbehaviour of the US TI is of worldwide concern given the dominant role that US companies play in the global TI, and their increasing promotion of cigarette smoking in developing countries.

The following risks of subversion are foreseen. First, the TI can be expected to attempt to undermine cigarette advertising bans by arguing: (1) that smokers need to be informed about the relative benefits of using snus and other SLT products; and (2) that allowing them to advertise these advantages is the best way to do so. Second, the US TI is now marketing snus and other SLT products under the same brands as smoked tobacco. This is clearly intended to promote continued smoking in the face of smoking bans, and the recruitment of new smokers. Industry data suggest that these products have very low nicotine delivery, and hence some have argued that they may be deliberately designed to be unsatisfying to smokers to prevent them from switching completely to SLT.

Third, the TI is promoting the use of SLT in ways that they hope will reduce quitting by promoting the dual use of SLT and smoked tobacco to minimize the impact of smoking bans on current smokers. This is now happening in the USA where SLT products can still be marketed and advertised provided that no health claims are made about them. It remains to be seen whether the TI will succeed in its aim of perpetuating smoking: they could inadvertently promote increased switching to SLT use among current smokers rather than dual use if smoking bans and the denormalization of smoking intensifies.

Fourth, the cigarette manufacturers will, of course, use their promotion of LNSLT to ‘rebrand’ themselves as ‘socially responsible’ corporations. They will do so by giving the appearance of taking action to reduce harm to their consumers, while continuing to profit from selling cigarettes and expanding markets for smoked tobacco products in developing countries where consumers are less well informed about the risks of their products.

Supping with the Devil

To many in the tobacco control community, the major objection to promoting LNSLT is the necessity to either work in some way that advantages the TI (e.g. by undertaking research that the industry will use to advance its interests) or by promoting their albeit less harmful newer products. In their often long experience, the TI has proven itself to be untrustworthy. Accordingly, they believe that anyone who is interested in protecting or promoting public health should have nothing to do with the TI.

There are understandable reasons for this view, as anyone who reads Alan Brandt’s depressing chronicle of the ‘cigarette century’ can attest. The last 50 years is an unhappy saga that reveals the ingenuity of industry lawyers in finding ways to delay, subvert and undermine public health regulations that aim to reduce tobacco smoking. The major success of public health advocates and plaintiff lawyers has been achieved by undermining any credibility that the TI has, making them argue about the social pariahs of the contemporary business world.

The TI now concedes the dangers of its products, and claims that it wants to work with public health authorities to reduce smoking and tobacco-related harm, but is hampered in doing so by the refusal of public health advocates to talk to the industry. The TI complains: ‘We have knowledge, we have scientific expertise, and we want to share our knowledge and expertise to reach a better understanding of how products can be made less harmful.’ Even involving third parties to broker such conversations have failed, as shown by recent attempts to establish a dialogue between the TI and public health professionals. The very few within the tobacco control community who have spoken at TI conferences have been met with opposition from their peers, and been the frequent subject of allegations of having sold out or going over to the ‘dark side’. Many funding bodies in the UK and the USA will not fund researchers or universities that receive TI funding.

Are these sensible policies? Would it be better to attempt to specify some terms for ethical public engagement with the TI? More radically, should we begin to think about the conditions under which ‘an ethical TI’ might operate?

Ethical terms of engagement with the tobacco industry

A frank admission by the multinational TI of its past malfeasance would seem a precondition for ethical engagement. However, the dominant role of lawyers in devising TI strategy, and of plaintiff lawyers among the TI’s opponents in the USA, mean that this is unlikely to happen. The fear of incurring legal liability for damages provides a major disincentive for honesty about past misbehaviour. Some have suggested that this could be accomplished via some form of a truth and reconciliation process, like that in post-Apartheid South Africa.

The industry these days acknowledges that their products are addictive and dangerous to smokers’ health, but many tobacco control advocates understandably doubt the sincerity of these admissions. A more sincere expression of regret for past malfeasance and of concern for the public’s health would be the decision not to market smoked forms of tobacco on the grounds that they are an unacceptably hazardous consumer product. It is unlikely that any individual tobacco company would unilaterally relinquish the right to sell one of the most profitable products on the planet while
any of their major competitors continued to do so. So, how could we get from where we are, with large profitable multinational companies selling tobacco cigarettes, to a smaller and much less profitable tobacco industry that only sold low-risk LNSLT products or PN in socially responsible ways?

We could legislate to force tobacco companies to do so. We could, for example, legislate to segregate the markets for smoked and LNSLT products, e.g. by prohibiting the use of cigarette brand names on LNSLT products, the promotion of dual use and any tobacco advertising. Or we could require tobacco companies that wanted to market LNSLT products to commit to phasing out smoked tobacco manufacture and sale over a period of 10–15 years. This would provide an incentive for the TI to disengage from the production and sale of smoked tobacco; something that does not exist in the current regulatory situation.

By combining current tobacco control polices with lower taxes for LNSLT, we could gradually introduce de-facto prohibition on smoked tobacco products, as suggested by the Institute of Medicine. We could also legislate to cap the total amount of smoked tobacco that could be produced and marketed in any year, and then progressively reduce this amount to zero over a 10-year period, allowing companies to trade unused quotas during that time. The latter would be a form of performance-based regulation (see Sugarmann paper in this issue). More coercively, we could, as have some advocated, progressively reduce the nicotine content of smoked cigarettes to zero. Or we could impose increasingly high rates of taxation on the nicotine content of smoked cigarettes. Any of these strategies would need to be combined with a continuation of current tobacco control policies to make the use of LNSLT more attractive to current tobacco users than smoked tobacco.

De-facto prohibition on smoked tobacco would probably generate more illicit tobacco production and smuggling. An illicit tobacco market much like the existing cannabis market may well attract more illicit tobacco manufacture and sale over a period of 10–15 years. This would provide an incentive for the TI to disengage from the production and sale of smoked tobacco; something that does not exist in the current regulatory situation.

A graduated policy sequence

The following steps could be undertaken to explore the public health potential of THR using LNSLT in those countries in which their production and sale is prohibited, such as Australia, New Zealand, Europe and the UK. First, the utility of LNSLT for smoking cessation as a second line after smokers had failed at nicotine-replacement therapy (NRT) could be cautiously trialled. Smokers who failed to quit using NRT could be encouraged to switch to LNSLT rather than return to smoking. This type of research would provide information regarding how attractive these products may be to invertebrate smokers. Second, the regulation of PN products could be liberalized to allow the delivery of nicotine doses in ways more like SLT, and smokers who failed to quit smoking could be encouraged to switch to the use of these products. Third, if there was sufficient interest in switching to LNSLT among invertebrate smokers, restricted sale of LNSLT products to these smokers could be allowed. Legislation could be introduced to authorize differential taxes to reflect the harm that LNST products cause compared with cigarettes. This would need to be accompanied by research that rigorously evaluated the impacts of their sale on population smoking cessation rates, tobacco use among youth, and TI marketing of these products.

Conclusion

LNSLT and clean PN represent the most promising ways of substantially reducing the harm from nicotine use among existing smokers who are unable or unwilling to quit all tobacco or nicotine use. The Swedish experience with snus among men has been positive, and its results are worth attempting to replicate elsewhere.

Some who object to this approach to THR insist upon the unrealistic goal of a tobacco-free society. Some express scepticism about the evidence for the benefits of THR, which is reminiscent of the approach taken by the TI in setting impossibly high standards of evidence for proof, whilst others argue that it will not work outside the cultural setting of Sweden. The current attempts by the TI in the USA and Canada to test market snus products may provide an important empirical test of this claim, but only if regulators ensure that US snus products provide sufficient nicotine delivery to compete with cigarettes.

There are good historical reasons for being very cautious about the use that the TI will make of LNSLT and other purported THR products. However, the authors do not share the pessimistic view that these risks cannot be addressed by creative legislation and regulation. Indeed, the existence of lower risk LNSLT products may provide a powerful reason for increased regulation of all tobacco products. Currently, the TI in Australia and other countries that ban SLT is free to develop and market new tobacco products, including reduced exposure combustible tobacco products, as long as they are smoked.

The establishment of a nicotine regulatory authority which would control the marketing and use of all nicotine products, including cigarettes, LNSLT and PN, is an important policy goal. It will permit the development of policies that provide regulatory and tax incentives for the industry to sell and tobacco consumers to use the lowest risk LNSLT and PN products. A failure of the public health community to find ethical ways of regulating and engaging with THR leaves the TI free to pursue its profits from smoked tobacco with a continuing minimum of regulation, while recalcitrant smokers are unjustly denied access to ways of reducing the health consequences of their tobacco use.

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