INFORMATION SHEET ABOUT MEETING/CONTACTS WITH THE TOBACCO INDUSTRY	
Date of the meeting:	2013-04-09
Time and duration of the meeting:	10:00, 30 minutes
Place of the meeting:	European parliament, 06E264
Participants in the meeting :	• *Ulf Pettersson, (the writer of this) assistant to Amelia Andersdotter, (a very cool MEP)* • *Johan Gabrielsson, Swedish Match, tobacco company (and thus considered evil)* • *Karin Riis-Jørgensen, Kreab Gavin Anderson, pr-firm (she used to be a MEP and is treated like a Very Important Person)*
Short minutes of the meeting:	• Bringing lobbyists to the office, entering, sitting down. • UP: Sorry for Amelia not being able to attend, would you like some coffee? etc • JG: This is why we believe that the sale of snus should be permitted in the EU. Snus has resulted in Sweden having the lowest cigarette consumption in the EU. We would like to see a harm reduction policy. According to health research, snus is not bad for your health, etc. Please see these documents. • UP: Ok. What about your monopoly position in this market and these other critical points? • JG: Well we have 70 % of the market but have several competitors, etc. • KRJ: Looks at UP as if saying: "I'm too important to be talking only to an assistant, we set up the meeting with the MEP and here I have to sit and talk to this nobody assistant" (to be clear: she didn't actually say this). Does not say much. • UP: And what about the Dalli affair? • JG: I was part of this myself. We met Dallis people in a restaurant. When I heard Dallis request of a bribe I was astonished, they asked my company to give them 60 million euro. We did not know really who to turn to. We reported the bribe attempt first to the Swedish government, then to the Commission, etc. Tells whole story. • UP: Ok, thank you for that detailed story. Bye. • On the way out we meet Amelia who is just arriving.
Documents/material received before/during or after the meeting	*6 scientific papers and documents on the health effects of snus (see below)* *……*

SPECIAL COMMUNICATION

European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health

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Tobacco Control 2003;**12**:360–367

Rationale: This statement is an updated version of one released by the same authors in February 2003. The statement was produced to follow up the Royal College of Physicians (RCP) Tobacco Advisory Group report ''Protecting smokers, saving lives: the case for a tobacco and nicotine regulatory authority'',[1] which argued for an evidence based regulatory approach to smokeless tobacco and harm reduction and posed a series of questions that regulators must address in relation to smokeless tobacco.

The purpose of this statement is to provide arguments of fact and principle to follow the RCP's report and to outline the public health case for changing existing European Union (EU) regulation in this area. A review of regulation in relation to harm reduction and regulation of tobacco products other than cigarettes is required in Article 11 of EU directive 2001/37/EC,[2] and this is a contribution towards forming a consensus in the European public health community about what policy the EU should adopt in the light of this review, or following ongoing legal action that may potentially strike out the existing regulation altogether.

Public health case: We believe that the partial ban applied to *some* forms of smokeless tobacco in the EU should be replaced by regulation of the toxicity of *all* smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a ''gateway'' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco related disease in Europe. We think it is wrong to deny other Europeans this option for risk reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco—the alternative being to ''quit or die''… and many die. While nicotine replacement therapies (NRT) may have a role in harm reduction, tobacco based harm reduction options may reach more smokers and in a different, market based, way. Chewing tobacco is not banned or regulated in the EU but is often highly toxic, and our proposal could remove more products from the market than it permitted.

Regulatory options: We believe that the EU policy on smokeless tobacco should adapt to new scientific knowledge and that the European Commission should bring forward proposals to amend or replace Article 8 of directive 2001/37/EC with a new regulatory framework. Canada has developed testing regimens for tobacco constituents and these could be readily adapted to the European situation. A review of EU policy in this area is required no later than December 2004, and we believe the Commission should expedite the part of its review that deals with harm reduction and regulation of tobacco products other than cigarettes so as to reconsider its policy on smokeless tobacco. We held this view before Swedish Match brought its legal proceedings to challenge EU legislation and we will continue to hold these views if its action fails.

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PUBLIC HEALTH ARGUMENTS

Purpose of tobacco control

The ultimate purpose of tobacco control campaigning and organisations should be clearly stated: in our view it is to reduce the burden of disease and death, mostly from cancer, cardiovascular disease (CVD), and lung disease, arising from tobacco use. The aim is not *in itself* to campaign against tobacco. Because of the dominance of the cigarette market, in most situations those two strategies coincide. However, there may be some situations where they conflict—where this is the case, we give priority to reducing disease. Such a case arises where two conditions are met:

- where the use of a tobacco product is substantially less hazardous than cigarettes
- where that tobacco product may substitute for cigarette use or facilitate increased smoking cessation at individual and population level.

This is the situation with oral tobacco products, such as ''snus'', a form of oral tobacco widely used in Sweden and to a lesser extent in some other North European countries. New products are also emerging on the US market, which may also be targeted in this way. For this reason, there is a strategic question about how the tobacco control community should respond to such products. This is brought into a sharper focus in the EU because of legal challenges to EU regulation in this area, and a commitment to review policy by the end of 2004.

Abbreviations: COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; ECJ, European Court of Justice; EU, European Union; NRT, nicotine replacement therapy; PP, precautionary principle: RCP, Royal College of Physicians

Position of addicted smokers

It is also important that we are realistic about the situation of many tobacco users. Tobacco delivered nicotine is powerfully addictive and many users cannot or will not give up. Though addiction is a type of disease in its own right, the aspiration to tackle both the addiction and the physical harm by complete tobacco cessation may only work for a subset of users. The attempt to tackle both addiction and harm may end in tackling neither. For some—for example, those with certain mental health conditions—there may be therapeutic benefits derived from nicotine or tobacco. For others, it is poverty and the ubiquity of tobacco in their communities that create a powerful barrier to individual cessation. We also know that the strength of addiction (as measured by nicotine intake) can increase with poverty. There are over 1.2 billion tobacco users world wide—increasing at about 80 000 per day. In the EU there are almost 100 million smokers, and smoking kills 550 000 EU citizens per year. We believe it is essential that every option be considered for reducing this toll. That includes harm reduction and product regulation strategies based on reducing the damage done to people that continue to use tobacco or nicotine for whatever reason.

Harm caused by smokeless tobacco

Smokeless tobacco is *not* harmless. For example, smokeless tobacco products used on the Indian subcontinent and some products in the USA cause oral cancer. In India, smokeless tobacco is a major cause of oral cancer. But the evidence shows that any link between smokeless tobacco in the form of Swedish snus and oral cancer is not established.[3 4] The largest review, Nilson (1998),[5] concluded that although:

> ''…20% of all grown-up Swedish males use moist snuff, it has not been possible to detect any significant increase in the incidence of cancer of the oral cavity or pharynx—the prevalence of which by international standards remains low in this country.''

There are other health effects that arise in the oral cavity—such as lesions and gingivitis—and a cancer risk from products other than Swedish snus must be anticipated. Smokeless tobacco may also be associated with CVD, though the evidence is contradictory and far from clear. Asplund, in a review of the evidence, indicated that smokeless tobacco was associated with a much lower risk of adverse cardiovascular effects than smoking[6] and in a literature review commissioned by ASH,[7] he concluded:

> ''Smoking increases the risk of myocardial infarction, sudden death, stroke and peripheral artery disease of the legs by 2–4 times. Whether or not snuff use is associated with an increased risk of myocardial infarction and sudden death is still controversial. If there is an excess risk, it is very much smaller than for smoking. For stroke or peripheral artery disease, there is no scientific information on possible risks of snuff use.''

A subsequent study has found that snuff use is not associated with any apparent excess risk of stroke.[8] However, for oral tobacco to play a role in harm reduction it is not necessary to show that it does not cause cancer—it just needs to be substantially less hazardous than smoking. Even allowing for cautious assumptions about the health impact, snus—and other oral tobaccos—are *a very substantially less dangerous way to use tobacco than cigarettes*. Smokeless tobaccos are not associated with major lung diseases, including chronic obstructive pulmonary disease (COPD) and lung cancer, which account for more than half of smoking related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco, and we believe the public health community has a moral obligation to explore this strategy. It is likewise ethically wrong to actively *deny* users the option to reduce their risk in this way.

Addictiveness and nicotine delivery

Smokeless tobacco use is an effective delivery system for nicotine and is therefore addictive. Addictiveness is in itself a bad characteristic compared to not using the product at all. However, it is the nicotine delivery characteristics of smokeless tobacco that make it both addictive *and* a viable alternative to cigarette use for many users—it is capable of delivering a satisfactory nicotine dose. Smokeless tobacco use does not match the arterial nicotine ''bolus'' (sharp spike) delivered by smoking, but still creates a peak venous blood-nicotine level that exceeds all NRT products (including the nasal spray) and is similar to smoking. The fact that it more closely matches the nicotine delivery profile of smoking may be one reason why users find it more effective that NRT as an alternative to smoking.

Risks to users

The risk to the user arising from use of a smokeless tobacco product varies by product and is to some extent uncertain—notably in the area of heart disease (though *at worst* the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base described above and elsewhere[9] suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or some American smokeless tobaccos are at least 90% less hazardous than cigarette smoking*. In a spectrum of risk, snus is *much* closer to NRT than it is to cigarette smoking. Further, the actual risk can be controlled through regulation—for example, by setting maximum thresholds for specific carcinogens or other toxins such as heavy metals. These data were not readily available at the time the ban was originally implemented in the early 1990s and therefore justify consideration of a change of approach in response to new knowledge.

Risks associated with *banning* smokeless tobacco

It might be argued that removing a ban on a product with known dangers, however low, can only increase risks. This is not the case because bans on smokeless tobacco also carry risks. It is quite possible that a ban on smokeless tobacco would mean more tobacco users use cigarettes because the opportunities to switch to or start on smokeless tobacco are denied. To the extent that the ban promotes cigarette use, it carries risks. There is no evidence to show that the status quo in EU policy represents an optimum public health outcome or that the policy does not increase tobacco related harm.

Evidence from Sweden

Evidence from Sweden suggests snus plays a positive public health role as a substitute for smoking and as an aid to smoking cessation. It is impossible to be definitive about this, because it is impossible to run a controlled trial on a whole nation. However, consider the following:

- Sweden has the lowest levels of tobacco related mortality in the developed world by some distance—approximately *half* the tobacco related mortality of the rest of the EU.[10]

- Sweden has the lowest male smoking prevalence in Europe (15% daily) and low female (around 20%) prevalence (adults 18–70 years old in 2002).
- However, it has comparable male *tobacco* prevalence and total consumption to neighbours Norway and Denmark—suggesting the big difference is in the *type* of tobacco used, rather than overall propensity to use tobacco or consume nicotine.
- About half of tobacco in Sweden is now consumed as snus—this share has steadily grown since the 1970s.
- A study of current and former smokers 25–55 years old found that 33% of ex-smokers report use of snus—almost twice the number that report use of a pharmaceutical treatment (17%).[11] A large nationwide representative study found that among males who have used a single aid to stop daily smoking, and succeeded in doing so, some 70% had used snus and some 30% had used some kind of NRT.[12]
- There are far more ex-smokers among snus users, than ex-snus users among smokers—a substantial population study has been conducted by Ramstrom with funding from the National Institute of Public Health in Sweden; the data has been presented at conferences and is in the public domain, though not yet published.[12] A published study by Rodu also showed similar results.[13]
- It is possible—though difficult to test—that snus use has contributed to ''denormalisation'' of smoking and to the unacceptability of ETS. This may be a factor in low rates of smoking among women (who do not use snus very much) and acceptability of smoke-free places.

Reasons for low rates of tobacco mortality in Sweden

An important explanation for the low rates of tobacco related mortality in Sweden is the contribution made by the high use of smokeless tobacco. It is difficult to conclude anything other than a positive public health role for snus in Sweden, though there remains doubt over the magnitude of the effect. There are no other convincing explanations for low smoking prevalence in Sweden, combined with relative high tobacco use. The population data from Sweden are much clearer now than when the ban was introduced and again justify a reconsideration of policy at the European level.

Human and consumer rights

There is an emerging literature on the ''human rights'' dimension to this problem, stressing the right of smokers to good information and the choice of risk reduction strategies.[14 15] Through the ban, the EU is actively preventing smokers having access to a product *at least* 90% less dangerous than cigarettes, but that is clearly an effective substitute for at least some people (and for many people in Sweden). It is important to consider where the EU draws its moral (and legal) authority to make such ''life-or-death'' choices on behalf of its citizens—especially as, on the basis of Swedish evidence, it appears to be making the wrong choices.

How would smokeless tobacco be used outside Sweden?

There is legitimate doubt about whether snus or similar products would be used in the same way in other member states as in Sweden, or to the same extent. However, that is unknowable in advance and the ban explicitly rules it out. By banning we know how it will be used—either not at all, or on a black market. We cannot really know what would happen until it is available, marketed, and a suitable regulatory regime and tax structure in place—these are all variables that would affect its use. What we do know is that it has the potential to be used to reduce harm. If it looked as though there was an emerging overall negative impact (unlikely in our view) policy drivers such as taxation and modifications of the product standards could be used to trim demand. Even if a small number—relative to Sweden—used it, there may still be a considerable public health gain. An important area for further research is how consumers might respond to the introduction of new tobacco products that are positioned as less hazardous than cigarettes.

Gateway effects

There is concern that smokeless tobacco will function as a lead-in to smoking for people who would not otherwise smoke. Such ''gateway effects'' are always contentious, and they are hard to demonstrate for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco—they may have simply moved straight to smoking. Gateways can act in the opposite direction too—they can be ''exits'' rather than ''entrances''. Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the USA and Sweden, most smokeless tobacco use *cannot* be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes they may or may not have had their smoking caused by smokeless use.

Exit or entrance gateway

Understanding the order in which tobacco users take up different products is an important and necessary factor in establishing a gateway effect and whether the gateway is an exit from or entrance to smoking, but it is not in itself sufficient to establish a gateway from smokeless to cigarettes. The basic problem is that it is difficult to know whether those that start with smokeless tobacco would otherwise have started on cigarettes in the absence of smokeless tobacco. The data from Sweden suggest that the gateway is more likely to be an ''exit'' from smoking rather than an ''entrance''. Among Swedish males with a primary use of snus no more than 20% ever started smoking, while 45% of other males did become smokers.[12] In addition to this compelling evidence from the pattern of transitions, Sweden has the lowest rate of male smoking in Europe, combined with high levels of snus use. There is no other credible explanation for such low male smoking prevalence than the displacement and cessation of smoking through smokeless tobacco use. In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit. There have been studies in the USA that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users.[16] However, these studies or related commentary have generally drawn causal inferences based on observation of transitions between often poorly defined categories of tobacco use, and sometimes from groups that are unrepresentative of the general population, such as the military. Psychosocial predictors of smoking initiation (school performance, parental smoking, risk taking, etc) can be used to assess which smokeless tobacco users might otherwise have been smokers. When these confounding factors are taken into account, the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker.[17 18]

Unintended population effects

There are numerous other potential population effects under discussion: will there be reduced cessation, increased relapse,

wider use, etc? Though some of these ideas are plausible, all such theories are at present contentious and with minimal or no supporting evidence. To take one example: does smokeless undermine the propensity to quit smoking by helping smokers survive the discomfort of smokefree policies? For snus to be shown to be dissipating the pressure to quit caused by smokefree policies (and therefore have a negative impact on public health) we would need to assess the following contributory factors:

- How much combined daily snus and smoking use is there? (Only 2% among men in Sweden compared to 19% with snus as their only daily tobacco use).[12] If the combined use is not daily, it is unlikely to be used in overcoming smokefree restrictions.
- How much does smokefree contribute to smoking cessation? There is clearly an effect. One estimate suggests that completely smokefree workplaces in the UK would reduce consumption by 8%. This is one of the most important tobacco control measures, but it is still only one factor of many (price, health, media campaigns, etc) in causing smokers to quit.
- How much would availability of smokeless tobacco reduce (or increase) likelihood of quitting due to smokefree places? (Note: the magnitude *and* sign of this effect is unknown). Some assume that it is withdrawal that drives smoking cessation arising from smokefree areas and therefore smokeless tobacco would remove the pressure to quit created by repeated temporary withdrawal. However, it could easily be ''denormalisation'' of smoke due to reduced smoke. In which case smokeless might contribute to cessation.
- Is it right to deny people products so that they are forced to feel discomfort in smokefree areas because this makes them more likely to quit? This ethical point is important.

Role of surveillance

In general we believe there is too little surveillance of the tobacco market and its impacts on health in Europe. In a comprehensive surveillance regime, any adverse trends that developed in the use of smokeless tobacco or other tobacco products could be detected and addressed with new regulation—such as taxation, marketing restrictions, labelling, or product standards. Note that it is impossible to be absolutely certain about the outcome of a change in policy on smokeless tobacco, just as it is impossible to be certain that *not* changing policy is the best course. However, a surveillance regimen would create some safeguards.

Should the ''precautionary principle'' apply?

Some have argued that because there is not complete knowledge of how smokeless tobacco would be used or all its health effects, we should invoke the precautionary principle (PP) and keep it banned until there is a complete evidence base. Though this sounds reasonable at first take, it is actually a misuse of the PP. The PP is designed for use where there is some concern that a human activity is causing damage (usually to the environment) and scientific uncertainty about whether it is happening or the magnitude of the effect might otherwise be used as a reason not to act to mitigate or control the activity. The PP usually challenges those defending the status quo with uncertainties about the impact of change. The situation with smokeless tobacco is completely different to those situations where the precautionary principle is typically invoked. It may be that the status quo in tobacco use, the dominance of cigarettes, is causing the most harm and that the ban on oral tobacco is *increasing* the harm—that would almost certainly be the case if the experience of Sweden was generalised to Europe as a whole. So one can easily see the ban as problematic and invoke the precautionary principle on the basis of what is known about Sweden as a reason to act to remove the ban.

Why not use NRT?

It is sometimes claimed that anything that can be done with smokeless tobacco in harm reduction terms could equally be done with NRT—and with virtually no risk. This view misunderstands two crucial differences between NRT and smokeless tobacco. The first is the nicotine delivery profile—smokeless tobacco far more closely matches cigarettes[19] and therefore can more easily be an acceptable substitute for addicted users. The NRT nasal spray comes close but this is difficult to use and not popular. There may be other tobacco related sensory effects that are important and not present in NRT. The success of any harm reduction strategy would depend on the numbers of people that made a switch—and that in turn would depend on the consumer acceptability of the product. The second difference is the position of smokeless tobacco in a market place: smokeless tobacco would be occupying a different cultural space. Switching to smokeless tobacco is not a ''medical intervention'', rather it is what concerned smokers may do as a way of changing their tobacco use.

Characterising the two sides of the debate

Many health advocates are uncomfortable with the concept that a certain class of tobacco products could play a role in a health strategy and fear that such strategies may be divisive. They characterise the debate as ''pro-snus'' versus ''anti-snus''. However, there is a substantial body of informed and independent opinion that sees the value of harm reduction strategies based on smokeless tobacco. For them the debate is not ''pro-snus versus anti-snus'', rather they would frame it as ''a smoker's right to options for harm reduction'' versus ''health professional's authoritarian insistence that the only valid choice for smokers is to quit or die as an addicted cigarette user''—or to shorten this: ''harm reduction'' versus ''quit or die''. In practice there is a spectrum of views about the evidence and how to act in the face of uncertainties.

Pro- or anti-tobacco industry

Both sides claim they are taking an anti-tobacco industry stance. The ''quit or die'' grouping simply asserts that smokeless tobacco is made by the tobacco industry. The ''harm reduction'' side recognises that the tobacco industry is heterogeneous and developing all the time. They believe that smokeless tobacco is a viable competitor to the hegemony of the cigarette makers, that it will disrupt the market and usher in new forms of regulations that the biggest tobacco companies will be hard pressed to satisfy with their conventional cigarette designs. The ''harm reduction'' grouping sees the ''quit or die'' grouping as unwitting and naïve allies of Big Tobacco—Philip Morris and British American Tobacco—cigarette companies that do not make smokeless tobacco.

Fear of repeating the ''lights'' mistake

The most promising approach to harm reduction in the last century was identified as reducing tar yields. This policy was based on machine tests of tar yield which were misleading as they ignored the nicotine compensating behaviour of smokers. Industry documents reveal how this was exploited, as the industry knew that although machine tested yields were reduced, smokers would alter their smoking patterns to maintain nicotine levels and hence also the extent of toxin exposure.[20] Yet the industry marketed the products in ways that implied harm reduction and many smokers believed the

cigarettes were less harmful than regular cigarettes.[21 22] On this occasion there was no reduction in harm and smokers were misled by the industry which provided false reassurance. Some tobacco control advocates are afraid of repeating this mistake with smokeless tobacco, but the situation here is different. With smokeless tobaccos like snus, there is a substantial reduction in harm compared with smoking cigarettes, since nicotine exposure is no higher and there is no exposure at all to the combustion products in tobacco smoke—that is, the smoke constituents known to be the most harmful ones. Yet it is the public health community which is in danger of misleading consumers by pretending there is no difference in risk or banning the product. For example, the following quotes were made in June 2003 by the US Surgeon General before a Congressional Committee:[23]

> ''No matter what you may hear today or read in press reports later, I cannot conclude that the use of any tobacco product is a safer alternative to smoking'', and
>
> ''There is no significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes''.

REGULATION OF SMOKELESS TOBACCO IN EUROPE AND THE LEGAL CHALLENGE

Regulation of smokeless tobacco in the EU

Smokeless tobacco in the EU is now regulated under directive 2001/37/EC[2]. This retains provisions originally introduced in directive 92/41/EEC. Under its treaty of accession, Sweden is exempted from this ban and this exemption is reflected in the directive as below. The 2001 directive states:

Article 2.4. ''tobacco for oral use'' means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product.

Article 8. Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to [the exemption granted for Sweden].

Legal challenges

This position is now facing two legal challenges—from a German tobacco distributor backed by Swedish Match, and by Swedish Match directly through a judicial review of the UK government's implementation of these directives that will be referred to the European Court of Justice. The case made by Swedish Match argues the EU's actions are unlawful, unreasonable, unfair, unjustified, disproportionate, and arbitrary, as follows:

- Inadequate legal base because the ban is a public health measure with no single market justification.
- Total prohibition is disproportionate to achieving single market or public health aims. It draws on the case of the advertising directive[24] in which a complete ban was imposed as a single market measure. The successful defence of 2001/37/EC[25] was in part because this regulated but does not prohibit trade.
- The ban is arbitrary and discriminatory as it does not include chewing tobacco.
- No reasons have been given for the ban and this breaches a general duty in breach of Article 253[26] of the treaty.
- The ban violates the company's property rights under the European Convention on Human Rights and European Charter of Fundamental Rights of the EU.
- The ban violates the EU treaty provisions on free movement of goods[27]
- The EU has not considered new scientific evidence.

Has Swedish Match got a case?

We believe the regulation of smokeless tobacco products in the EU *is* arbitrary and disproportionate, and impossible to justify as a single market measure or a health measure. The current regulation is absurd, as it applies a complete ban to oral tobacco products that are sucked, but no ban or even regulation to oral tobacco products that are chewed. Only meaningless regulation is applied to smoked tobacco as long as they are cigarettes, and no regulation to cigars or hand-rolling tobacco. It is impossible to justify the logic applying polar extremes of regulation to different products depending on what the user does with it once it is placed in the mouth (no regulation if you chew, complete ban if you suck). It is arbitrary and disproportionate because it does not prohibit cigarettes, which are substantially more toxic (*at least* 10 times more toxic) than snus.

Burden of proof regarding health claims

Although we make a case based on public health *benefits* above, showing a positive public health impact beyond reasonable doubt would not be the issue in the European Court of Justice (ECJ). The burden of proof would be on the EU to show that there was a case for a ban by showing an additional health impact. The directive 2001/37/EC also acknowledges a lower risk for smokeless tobacco products by requiring weaker warnings than for cigarettes (Article 5.4 of 2001/37/EC), in those situations where smokeless tobacco is permitted in the EU, and a weaker warning than was required in the previous directive.

What would happen instead of a ban?

We believe that the ban should be replaced by regulation. This is an opportunity to shape the smokeless tobacco market and ensure that if such products are used, they are placed on the market with a high level of protection for human health and the consumer, and to ensure that the worst products are either removed from the market or do not come in. Regulation should apply to all smokeless tobacco, including chewing tobaccos that are currently allowed on the market unregulated. It could also apply to the tobacco intended for smoking. The highly toxic chewing tobaccos available in India are actually permitted in the EU at present, whereas much less dangerous products like snus are banned. A rational regulatory approach would reverse this situation, and effectively ban the most toxic smokeless tobacco products.

What regulatory standards could be used?

A regulatory approach could involve setting maximum standards for a range of target toxins implicated in the main tobacco related diseases. The Canadian government has introduced legislation implementing a measuring and disclosure regimen for all tobacco products,[28] including smokeless, and this requires extensive testing of tobacco product constituents. The methodologies available for measuring tobacco constituents are listed in the appendix. Note that these measurements are also required for smoking tobacco as well as smokeless tobacco. Such standards could be adapted for Europe by the European Committee for Standardisation (CEN—*Comité Européen de Normalisation)* and used in EU regulation.

Other standards issues

Other approaches to a standard might relate the proportion of toxins to the quantity of active drug nicotine and might also

regulate additives. Some of the contaminants also change with age of the product—and shelf life restrictions might be also imposed. It would require products to be tested to an agreed methodology. In addition, it would be necessary for health claims to be subject to some sort of official scrutiny and backed by evidence—or for EU approved information to be specified for packaging. Such standards could also be applied to smoking tobacco—cigarettes, cigars, pipe and hand-rolling tobacco—on the basis that there is no reason to allow tobacco to be placed on the market that is more toxic simply because the intention is to burn and multiply the toxicity considerably.

Example of a standard

Voluntary, market based, toxicity standards do exist. For example, table 1 shows the Gothiatek standard (used by Swedish Match).[29]

Impact of regulation

The Gothiatek standard is quite exacting, and would rule out most products on the market—it might be possible to taper its introduction to allow time for adjustment of growing, manufacturing, and curing processes. If this standard were applied to all smokeless tobacco products, it could take more tobacco products off the market in the EU than it allows on. Some of these products may have high levels of TSNA, but are not regulated or tested at all—simply (and absurdly) because they are intended to be chewed. If applied to smoking tobacco too, it could cause disruption for the cigarette industry, and begin reducing toxins in *all* tobacco.

Problems of regulation

The main problems with regulation would be the burdens of testing and verification. However, these should fall on manufacturers—as is the case with cigarettes. For small manufacturers—for example, firms exporting from the Indian subcontinent—the application of *any* standards would be a barrier to trade, but one that could be justified on health grounds. There is a problem with an absence of ISO standards for measuring toxic constituents for smokeless tobacco, though the measuring techniques are simple and readily available. However, measuring standards do exist for the main toxic constituents in tobacco and are in use in Canada—see appendix.

European Commission review of policy will happen anyway

The European Commission is required to revisit policy on smokeless tobacco in its review of the effectiveness of 2001/37/EC under article 11 of that directive. The Commission is required to review the directive ''*in the light of developments in scientific and technical knowledge*'' with special heed to several important regulatory issues which include:

> – tobacco products which may have the potential to reduce harm
>
> – development of standards concerning products other than cigarettes…

Furthermore, the European Commission should take proper scientific advice so that it can produce evidence based proposals:

> …the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available

The review should also include legislative proposals as necessary.

> That report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco products…

Table 1 The Gothiatek standard

Toxin	Limit
Nitrite	3.5 mg/kg
TSNA	5 mg/kg
NDMA	5 μg/kg
BaP	10 μg/kg
Cadmium	0.5 mg/kg
Lead	1.0 mg/kg
Arsenic	0.25 mg/kg
Nickel	2.25 mg/kg
Chromium	1.5 mg/kg

mg/kg is equivalent to parts per million (ppm); μg/kg is equivalent to parts per billion (ppb). Limits based on 50% water content—double the limits for dry weight equivalents.

Is the EU's current position based on scientific advice?

To our knowledge, the EU did not revisit the scientific advice for Article 8 in the 2001 directive—though much new data had become available. The Commission relied on advice from its Cancer Experts Committee to underpin much of the 2001 directive, but this committee did not give a view on smokeless tobacco.[30] This is important because the ECJ does not usually see its role as judging scientific advice, but if there is no scientific argument backing the ban then it will prove less of an obstacle to Swedish Match in the ECJ. Part of its case is that the EU provided no reasons for its ban and the recitals to the 2001 directive simply refer to the existing practice. In support of its case, it is quite possible that Swedish Match could call witnesses from the tobacco control community.

Next steps—begin the review

It would make sense to expedite the review under Article 11 as it applies to smokeless tobacco and convene the necessary experts to give advice. The Commission can either conclude that the policy is sound, in which case it will have built its evidence base for defending the action in the ECJ, if it proceeds to a full hearing. It could also decide that its policy needs to change, in which case it could introduce a legislative proposal. That may avoid a potentially wasteful legal process and is more likely to create a policy that works for public health. An adverse ECJ ruling may also establish principles that constrain the Commission and limit its options for regulation of smokeless tobacco. The Commission (and member states) will have to do the work to defend the case in the ECJ anyway, and we believe that longer term policy on smokeless tobacco will be formed during this period rather than in whatever formal consultation process is established for the review under Article 11—probably in 2004.

Public health community

We hope that this paper will stimulate debate and thinking within the public health community and that over time we can come to a consensus on the way ahead. We urge a thorough examination of the evidence and arguments, and a determined focus on reducing disease. This is both a scientific

What this paper adds

Smokeless tobacco is not harmless. However, some products, in particular the Swedish smokeless tobacco, snus, are considerably less harmful than others. Current EU regulation bans snus, but permits the marketing of chewing tobacco. The highly toxic varieties which exist in India are thereby allowed on the European market.

Toxicological and epidemiological data indicate that snus and some US smokeless tobacco products are at least 90% less hazardous than cigarette smoking. The limited actual risks can be further controlled through the setting of regulatory standards for specific carcinogens and other toxins. Data also indicate that in Sweden the high use of snus has contributed to a low prevalence of cigarette smoking in men, and so has made an important contribution to the low rates of Swedish tobacco related mortality. We argue that the ban on some of the least harmful forms of smokeless tobacco throughout the EU should be replaced by a regulatory framework applying to all smokeless tobacco products and focusing on eliminating those that are most harmful.

and ethical issue and where there is uncertainty we are obliged to use judgement informed by evidence. Though there is an understandable reluctance to see any kind of ban reversed, it is important that we give primacy to the health of smokers, many in difficult circumstances and heavily addicted to nicotine, and this may involve us in some uncomfortable choices. All the authors of this statement approach the subject with an open mind and are receptive to any arguments and evidence—we hope others will take a similar approach.

CONCLUSION

Benefits of proposed approach

We support the replacement of the ban on oral tobacco with an approach that regulates the toxicity of all smokeless (and smoking) tobacco products. Our approach has the following advantages:

- It would create a legally defensible, fair and rational policy—in which public health is given primacy consistent within the framework of EU law.
- It could create public health benefits through smoking cessation and smoking substitution.
- It gives smokers an extra strategy for controlling their risk and eliminating environmental tobacco smoke risk, and thereby respects their consumer and human rights.
- It would apply toxicity controls to the currently unregulated chewing products such as gutkha and paan available in the EU and currently unregulated.
- It could have benefits beyond Europe if a good regulatory model is developed for controlling toxicity of smokeless tobacco—for example, by establishing regulatory norms in the World Health Organization Framework Convention on Tobacco Control.
- It opens the dominant cigarette makers to competition from tobacco products that do far less harm.

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APPENDIX: CANADIAN STANDARDS FOR TESTING TOBACCO CONSTITUENTS

SCHEDULE 1

(Section 1 and subsection 12(3))

Official methods for the collection of data on constituents

Item	Constituent	Official method
1	(a) Nicotine; (b) nornicotine; (c) anabasine; (d) myosmine; (e) anatabine	Official method T-301, *Determination of alkaloids in whole tobacco*
2	Ammonia	Official method T-302, *Determination of ammonia in whole tobacco*
3	(a) Glycerol; (b) propylene glycol; (c) triethylene glycol	Official method T-304, *Determination of humectants in whole tobacco*
4.	(a) Nickel; (b) lead; (c) cadmium; (d) chromium; (e) arsenic; (f) selenium; (g) mercury	Official method T-306, *Determination of Ni, Pb, Cd, Cr, As, Se and Hg in whole tobacco*
5.	Benzo[a]pyrene	Official method T-307, *Determination of benzo[a]pyrene in whole tobacco*
6	Nitrate	Official method T-308, *Determination of nitrate from whole tobacco*
7	(a) N-nitrosonornicotine; (b) 4-(N-nitrosomethylamino)-l-(3-pyridyl)-1-butanone; (c) N-nitrosoanatabine; (d) N-nitrosoanabasine	Official method T-309, *Determination of nitrosamines in whole tobacco*
8	Triacetin	Official method T-311, *Determination of triacetin in whole tobacco*
9	Sodium propionate	Official method T-312, *Determination of sodium propionate in whole tobacco*
10	Sorbic acid	Official method T-313, *Determination of sorbic acid in whole tobacco*
11	Eugenol [2-methoxy-4-(2-propenyl)-phenol]	Official method T-314, *Determination of eugenol in whole tobacco*

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The lighter side

Bernie Ecclestone offers the condemned man his last cigarette. ©Garneau, Le Devoir, Montreal, 9 August 2003

BRIEF REPORT

Levels of toxins in oral tobacco products in the UK

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Objective: This study examined the constituents of smokeless tobacco products available in the UK and compared them with products available in India, Sweden, and the USA

Methods: Seven UK brands of smokeless tobacco, including a tooth cleaning powder, and four international brands of smokeless tobacco were tested for a range of toxins and known carcinogens, such as tobacco specific N-nitrosamines (TSNA), as well as nicotine availability.

Results: Ten of the 11 brands tested had detectable levels of tobacco specific nitrosamines, which are proven carcinogens, and levels varied 130-fold. All had detectable levels of benzo(a)pyrene, another proven carcinogen (with around 175-fold variation) and several toxic metals (with nearly 150-fold variation). Nicotine availability varied in the UK products from 0.1 mg/g to 63.2 mg/g. All the tobacco products tested are likely to be hazardous to users' health, but the data indicate that it should be possible to reduce key toxins to non-detectable levels.

Conclusions: Smokeless tobacco products should be regulated and standards set for maximum levels of toxins and carcinogens.

Cigarettes are by far the dominant form of tobacco used in the UK, with small numbers of people also smoking tobacco in other forms such as cigars and pipes. Smokeless tobacco products are much less common in the UK than in countries like India where they represent over a third of all tobacco consumed.[1] Nevertheless, one main form of smokeless tobacco, chewing tobacco (a form of smokeless tobacco consisting of loose leaf tobacco in pouches of tobacco leaves, ''plug'' or ''twist'' form), is used in the UK, particularly among people of South Asian origin. Of the 2.4 million South Asians in the UK, estimates of smokeless tobacco usage vary from 27–98% depending on the community and sex.[2] The other main form of smokeless tobacco, oral snuff, is banned throughout the European Union[3] except in Sweden because of the traditional and widespread use there among men of snus (a form of moist oral snuff in which a pinch of tobacco or a teabag-like sachet of tobacco is placed between the lip and gum).

The chewing tobacco forms used in the UK are similar to those commonly used in Southern Asia and often involve other substances, and include:

- Gutkha—a sweet chewing tobacco containing betel leaf, catechu, and saffron.
- Zarda—a moist or dry chewing tobacco mixed with a variety of colourings, spice essences, and perfumes.
- Dried whole and chopped tobacco leaves—often purchased in shops to be used in oral preparations (the leaf can be ground to prepare a type of zarda).
- Tooth cleaning powders—originating from Southeast Asia and comprising abrasive powdered tobacco with aromatic ingredients added to make the breath sweet.

Some of these products, such as zarda and dried leaves, are used in conjunction with paan (or betel quid which is a combination of betel leaf, areca nut, and lime paste) and are individually made to one's own taste, so the ingredients vary and commercialisation of the products is limited.

Smokeless tobacco products deliver nicotine and are dependence forming. In South Asia the use of chewing tobacco causes considerable health risks; in particular, it is a major cause of oral cancer and is also harmful in pregnancy.[4] A recent study[1] demonstrated substantial amounts of tobacco specific nitrosamines (TSNAs) in smokeless tobacco products marketed in India. TSNAs are the most common carcinogens in unburnt tobacco which are formed during the aging, curing, and fermentation of tobacco.[5] Given similar types of tobacco are allowed on the market in Europe, concerns have been expressed that they may also pose health risks. This study therefore examined chewing tobacco products purchased from outlets in the UK and compared their toxin content and nicotine availability with snus and three other forms of smokeless tobacco purchased in India and the USA.

METHODS

Twenty five consumers and 25 shopkeepers (aged 16 or above) were selected opportunistically from South Asian communities from two locations in the UK, chosen because of their high prevalence of people from South Asian communities, and administered a short questionnaire requesting information concerning popular smokeless tobacco products used by these communities. The responses of the two populations were compared in order to identify 17 most popular brands, a method used in other studies.[6] Samples of these were then purchased randomly from different shops and locations and analysed by the Laboratory of the Government Chemist for a variety of toxins. The results of this pilot test were used to identify a smaller subsample of seven products, including some having the highest levels of some of the toxins: two gutkha products (Manikchard and Tulsi mix), three zarda products (Hakim Pury, Dulal Misti, and Baba Zard Gulabi Patti), one tooth cleaning powder (A Quardir Gull) and a tobacco leaf. These products were then tested alongside four international products: the most popular zarda product in India (Baba 120), snus (general pouch) from Sweden, and two smokeless tobacco products available in the USA (US Copenhagen snuff original fine cut, the leading snuff brand for a few decades, and Ariva, a more recent addition to the US market, a tablet of tobacco placed in the mouth and allowed to dissolve slowly). Zarda products in India were recently shown to have

Abbreviations: BaP, benz(a) pyrene; NAB, N-nitrosoanabasine; NAT, N-nitrosoanatabine; NDMA, N-nitrosodimethylamine; NNK, 4(methylnitrosamino)-1-(3-pyridyl)–butanone; NNN, N-nitrosonornicotine; TSNA, tobacco specific nitrosamine

relatively high TSNA levels.[1] In contrast, the manufacturers of snus and Ariva claim that these products have very low levels of certain toxins and carcinogens.[7 8] Levels of TSNA have recently been found to be very low in snus[9] with some evidence that users of this product have minimal levels of carcinogen uptake.[10]

The products were purchased using a consistent methodology. Five samples of each product were chosen randomly from shop displays from each of three shops chosen randomly from the East London area, Mumbai in India, Stockholm in Sweden, and New Jersey in the USA. The products were received over a period of four months and stored in a freezer before being tested when the 15 samples were mixed thoroughly to yield representative samples of each product.[11]

The products were tested for 4 TSNAs (N-nitrosonornicotine (NNN), N-nitrosoanatabine (NAT), N-nitrosoanabasine (NAB), and 4(methylnitrosamino)-1-(3-pyridyl) – butanone, (NNK)), N-nitrosodimethylamine (NDMA), a marker for volatile nitrosamines and a carcinogen, toxic metal content, nitrites (which react with nicotine or other alkaloids contained in tobacco to form TSNAs), and benz(a) pyrene (BaP), another established carcinogen. Total TSNA content was calculated by adding NNK, NNN and NAB. Moisture content, nicotine content, and pH (a measure of alkalinity thought to influence buccal absorption of nicotine through affecting the proportion of nicotine in freebase form) were measured and the latter two measures used to calculate the proportion of freebase nicotine (unprotonated nicotine, absorbed much more quickly through the mucous membrane than protonated nicotine[12 13]). Methodologies used were based on Centers for Disease Control, Health Canada, International Standards Organisation (ISO) Standards or in house techniques based on the most up to date literature.

RESULTS

Table 1 shows the characteristics of the products measured in this study. Dry weight measurements are given as the moisture levels of the samples varied considerably (from 1.7–48%).

TSNA levels ranged from non-detectable (in Ariva) to 5.12 µg/g n the tooth cleaning powder and to 29.7 µg/g in Hakim Pury. Four other samples had significant levels of total TSNAs (>1 µg/g). For benz(a)pyrene (BaP), all the products had detectable levels, ranging from 0.11 ng/g in the tobacco leaf to 19.33 ng/g in the Copenhagen samples. Among the UK purchased products Dalal Misti Zarda had the highest level with 8.89 ng/g content of BaP. All products had non-detectable levels of NDMA except the tooth cleaning powder, and non-detectable levels of nitrite except for Copenhagen. All products had detectable levels of the four toxic metals tested in this study. Although the two UK gutkha products had the lowest toxic metal content, in all cases except for lead (where the highest level was in the Indian purchased brand) the highest toxic metal contents were found in other UK purchased products. The tooth cleaning powder generally showed the highest levels. Nickel was the most predominant metal found.

Nicotine content ranged from 3 mg/g in one gutkha product to 83.5 mg/g in the tobacco leaf. The pH ranged from 4.9 to 9.9 for these samples, the tooth powder and the two gutkha products being the most alkaline. Freebase nicotine was highest in the tooth cleaning powder at 63.2 mg/g nicotine; it was high also in the two gutkha products (at 3 and 8 mg/g nicotine in Manikchard and Tulsi mix, respectively), and in the products originating from Sweden (6.3 mg/g) and the USA (2.4 mg/g for Ariva and 4.9 mg/g for Copenhagen), with the remaining products less than 1 mg/g.

DISCUSSION

To our knowledge this is the first study to examine the toxin content of chewing tobacco products used in the UK. All of the products had detectable levels of at least some of the carcinogens examined, and are therefore likely to be hazardous to users' health. Some UK products (in particular one zarda product and the tooth cleaning powder) are of great concern as they have high levels of some established carcinogens and are clearly putting the health of users at risk. These products also had the highest toxin levels in the pilot test. It is not clear why the levels of toxins varied and further research is needed to establish the contribution played by selection, curing, and manufacturing processes,[14] and shelf life.[15] It cannot be assumed that products with low levels of the toxins measured in this study are safe as only a small number of toxins were measured.

The high levels of carcinogens appear unnecessary as levels of the same toxins in other smokeless tobacco products (some of which are banned in the UK) are considerably lower. In addition, while all the products release nicotine, two UK products had the highest proportions of freebase nicotine suggesting that they may also be the most addictive.

As the UK products have established usage within Asian communities in the UK and are very much part of their culture, we are not suggesting that these products be banned. Instead, toxin standards should be set for all the smokeless tobacco products available on the UK market, with a reasonable timescale for compliance. The toxin standards set by parts of the industry—for example, the Gothiatek Standard by Swedish Match[7]—could be used as a starting point, but it should be possible over a short time frame to reduce the key toxins and carcinogens to the lowest levels which are technically feasible which in most cases would be non-detectable levels (shown in this study and other research to be technically feasible[9]). Standards for other similar products could also be used as a starting point—for example, the tooth cleaning powder should be subject to the same regulations as other toothpastes or removed from the market. It is also clear that standards would need to apply for imported products and such a regulatory framework may therefore need to be agreed internationally so that the proposed standards are implemented and monitored in countries where these products are manufactured. Where the products are not commercially produced (for example, the tobacco leaf) it will be more difficult to set stringent standards for toxins. A starting point may be to set a higher level, with random testing carried out by local trading officers to check that the leaves sold comply with the regulations. Further research into the demand for tobacco leaves is necessary before deciding how to apply stronger regulations to the product or take them off the market.

When reducing carcinogens, however, the products must be monitored to ensure that the reduction of, for example, TSNAs is not accompanied by unwanted side effects in the form of increased levels of other toxins. No communication about these reductions should be made to the consumer because although they are likely to make the products less harmful, they will not make the products safe.

Over time, consideration could be given to setting standards for a broader range of specifications such as pH and free nicotine. However, further research is needed because the consequences of such a strategy are unknown and may lead to greater use of the products to satisfy a consumer's addiction.

The introduction of toxin standards will raise the need to consider lifting the ban on oral snuff in the UK for compliant products.[16] If the ban is lifted, tight regulatory controls would be needed on the marketing of such products to prevent an increase in demand for them. The dangers of smokeless

Table 1 Content of smokeless tobacco products tested in this study*

Brand	Moisture % w/w	TSNA† µg/g	BaP ng/g	NDMA ng/g	Nitrite µg/g	Chromium mg/kg	Nickel mg/kg	Arsenic mg/kg	Lead mg/kg	Nicotine mg/g	Average pH	Free nicotine mg/g
UK purchased products												
Gutkha products												
Manikchard	1.68	0.289	0.40	ND	ND	0.26	1.22	0.04	0.15	3.1	9.19	3.0
Tulsi mix	1.25	1.436	1.28	ND	ND	0.33	1.43	0.06	0.19	8.2	9.52	8.0
Zarda products												
Hakim Pury	4.91	29.705	0.32	ND	ND	2.15	5.35	0.29	1.36	42.7	6.00	0.4
Dalal Misti Zarda	8.96	1.574	8.89	ND	ND	0.87	2.09	0.11	1.14	8.6	6.15	0.1
Baba Zarda (GP)	7.88	0.716	2.04	ND	ND	2.34	5.88	0.24	1.18	48.4	5.32	0.1
Tooth cleaning powder												
A. Quardir Gull	3.35	5.117	5.98	7	ND	3.56	5.31	0.46	1.39	64.0	9.94	63.2
Dried tobacco leaves												
Tobacco leaf	5.16	0.223	0.11	ND	ND	2.34	4.37	0.20	1.06	83.5	5.52	0.3
Products purchased outside UK												
Baba 120 (India)	13.18	2.361	2.83	ND	ND	2.08	2.94	0.40	1.56	55.0	4.88	0.04
Snus (Sweden)	45.84	0.478	1.99	ND	ND	1.54	2.59	0.30	0.50	15.2	7.86	6.3
Ariva (USA)	2.40	ND	0.40	ND	ND	1.40	2.19	0.12	0.28	9.2	7.57	2.4
Copenhagen (USA)	48.10	3.509	19.33	ND	6.7	1.69	2.64	0.23	0.45	25.8	7.39	4.9
Detection limits		0.025 for each		5	0.2							

*All figures are averages of two measurements except for pH which gives the average of three measurements. On average measurements agreed by less than 10%.
†Total TSNA = total tobacco specific N-nitrosamines = NNK+NNN+NAB.
BaP, benz(α)pyrene; NDMA, N-nitrosodimethylamine.

What this paper adds

It is already known that types of smokeless tobacco commonly used in Southern Asia contain high levels of toxins and carcinogens and cause considerable health risks. Similar tobacco products are used in the UK, particularly among people of South Asian origin, but no research has been carried out on their content.

This work demonstrates that smokeless tobacco products available in the UK vary greatly in concentrations of nicotine, toxic metals, and carcinogens, often containing higher levels than products which are not allowed on the market. We recommend that these products are regulated and standards set for maximum levels of toxins and carcinogens, which could be internationally applied.

tobacco use would need to be communicated widely to all consumers in the UK and users should be actively encouraged to give up.[17] However, smokeless tobacco users should also be informed about the much greater health risks of cigarette smoking to prevent them switching to this more dangerous form of nicotine delivery.

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Snus—what should the public-health response be?

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Cigarettes account for 96% of global sales of manufactured tobacco by value, and global cigarette production continues to increase dramatically (eg, from 1686 billion cigarettes in 1950 to 5604 billion in 2002).[1] Snus, a form of smokeless tobacco that has lower levels of many toxins than most other smokeless tobaccos, has become the dominant form of tobacco used by Swedish men, who now have an unusually low smoking rate.[2] In most developed countries about a fifth of annual deaths are caused by smoking, and about 20 times as many people have a serious smoking-caused illness each year, most of these being chronic respiratory diseases.[3] It is in this context that the potential public-health impact of the availability of a smokeless tobacco product that has been estimated as 90% less harmful than cigarettes[4] should be carefully considered.

Two articles in today's *Lancet* examine the effects of Swedish snus on health. One reports on cancer risks in Sweden[5] and the other estimates the health effects if snus were to be launched in Australia.[6] Juhua Luo and colleagues[5] report on the risk for three different types of cancer in a cohort of almost 280 000 Swedish male construction workers followed up for 20 years. As in previous studies,[2] they found that snus use did not increase risks of oral cancer whereas smoking more than doubled the risk (relative to never-tobacco users). Similarly, snus users had a slightly lower rate of lung cancer than never-tobacco users whereas smokers' risks of lung cancer were over tenfold greater. The novel finding in this study was that snus users had about twice the risk of pancreatic cancer compared with never-tobacco users, but again risks were highest for smokers (figure).

Snus is not harmless. It can cause gingival recession[7] and adverse outcomes in pregnancy,[8] and there is conflicting evidence on cardiovascular risks.[9] However, for all the major smoking-caused diseases, including this new finding for pancreatic cancer, the risks are lower with snus than with smoking. Importantly, for two of the most prevalent smoking-caused diseases (lung cancer and chronic obstructive pulmonary disease), snus poses no risk. It is particularly noteworthy that in Luo and colleagues' analyses of the whole male cohort, men who had ever used snus were significantly less likely to develop lung or oral cancer and non-significantly less likely to develop pancreatic cancer, compared with men who had never used snus (presumably because snus use reduced smoking[10,11]). Most snus users who developed pancreatic cancer in Luo's study had used snus before the 1980s. Since that time the levels of carcinogens in snus have reduced.[12]

Snus is currently banned in the European Union (apart from in Sweden) and in Australia. Coral Gartner and colleagues used the best available data and expert reviews to estimate the likely health impact of snus in Australia.[6] They conclude that snus is likely to produce a net benefit to population health, with the size of the benefit dependent on how many inveterate smokers switch to snus. This finding challenges the wisdom of bans on snus where cigarettes are widely used, and also encourages public-health professionals to disclose accurate health information on the relative risks of snus compared with cigarettes.[13] We are not suggesting that clinicians should advise their smoking patients to switch to snus, when safe and effective medications are available to treat cigarette dependence. Nor do we agree with Gartner and colleagues' suggestion that health departments should promote snus. On the contrary,

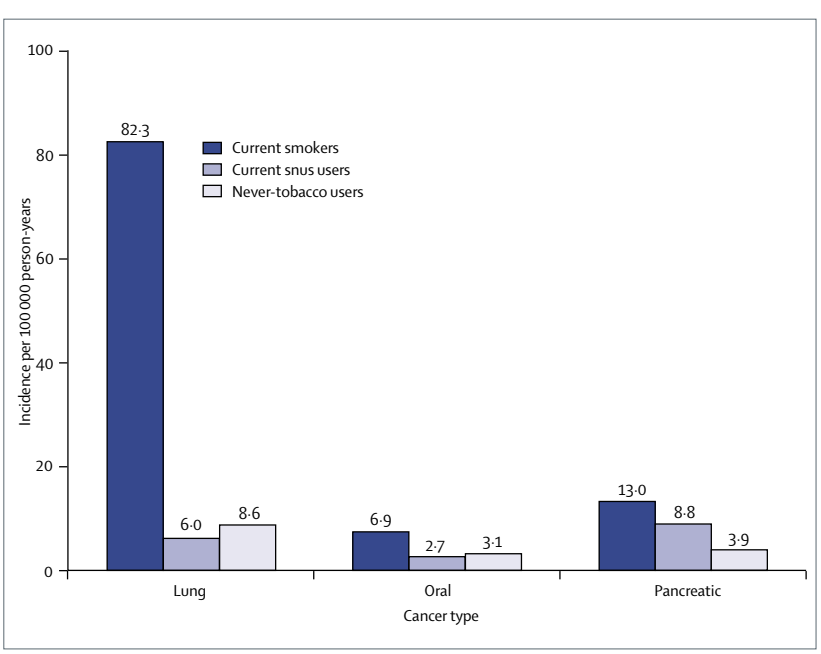

Figure: **Age-adjusted incidence rates for three cancers (by 2004) as function of tobacco-use status in male Swedish construction workers at recruitment (1978–92)**
Redrawn from data in tables 2 and 3.[5]

Lung cancer mortality: Comparing Sweden with other countries in the European Union

Brad Rodu and Philip Cole

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Commentary

Harm reduction policies for tobacco users

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ABSTRACT

Tobacco harm reduction is a controversial policy due to the experience with filtered and 'light' cigarettes and concerns that the tobacco industry will use reduced harm products to undermine tobacco control strategies. The most promising harm reduction products are high dose pharmaceutical nicotine preparations and low nitrosamine smokeless tobacco, such as Swedish snus. However, despite widespread availability, existing pharmaceutical nicotine preparations have not been taken up by smokers as an alternative to smoking. In Sweden, increased snus use was associated with decreased cigarette smoking and mortality from tobacco-related disease. We suggest a graduated series of policies to explore of the public health costs and benefits of encouraging smokers to switch to these less harmful nicotine products.

Tobacco harm reduction is a controversial policy because of history: a miscarried attempt at developing "safer" cigarettes in the 1950s was dishonestly used by the tobacco industry to deter smokers from quitting. When the harms of cigarette smoking first became apparent in the 1950s it seemed sensible to design less harmful cigarettes (Brandt, 2007; Parascandola, 2005). The first such "reduced harm" product was the filtered cigarette, followed by "light", "low tar" or "low nicotine" cigarettes, all of which proved attractive to smokers and were supported by the National Cancer Institute and the US Public Health Service (Parascandola, 2005). Tobacco industry documents reveal that the industry knew these "safer" cigarettes did not benefit smokers because of compensatory smoking (e.g. drawing harder on the cigarette, covering the filter holes, smoking more cigarettes) (Pollay & Dewhirst, 2002). The industry nonetheless aggressively used these products to reassure smokers that they could continue smoking whilst reducing their risks. This experience is routinely invoked by opponents of any form of tobacco harm reduction, a less appropriate argument in the case of more defensible forms of tobacco harm reduction such as using low nitrosamine smokeless tobacco and pharmaceutical nicotine (PN) products that are not smoked.

In Sweden, a form of moist oral snuff, known as snus, has lower levels of nitrosamines than snuffs from other parts of the world due to its method of manufacture. This traditional tobacco product resurged in popularity in the 1970s and 80s amongst Swedish men, assisted by marketing campaigns and a lower taxation rate compared to cigarettes. Patterns of use in Sweden suggest that snus has been used as a cessation aid by existing male smokers and as an alternative to smoking by younger males (Gartner & Hall, 2009).

Increased snus use was associated with decreased cigarette smoking and mortality from tobacco-related disease (Foulds, Ramström, Burke, & Fagerström, 2003). Because it is not smoked, snus does not carry any of the risks associated with smoked tobacco (e.g. exposure to carbon monoxide, fine particulates, etc.). Epidemiological studies suggest that snus use poses a low risk of oral or lung cancer, but may increase the risk of pancreatic cancer compared to no tobacco use (Broadstock, 2007). Epidemiological modelling suggests that the health gains from switching to low nitrosamine smokeless tobacco (LNSLT) are nearly as large as those from quitting all tobacco use (Gartner et al., 2007).

Another approach to tobacco harm reduction involves using pharmaceutical or "clean" nicotine products (PN). Its major disadvantage 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 minimising their abuse potential. They are also not marketed in a way that would make them attractive long-term alternatives to tobacco smoking. For these products to gain popularity, we would need to liberalise the regulation of PN products to allow them to be reengineered to increase their attractiveness to inveterate smokers.

Concerns about tobacco harm reduction: Many health professionals are reasonably concerned that the tobacco industry will use LNSLT to discourage smokers from quitting. Indeed, as public smoking bans have expanded throughout the United States, cigarette manufacturers have marketed these products, using cigarette brand names (e.g. Camel snus, Lucky Strike snus, Marlboro snus), as something to use when smoking is not permitted. This has raised

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Tobacco, nicotine and harm reduction

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Abstract

Issues. *Tobacco smoking, sustained by nicotine dependence, is a chronic relapsing disorder, which in many cases results in lifelong cigarette use and consequent death of one out of two lifelong smokers from a disease caused by their smoking. Most toxicity due to cigarette smoking is related to the burning process.* ***Approach.*** *Models of harm reduction applied to tobacco suggest that use of non-combustible, less toxic, nicotine-containing products as a substitute for cigarette smoking would reduce the death toll arising from tobacco use. Available options include medicinal nicotine and smokeless tobacco products.* ***Key Findings.*** *The potential role of nicotine replacement therapy (NRT) products in a harm reduction strategy is currently severely restricted by strict regulations on dose, safety and potential addictiveness. As a result, NRT products are designed to provide much less nicotine, and deliver it to the brain more slowly, than cigarettes, which are widely accessible and poorly regulated. Smokeless tobacco (snus) has proved to be an acceptable reduced hazard alternative to smoking in Sweden, but supply of snus is illegal elsewhere in the European Union.* ***Implications.*** *To increase accessibility and reach more smokers, barriers to the use of NRT use need to be removed and more effective NRTs need urgently to be developed. Smokeless tobacco could also play an important role in harm reduction, but current European Union regulations and concerns over exploitation by tobacco companies currently preclude wider use.* ***Conclusion.*** *To improve public health there is an urgent need for an appropriate regulatory framework and regulatory authority at the European level, controlling both tobacco and nicotine products to ensure that the least harmful products are the most accessible.* [Le Houezec J, McNeill A, Britton J. Tobacco, nicotine and harm reduction. *Drug Alcohol Rev* 2011;30:119–123]

Key words: tobacco, nicotine dependence, harm reduction, smokeless, drug regulation.

Tobacco smoking is a chronic relapsing mental disorder

Tobacco smoking, sustained by nicotine dependence, is classified as a chronic relapsing mental disorder [1,2] that for most users entails a struggle to achieve long-term abstinence. Current smoking cessation best practice involves the delivery of behavioural support in conjunction with pharmacotherapy [3,4]. The overall efficacy of these interventions is relatively low however, with at best approximately 20% of smokers typically achieving cessation at 1 year. The proportion of smokers using cessation services is also very low. For example, in Great Britain, where national networks of cessation services available to all smokers have been established, it is estimated that approximately 9% of current smokers had been referred or had self-referred to such a service in 2007 [5]. In practice, most smokers try to quit by themselves, without support, which is the least effective method (rate of success of 1–3%) [6]. It is therefore important to find methods of improving the efficacy and the acceptability and uptake of cessation support. However, given the difficulties in quitting and the harm caused by continued smoking, it is also important that efforts are made to reduce the harmfulness of those who cannot, or do not want to, stop.

Most of the harm is caused by smoking, not nicotine

Tobacco smoking is the largest single preventable cause of many chronic diseases, including cancers, pulmonary and cardiovascular diseases, and currently causes around 730 000 deaths in the European Union (EU) each year (including 80 000 from passive smoking) [7]. In Europe, as in many parts of the world, tobacco use is

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dominated by cigarette smoking. Cigarettes are the most deadly smoked tobacco product, because most toxicity is related to the burning process, and the health hazards of cigarette smoking are well known [8]. Smoke is harmful (the combustion of any plant produces toxic substances, such as carcinogens, carbon monoxide or oxidant gases), and smoking is the most addictive route of administration for a drug (e.g. crack vs. cocaine) because it delivers high doses of the drug very quickly to the brain [9,10].

Nicotine is considered to be the major substance responsible for tobacco dependence. Nicotine is not completely harmless, but it is not responsible for most of the diseases due to tobacco use. Unfortunately, over the years, nicotine has been associated with tobacco-related diseases in many media campaigns against smoking. Because of this, there are strong barriers to the use of nicotine for treatment of tobacco dependence, coming not only from tobacco users, but also from the medical community [11,12].

Models of harm reduction applied to tobacco suggest that the use of non-combustible, less toxic, nicotine-containing products would be better than cigarette smoking in limiting the death toll. Nicotine replacement therapy (NRT) is generally regarded as safe other than when used in pregnancy where the evidence is limited [10]. Although there is little evidence on long-term use of NRT, it is thought to be unlikely that there would be major long-term adverse effects on health, and certainly not in relation to the hazards of smoking. Smokeless tobacco products (STPs) are not a homogeneous category and the risk profile varies according to the products [10]. Evidence of the key risks to health from STPs is summarised in the next section.

Health risks of STPs

Respiratory diseases, predominantly lung cancer, chronic obstructive pulmonary disease and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU [7]. There is no evidence that STPs cause any of these major respiratory diseases. If smoked tobacco were completely replaced by STPs therefore, nearly half of all deaths caused by smoking might be prevented. In addition, as STPs do not produce smoke, they will not cause any of the health problems linked to passive smoke exposure in adults or children.

Other risks of STPs vary between the different products available [13]. Both animal experiments and epidemiological studies indicate that oral tobacco use has short-term effects on blood pressure and heart rate. Whether long-term use increases the risk of hypertension is uncertain. Although three large cohort studies have reported a statistically significant effect of STP on myocardial infarction, the evidence on snus and myocardial infarction is more mixed with only one out of six studies in long-term Swedish snus users finding an increased risk of snus over never tobacco users [10]. STPs vary widely in terms of content in carcinogenic compounds [13]. Some products also contain other substances (e.g. areca nut) that may also be carcinogenic, which makes difficult to disentangle these effects from those of tobacco itself [14]. The use of STPs, including snus, appears to be associated with an increased risk of pancreatic cancer, although to a lesser extent than the use of smoked tobacco. It also appears that the risk of oral cancer associated with the use of STPs with low levels of nitrosamines, such as snus, is small or non-existent [14].

Overall however, and with the exception of use in pregnancy, use of STPs and particularly snus are clearly substantially less hazardous than cigarette smoking [13]. This conclusion is also reached by the only systematic review of the evidence from studies that allow direct comparison of relative risks of smoking and smokeless in the same populations [15]. The magnitude of the overall reduction in hazard is difficult to estimate, but is at least 50% for cardiovascular disease, at least 30% for pancreatic cancer, at least 50% and probably more for oral and other gastrointestinal cancer, and possibly 100% for lung cancer and chronic obstructive pulmonary disease [13]. A recent study using a modified Delphi approach (judgement by a panel of experts) to estimate the relative hazard of snus concluded that the product was likely to be approximately 90% less harmful than smoking [16].

Harm reduction in tobacco use

To date, tobacco control policy has mostly focused on two principles: (i) that young people should not start smoking and (ii) that current smokers should quit. Harm reduction approaches have largely been focused on reducing the harmfulness of exposure to second-hand smoke. However, many smokers cannot or do not want to give up, and little effort has been put into reducing the harmfulness of their continued tobacco use. Tobacco harm reduction is the lessening of the net damage to health associated with the use of tobacco products. Smoking usually starts in adolescence and determination to quit probably peaks in middle age, typically at 35–50 years of age. This can result in a successful quit attempt where harm can be reduced to that of a never-smoker depending on the age at which cessation occurs [8]. Continued cigarette smoking will cause the maximum harm, so a reduction in harm will result from any action that decreases the risk from continuing smoking. The sooner the action starts and the less hazardous the product is, the greater the harm reduction [17].

The tobacco industry has developed potentially reduced exposure products, which deliver smoke containing lower levels of nitrosamines or other toxins. However, none of these products has been shown appreciably to reduce the health hazard of tobacco use, and it is perhaps unlikely that any product that involves inhalation of products of combustion will ever present as low a hazard as smokeless tobacco or medicinal nicotine alternatives. There is, however, a much broader spectrum of risk associated with these alternative nicotine products, in which smoked tobacco represents one extreme, and medicinal nicotine (NRT) the other [18]. Switching smokers from inhalation of the combustion products of tobacco in any form to a non-combustible nicotine delivery product would likely result in a vast reduction in tobacco-caused death and illness, via major reductions in lung cancer and chronic respiratory disorders. However, there are a number of obstacles to this route, many of them arising from the regulatory systems that currently govern the use of nicotine products in our society.

Nicotine replacement therapy products are currently produced and marketed as medicinal products for use as cessation aids, not as a longer-term substitute for cigarette smoking. The ideal NRT product would be one that provides nicotine in a dose and rate that satisfies the craving and other withdrawal effects experienced by the smoker, without the harmful components of cigarette smoke. The medicinal NRT products currently available have achieved only partial success with regard to these issues, in particular tending to provide nicotine at doses and rates of delivery that are a poor substitute for cigarettes [19]. This has been done largely because of risk adverse medicines regulatory frameworks, which compare the use of NRT against placebo rather than against continued smoking. In addition, NRT products are available through fewer retail outlets than cigarettes and their medicinal packaging and pricing means that they are less appealing to tobacco users than cigarettes. The regulation of NRT has recently been changed, and is more relaxed in some countries (e.g. France, UK), but if we want NRT to compete against tobacco efficiently we need to improve this situation and make NRT much more accessible, and much more affordable than cigarettes. It is also important to encourage the development of more effective NRTs. In its recently published report, Action on Smoking and Health in England focused on some of the steps needed to achieve this [20].

There is also potential for harm reduction by use of STPs. Snus is an example of a reduced harm product that is widely recognised to have contributed to reductions in tobacco-attributable mortality and oral cancer incidence rates in Sweden, and thus to reduce the net harm to health from tobacco use [21]. Although there is a concern that the availability of lower hazard tobacco products, marketed by tobacco companies, may lead to use among people who would not otherwise have used a tobacco product, at low levels of hazard, any public health impact from this is likely to be more than offset if substantial numbers of smokers switch to the lower hazard product [22,23]. However, there is disagreement on the extent to which snus has contributed to declining smoking prevalence in Sweden, and whether this experience and the balance of harm to benefit to society arising from the availability of snus could be replicated in other countries [13]. Currently, supplying snus is illegal in EU countries other than Sweden.

The ideal option, aside from quitting all nicotine use, would be for smokers to switch from cigarettes to a 'clean addictive nicotine delivery system' [24]; an idea that is now gaining increasing support. However, the development of such products is unlikely in the context of the regulatory systems that currently pertain across Europe.

Nicotine product regulation in the EU

The EU currently regulates nicotine products in a piecemeal and grossly inconsistent manner. Medicinal NRT products are controlled under drug regulations, and subject to strict controls on purity, promotion, prescription, and on the evidence base needed for licensing. Cigarettes, on the other hand, are subject to restrictions on advertising, printing of health warnings on packs and in some countries on use in enclosed places, but the product itself is unregulated. Some STPs, which in terms of hazard fall somewhere between the two extremes above, are subject to even more extreme and inconsistent regulation; products intended to be used by chewing or sniffing are widely accessible and virtually unregulated [25], while products that are intended to be sucked (including snus) are banned under EU directive 2001/37/EC2 [26]. Sweden alone is exempt from this directive.

This lack of regulatory consistency creates a strange situation in which smokers' choice of nicotine product is restricted, and smoked forms continue to be favoured over non-combustible nicotine delivery systems. This system clearly works against public health. If the development of new and improved nicotine delivery systems is to be encouraged in the future, it is imperative to have a clear regulatory framework within which all nicotine products can be assessed in relation to their health impact. The aim of such a framework should be to reduce the health effects of tobacco use by minimising the use of nicotine-containing products overall, but among regular users to maximise the use of safer nicotine products and minimise the use of combustible products. The ban on sucked tobacco products was

enacted amid concerns about introducing youth to tobacco. At that time, there were minimal restrictions on tobacco advertising and promotion and while many EU countries now have comprehensive bans on promotion, there are still concerns that the tobacco industry exploits loopholes to promote their products. Having access to a comprehensive surveillance system would be critical in order to be able to respond quickly to any untoward changes in nicotine use [10]. In its second report on the implementation of the 2001 Product Directive, the Commission commented that it would study the regulatory challenges with a view to at least ensuring that new tobacco and/or nicotine products marketed are regulated properly at EC level to serve the public health and internal market objectives. The Commission will also look at the relationship of the tobacco products regulatory framework with the novel foods and pharmaceutical legislation. We look forward to the outcome of this review [27].

New regulatory framework: the need for a nicotine and tobacco regulatory body

The prevention of smoking-related diseases has entered a new phase. Many countries have ratified the World Health Organization's Framework Convention on Tobacco Control, which came into effect on 27 February 2005. Countries signing up to the agreement committed themselves to introducing new governance that would enable them to implement various actions in the most effective way. The EU is also proposing to reinforce national policies on tobacco control. This context should encourage new thinking about tobacco and nicotine regulation and should favour taking tobacco and medicinal nicotine out of their existing regulatory frameworks and into a new structure.

Creating a new institution to manage regulation has been the approach favoured in many countries for the regulation of drugs and food, and has been the preferred approach at least in Ireland and Norway for tobacco regulation. Establishing a single institution with a combined remit of tobacco and nicotine regulation would probably be the most efficient and coordinated way to enable a comprehensive approach to co-regulate nicotine and tobacco products. A new institution would mean that a permanently staffed agency would be created with adequate authority to create an appropriate regulatory framework for tobacco and nicotine [10]. The Royal College of Physicians, in the UK, believes that developing a new institution is the optimum approach to nicotine and tobacco products commensurate with the scale of the problem and the complexities of the regulatory responses needed [10,14]. In France, the Comité National Contre le Tabagisme (National Committee Against Tobacco Use) and the Ligue Nationale Contre le Cancer (French Cancer League) have expressed a similar position, and have recommended the creation of a tobacco and nicotine regulatory authority (http://www.cnct.fr/tous-les-dossiers-73/plaider-pour-la-mise-en-place-d-une-autorite-nationale-francaise-1-19).html). This regulatory body should work with other national organisations across Europe, which are either in the process of being set up or already established as in Ireland and Norway. It would be responsible for formulating decisions about how tobacco and nicotine products will be regulated and overall responsibility for tobacco control [28]. An outline of the major duties and responsibilities of such an authority working at national level has been published in the UK [14].

Conclusions

As reflected by the recent smoke-free and other tobacco control policies established in many European countries, tobacco control has greatly progressed over the last decade. However, efficient control over tobacco use would mean that we take every possible step to improve public health. An urgent one would be to regulate tobacco and nicotine products in relation to their respective harmfulness in order to progressively eliminate the most harmful products and convince the smokers who cannot stop all tobacco use to switch to less harmful nicotine sources. This would also have an impact on youth smoking as these measures will participate to the denormalisation of tobacco use as is the case with smoke-free policies.

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the concern that promotion of these products could increase overall harm, if smokers continue to use both products (engage in dual use) and delay quitting. Alternatively, such use of LNSLT could lead some smokers to switch fully to LNSLT or even to quit tobacco use, as happens with PN. This pattern of short-term dual use as an intermediate step to full switching or quitting appears more common in Sweden than long-term dual use of LNSLT and cigarettes (Ramström & Foulds, 2006).

Another concern expressed by critics is that LNSLT will serve as a gateway to smoking amongst nonsmokers. The Swedish experience with snus is inconsistent with the gateway hypothesis (Foulds et al., 2003; Ramström & Foulds, 2006) in that most snus users are former smokers and few snus users become smokers. The relationship between SLT use and smoking has been more varied in US studies. Some studies have reported the same pattern as in Sweden (O'Connor, Kozlowski, Flaherty, & Edwards, 2005) but others have reported a "gateway" effect, with young SLT users "graduating" to smoking (Haddock et al., 2001). It is difficult to determine whether smokers who used SLT before cigarettes would have become smokers in the absence of SLT use. One analysis suggests that when the demographic and social factors associated with smoking initiation are taken into account, SLT does not appear to increase the uptake of smoking (Timberlake, Huh, & Lakon, 2009). In the USA, public health authorities may have also inadvertently encouraged such gateway effects by claiming that the health risks of SLT are the same as those of smoking (Kozlowski & O'Connor, 2003).

Options for promoting tobacco harm reduction

Information about tobacco harm reduction products

Harm reduction could be promoted by advising smokers to use less harmful products such as LNSLT and PN. This could be done via product warning labels on cigarettes and less harmful tobacco and nicotine products which indicate the relative harmfulness of each product. This option is most relevant for countries which allow the sale of these products. Information provided by governments and health authorities should also clearly indicate the relative harms of each product, rather than misleadingly suggesting that all tobacco products are equally hazardous (Kozlowski & O'Connor, 2003).

Regulation and promotion of tobacco harm reduction products

We could encourage smokers who seek help to quit and who fail to quit to use PN as a long-term alternative (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). This is one of the few tobacco harm reduction strategies supported by the majority of US tobacco control advocates (Warner & Martin, 2003). It was also advocated by the Royal College of Physicians in the UK (Royal College of Physicians, 2007) and experts in the EU (ASPECT Consortium, 2004). It would probably have limited public health impact if aimed solely at high-risk smokers who failed to quit because only a minority of these smokers seek help to quit, and probably few of them find existing forms of PN attractive (Warner, Slade, & Sweanor, 1997).

In order to have a larger public health impact, tobacco harm reduction requires as many smokers as possible to switch to PN or LNSLT. The Swedish experience suggests that LNSLT may be more likely to achieve this goal than current forms of PN (Foulds et al., 2003). This could change if regulators allowed more attractive forms of PN to be developed and marketed to smokers. In countries that ban LNSLT products, serious consideration should be given to relaxing sales bans on non-smoked, non-chewed oral tobacco products. More equal competition between cigarettes and less hazardous nicotine delivery devices could be achieved by making it harder to introduce new cigarette-like tobacco products and easier to introduce and promote the use of non-smoked tobacco harm reduction products and recreational PN products (Warner et al., 1997).

What does the future hold for tobacco harm reduction?

We believe that exploring the use of LNSLT is the most promising route for tobacco harm reduction. The development of faster acting and more attractive PN is likely to take some time. We suggest the following steps to explore the public health potential of tobacco harm reduction using LNSLT in those countries in which their production and sale is now prohibited, such as the EU, Australia and New Zealand.

First, we could cautiously trial the utility of LNSLT for smoking cessation in smokers who had failed to quit using PN and other smoking cessation medications. Smokers who failed to quit using current medications could be encouraged to switch to LNSLT rather than return to smoking. Evaluations would provide information on how attractive these products are to inveterate smokers. Second, we could liberalise the regulation of PN products to encourage their use for long-term substitution if smokers fail to stop by enabling the delivery of nicotine doses in ways more like SLT. Third, if there was interest in switching to LNSLT amongst inveterate smokers we could allow restricted sale of LNSLT products to these smokers. We could impose differential taxes on LNSLT and smoked tobacco to reflect the relative harmfulness. Fourth, we should rigorously evaluate the impacts of the sale of these products on: population smoking cessation rates; all forms of tobacco use amongst youth; and tobacco industry marketing.

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ORIGINAL ARTICLE

Lung cancer mortality: Comparing Sweden with other countries in the European Union

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Abstract
Aims: To describe how snus use has reduced smoking among men in Sweden, and to estimate how smoking-attributable lung cancer mortality would decline in other European Union countries if they had the smoking prevalence of Sweden. *Methods:* Lung cancer mortality rates (LCMRs) and numbers of deaths among men and women age 45+ years in 25 EU countries in 2002 were obtained from the World Health Organization mortality database, and the number of lung cancer deaths expected in each country at the LCMR of Sweden was calculated. LCMRs for EU countries were obtained during the period 1950–2004, and per capita consumption of nicotine from cigarettes and snus was estimated for men in Sweden from 1931 to 2004. *Results:* There were 172,000 lung cancer deaths among men in the EU in 2002. If all EU countries had the LCMR of men in Sweden, there would have been 92,000 (54%) fewer deaths. In contrast, the LCMR among Swedish women was the sixth highest in the EU; at the Swedish rate, deaths among EU women would have increased by 14,500 (26%). These LCMR patterns were in place for most of the last 50 years, and LCMRs among Swedish men can be correlated with snus and cigarette consumption. ***Conclusions:*** **This study shows that snus use has had a profound effect on smoking prevalence and LCMRs among Swedish men. While it cannot be proven that snus would have the same effect in other EU countries, the potential reduction in smoking-attributable deaths is considerable.**

Key Words: *Cigarette smoking, European Union, lung cancer mortality, snus, Sweden*

Background and Aims

For more than two centuries men in Sweden and other Scandinavian countries have used snus, which consists of ground tobacco, salt, water and flavouring agents that undergoes heat treatment to prevent formation of unwanted contaminants [1]. Snus, available in loose form and more recently in small pouches, is placed inside the upper lip.

Several studies have shown that the use of snus has played a substantial role in the low smoking rate among Swedish men [2–5]. However, that explanation has been judged as not compelling by some authorities, such as the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Recently, a SCENIHR report acknowledged that "particularly in Swedish men, there is a clear trend over recent decades for smoking prevalence to decrease and for use of oral tobacco (snus) to increase," but it concluded that "these trends could also be due to successful smoking reduction programs or other socio-cultural factors, and it is therefore not clear whether or by how much the availability of snus has influenced smoking prevalence." [1] The report also stated that "it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco if it were made available in a European Union (EU) country where it is now unavailable."

The purpose of this study is to clarify how much the availability of snus has influenced smoking among men in Sweden, in the context of all other EU countries. Studying smoking prevalence per se in the EU is difficult because standardized and comparable data are not available for all 27 countries. But there is

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a measure that reflects differences in smoking among EU countries: lung cancer mortality. Lung cancer is the sentinel disease of smoking [6], and a country's lung cancer mortality rate (LCMR) in any single year provides a reasonable indication of the amount of smoking in that country about 20 years earlier. While it is not possible to predict to what extent the availability of snus would reduce smoking prevalence in EU countries other than Sweden, it is possible to estimate how smoking-attributable mortality would decline if these countries had the smoking prevalence of Sweden.

Methods

LCMRs and numbers of deaths were obtained separately for men and women age 45+ years in 25 EU countries in 2002 (Denmark, 2001) from the World Health Organization (WHO) mortality database [7]. No data are available for Cyprus and the latest data for Belgium are from 1997. LCMRs were age-adjusted by the WHO to the World Standard Population and were expressed as deaths per 100,000 person-years. We calculated rate ratios for each country, expressed as that country's LCMR divided by the Swedish LCMR. A rate ratio greater than one indicates that the country's LCMR is higher than that of Sweden; a ratio less than one indicates that the Swedish rate is higher. For both genders we calculated the number of lung cancer deaths expected if each country had the LCMR of Sweden.

LCMRs for EU countries except Cyprus were obtained for all available years during the period 1950–2004. Based on data availability and general LCMR trends, the countries were divided into two groups: the 15 countries comprising the EU in 1995 (EU-1995 countries) and the 11 countries that joined the EU in either 2004 or 2007 (EU-expansion countries). Countries with similar LCMRs were combined, and data are illustrated as three-year moving averages.

We estimated the annual per capita consumption of nicotine from cigarettes and snus by men in Sweden from 1931 to 2004. Annual population estimates (men and women aged 15+ years) and annual Swedish tobacco consumption (number of cigarettes and the amount of snus in grams) were obtained from Research and Consulting Bureau VECA (Hässelby, Sweden). It was assumed that all snus consumption was by men. Cigarette consumption by men in each year was estimated by adjusting total consumption using gender-specific LCMRs 20 years later. LCMR trends were projected to 2024 to estimate gender-specific cigarette consumption through 2004. We estimated per capita nicotine consumption using conversions developed by Fagerström [8], 1.4 mg of nicotine per cigarette and 2.0 mg per g of snus. The snus conversion applies to traditional snus, which provides more nicotine than portion-pack forms that became popular recently [8].

Results

LCMRs among men in the EU

In 2002 the LCMR among men in the 25 EU countries was 166 (Table I). The LCMR among men in Sweden was 77, the lowest of all countries. The LCMR among Portuguese men (105), the second lowest in the EU, was 36% higher than that of Sweden, and 17 EU countries had LCMRs that were over twice as large as that of Sweden. The number of lung cancer deaths among all men in the EU was 172,000. If all countries had the LCMR of Swedish men, 80,000 deaths would have occurred, representing 92,000 fewer lives lost to lung cancer, a 54% reduction.

Figure 1a shows the LCMRs among men in Sweden and among men in other EU-1995 countries from 1950 to 2004. The LCMR among men in Sweden was 32 in 1951 and peaked in 1978 at 96, followed by a gradual decline to 77 in 2002. These LCMRs were much lower for all years than those for all but one EU-1995 country. The exception is Portugal, which had an LCMR of 26 in 1955 and has experienced a gradual increase ever since, passing Sweden in 1986. Spain, Italy, France, Ireland, Denmark and Greece also had low LCMRs initially (31–64 in 1952), with subsequent peaks between 180 and 220. Data are available for Germany starting in 1973, and the LCMR pattern is consistent with the overall pattern for this group. Belgium and the Netherlands had LCMRs of about 100 in the mid-1950s, with subsequent peaks near 300 in the early to mid-1980s. Finland and the United Kingdom (UK) had LCMRs above 150 in 1952, with subsequent peaks in the early 1970s at 261 and 281 respectively. No data are available prior to 1973 for Luxembourg, which had a peak LCMR of 273 in 1982. Austria had an LCMR similar to Finland in 1955, but its peak at 196 occurred in 1968. Despite the different LCMR patterns among these countries, there was a convergence of the rates over the last 20 years. By 2002 the range of LCMRs was from 120 (Finland) to 188 (the Netherlands) in all countries except Sweden and Portugal.

Figure 1b shows LCMRs among men in Sweden compared with those in EU-expansion countries.

Table I. Lung cancer mortality rates.[a] Number of deaths observed and number expected at Swedish rates among men and women in 25 European countries, 2002.

	Men				Women			
Country	Rate[a]	Observed deaths	Rate ratio[b]	Expected deaths[c]	Rate[a]	Observed deaths	Rate ratio[b]	Expected deaths[c]
Austria	138	2,354	1.79	1,313	44	1,002	0.84	1,194
Bulgaria	144	2,388	1.86	1,282	23	500	0.43	1,152
Czech Rep	217	4,242	2.80	1,511	46	1,258	0.87	1,440
Denmark	160	1,938	2.07	934	106	1,467	2.02	727
Estonia	227	551	2.95	187	28	122	0.54	227
Finland	120	1,376	1.55	887	30	462	0.58	803
France	163	20,315	2.12	9,586	29	4,646	0.55	8,437
Germany	148	28,320	1.91	14,793	41	10,077	0.78	12,981
Greece	175	4,715	2.26	2,082	26	858	0.50	1,706
Hungary	287	5,506	3.72	1,482	78	2,169	1.50	1,447
Ireland	135	920	1.75	525	63	533	1.21	442
Italy	170	25,492	2.20	11,582	32	6,344	0.61	10,336
Latvia	214	878	2.78	316	23	176	0.44	398
Lithuania	206	1,198	2.68	448	17	179	0.32	561
Luxembourg	164	145	2.13	68	31	33	0.59	56
Malta	158	122	2.04	60	18	13	0.35	38
Netherlands	188	6,321	2.43	2,599	66	2,425	1.25	1,933
Poland	260	16,426	3.37	4,880	50	4,393	0.96	4,586
Portugal	105	2,370	1.36	1,742	19	552	0.36	1,552
Romania	173	6,814	2.25	3,032	28	1,442	0.53	2,723
Slovakia	199	1,661	2.57	645	26	318	0.50	630
Slovenia	183	701	2.38	295	44	226	0.83	272
Spain	168	15,605	2.18	7,153	17	1,964	0.33	5,937
Sweden	77	1,761	–	1,761	52	1,329	–	1,329
UK	143	20,124	1.86	10,842	74	13,279	1.42	9,347
All	166	172,243	2.15	80,005	41	55,767	0.79	70,254

[a]Deaths per 100,000 person-years, age-adjusted to the World Standard Population.
[b]Country rate/Swedish rate.
[c]At the Swedish rate. UK = United Kingdom.

Data from these countries is more limited, but some trends are apparent. Swedish LCMRs are much lower than those for all other countries for all years. Among countries with data from at least 1960, Romania had an LCMR of 68 in 1959, with a pattern similar to that in Spain. LCMRs in Poland and Hungary in 1960 were 62 and 109, with subsequent peaks at 269 (1994) and 306 (1996) respectively. By 2002 LCMRs were declining in all of these countries except Romania and Bulgaria. However, in 2002 only Romania, Bulgaria and Malta had LCMRs that were lower than 188, the highest LCMR among EU-1995 countries in that year.

LCMRs among women in the EU

In 2002 the LCMR among women in the 25 EU countries was 41. The LCMR among women in Sweden was relatively high at 52; only Denmark, Hungary, Ireland, the Netherlands and the UK had higher rates. In 2002, the number of lung cancer deaths among women in the EU was 55,800. If women of all countries had the LCMR of Swedish women, 70,300 lung cancer deaths would have occurred, a 26% increase.

LCMRs among women in EU-1995 countries during the period from 1950 to 2004 are shown in Figure 2a. In the mid-1950s LCMRs ranged from 7 in Portugal to 23 in the UK. Denmark showed the sharpest increase to a peak of 104 in 1995, with little decline afterward. Ireland and the UK peaked at 75–79 in 1988–89, followed by modest declines to about 70. A peak has not occurred in any other country, although there are five separate slopes. The Netherlands' LCMR was at the level of that in Ireland and the UK in 2002, while Sweden had an LCMR of 52, which is fifth highest in this group. In 2004 Austria, Germany and Luxembourg had LCMRs around 40; France, Finland, Greece and Italy had LCMRs of 30; Portugal and Spain were the lowest among EU-1995 countries at 20.

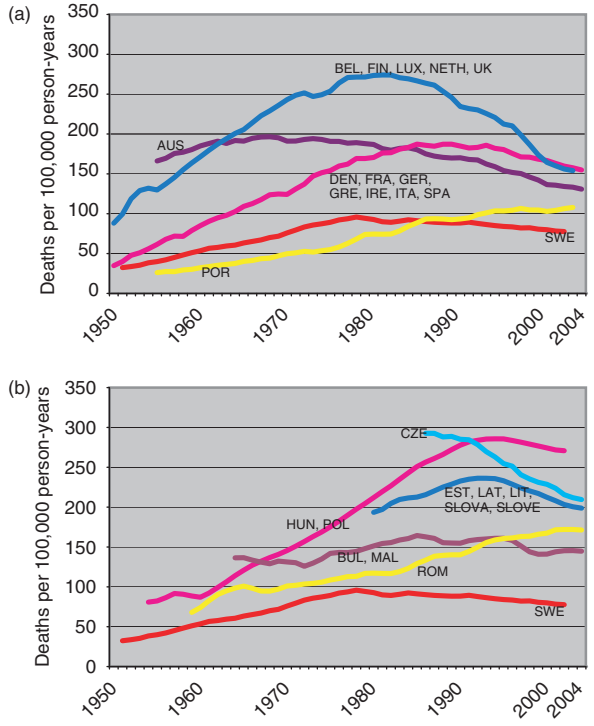

Figure 1. LCMRs among men age 45+ years in Sweden, in (a) EU-1995, and (b) EU-expansion countries, 1950–2004.

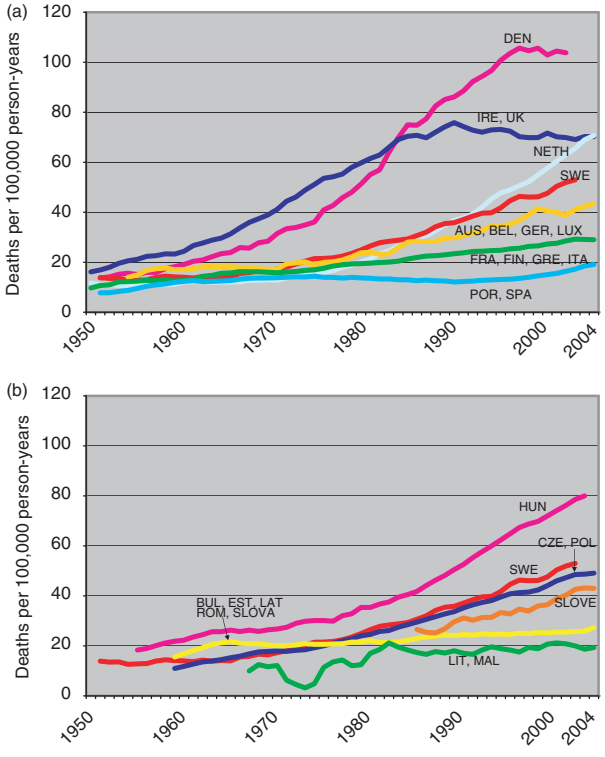

Figure 2. LCMRs among women age 45+ years in Sweden, in (a) EU-1995 and (b) EU-expansion countries, 1950–2004.

Figure 2b shows LCMRs among women in Sweden compared with those in EU-expansion countries. Throughout most of the period LCMRs among Swedish women were lower than those only in Hungary, which had a rate of 80 in 2003. LCMRs in the Czech Republic and Poland approached 50 by 2004, and the LCMR in Slovenia was over 40. LCMRs increased more slowly in Bulgaria, Romania, Slovakia, Estonia and Latvia, generally staying in the mid-20s. LCMRs in Malta and Lithuania were essentially stable at 20.

Nicotine consumption by Swedish men, 1931–2004

Figure 3 shows estimated annual per capita consumption of nicotine from cigarettes and snus by Swedish men age 15+ years. Prior to 1952, snus was the dominant nicotine source but was declining while cigarette consumption was increasing. Cigarettes were the preferred nicotine source from 1955 to 1985, but consumption peaked by 1975; the nadir of snus consumption was in 1969. After 1985 snus regained dominance, and the snus-cigarette gap has widened ever since.

Nicotine consumption from snus and cigarettes are strongly and inversely correlated (correlation coefficient $= -0.86$), but annual per capita nicotine consumption from both sources combined was fairly stable. The mean for all years was 4,600 mg. Nicotine consumption fell below 4,000 mg only during World War II (1942–45). Consumption was above 5,000 from about 1972 to 1988; during this period snus use increased while cigarette smoking had just started to decline. These usage patterns accelerated afterwards with total nicotine consumption remaining above 4,000 mg.

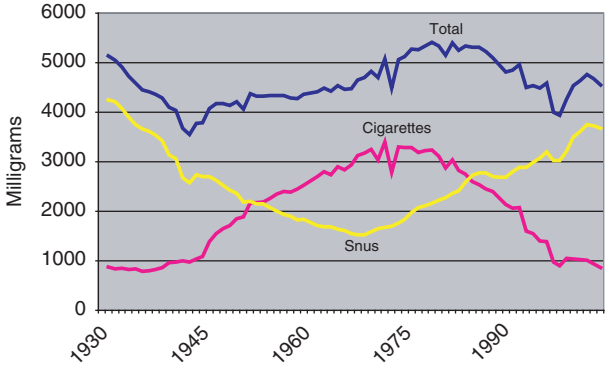

Figure 3. Estimated annual per capita nicotine consumption (mg) from cigarettes and snus by men in Sweden, 1931–2004.

Discussion

The major finding of this study is that snus use is inversely correlated with cigarette consumption among men in Sweden, resulting in the lowest LCMRs in Europe for most of the past 50 years. In 2002, there were 172,000 lung cancer deaths among men in the EU. If all EU countries had the LCMR of men in Sweden, there would have been 92,000 fewer lung cancer deaths. But the potential impact of low Swedish smoking rates is not limited to lung cancer. For men in the EU, 91% of all lung cancer deaths are attributed to smoking, and lung cancer accounts for only 31% of all smoking-attributable deaths [9]. Thus, we estimate that there were 511,000 smoking-attributable deaths among men in EU countries in 2002, which is consistent with other recent estimates [9]. If all EU countries had the smoking rates of Swedish men, there would have been only 237,000 deaths from all smoking-related diseases. In other words, 274,000 smoking-attributable deaths would have been avoided throughout the EU in 2002. In addition, longitudinal LCMR trends indicate that the difference between Swedish men and that of other EU countries was modest in 2002 compared with previous years.

The large differences in LCMRs between Sweden and other EU countries occur only in men. For most of the last 50 years, the LCMR among Swedish women was the sixth highest in the EU. This context is important, because it has been suggested that vigorous anti-smoking campaigns since the 1970s are the major determinant of the low Swedish smoking rates [10]. It is implausible that these campaigns were highly effective for Swedish men and almost completely ineffective for Swedish women. The striking difference in the relative EU ranking of Swedish men and women is firm evidence that snus use, not anti-smoking campaigns, has played the primary role in low LCMR rates among men in Sweden for over a half century.

World War II created millions of male smokers, resulting in very high LCMRs throughout Europe in the 1960s and 1970s. Men in Portugal, Spain and Italy, which had LCMRs similar to those in Sweden in the early 1950s, later experienced peak LCMRs that were four to six times higher, while the peak in Sweden represented only a three-fold increase. Even though snus consumption declined until 1969, its use was high enough to suppress smoking by Swedish men and to keep their LCMR among the lowest in the EU. Increasing snus consumption in the last two decades has been accompanied by further declines in smoking. If current trends hold, the LCMR for Swedish men may become lower than that for Swedish women by 2011. However, there is evidence that snus has started to become popular among Swedish women, with a consequential impact on smoking [3,11].

There are other risk factors for lung cancer besides smoking, but the latter is certainly the dominant cause throughout the EU. Furthermore, the proportion of lung cancer cases due to other causes is unlikely to differ significantly across countries, with the possible exception of women in Lithuania, Spain and Portugal, who have extremely low LCMRs [9]. Thus, while the number of lung cancer deaths reported here are not entirely due to smoking, other risk factors play a minor role in the trends seen in this study.

Nicotine consumption from snus and cigarettes are strongly and inversely correlated. But the LCMR decline among Swedish men started just 10 years after the upturn in snus consumption and only six years after cigarette consumption peaked. The expected lag is about 20 years. A possible explanation relates to differences in the available data; we had information on snus and cigarette consumption only for all men (age 15+ years), but lung cancer is mainly seen in persons age 45+ years. In the 1950s and 1960s snus use was seen predominantly in older Swedish men [12], which may have influenced the timing of the LCMR peak and decline in this study.

Currently, snus is banned in all EU countries except Sweden. While it cannot be proven that the availability of snus would reduce smoking prevalence in other EU countries, this study shows that snus use has had a profound effect on smoking among Swedish men. It also reveals that 274,000 smoking-attributable deaths would be avoided if all men in all EU countries had the smoking prevalence of men in Sweden. Britton and Edwards recently wrote that "the absence of effective harm reduction options for smokers is perverse, unjust, and acts against the rights and best interests of smokers and the public health." [13]. It is time for the European Commission to revise the Tobacco Directive to make snus available to all European smokers.

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with respect to its design, analysis, interpretation or preparation of the manuscript. Neither author has any financial or other personal relationship with regard to the sponsors.

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we recommend that clinicians advise their smoking patients on more flexible ways to quit smoking with existing approved medicines, rather than snus.[14]

Sometimes if a product is "not safe", this may be grounds for banning the product. But such an absolutist position can ignore the complex realities of many of the most important health risks we face. From the perspective of the never-user of tobacco, exposure to any level of residual risk from a tobacco product such as snus can seem to be an unnecessary risk. It may help the non-tobacco user to reflect that popular energy-dense diets and sedentary lifestyles are also "not safe", carrying significant risks of diabetes, heart disease, and cancers. We consider the appropriate response is to inform consumers and encourage alternatives while respecting individual choice. Public health is largely determined outside clinical settings. Price, advertising, legal restrictions, and availability of alternatives all have a large influence on health behaviour. Public policy should aim to strongly discourage highly dangerous behaviours, and provide appropriate information and warnings about lower-risk behaviours. It is a hallmark of addictive substances that users' ability to act on their decision to abstain becomes impaired by the unpleasant effects accompanying drug withdrawal and by the promise of satisfying effects produced by the drug. It is a perverse public-health policy that makes an addictive drug widely available in its most harmful form, yet bans or fails to properly inform consumers of availability of that drug in a much less harmful form (for both the consumer and those around them).[15]

5 years ago snus was almost entirely sold by one Swedish company to consumers from Scandinavia. Today, most of the big multinational tobacco companies are test-marketing low-nitrosamine snus products. Drug companies should develop smoking cessation medications and marketing formats that can effectively compete with the imminent launch of new smokeless tobaccos—and be more palatable than snus, especially for female smokers. Regulators should also address the uneven playing field on which nicotine is currently sold. Nicotine in its safest form (as an approved drug) is expensive, only recommended for short-term use, sometimes requires a doctor's prescription, and typically comes with labelling that may lead some consumers to believe that it is more harmful than smoking. Nicotine in its most harmful and addictive form—the cigarette—is typically cheap, available everywhere, to take for as long as you like, and in many parts of the world (including the USA) comes with minimum information on health risks. It is time for regulation of all nicotine-delivery products to provide access inversely proportional to harmfulness (ie, the opposite of the current situation).[15]

Around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. In Sweden, primary use of snus is associated with reduced risk of cigarette smoking in adulthood.[11] The *Lancet* papers published today, when added to mounting epidemiological evidence,[9] indicate that we should not delay in allowing snus to compete with cigarettes for market share, and we should be prepared to accurately inform smokers about the relative risks of cigarettes, snus, and approved smoking-cessation medications. In light of all the available evidence, the banning or exaggerated opposition[13] to snus in cigarette-rife environments is not sound public-health policy.

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