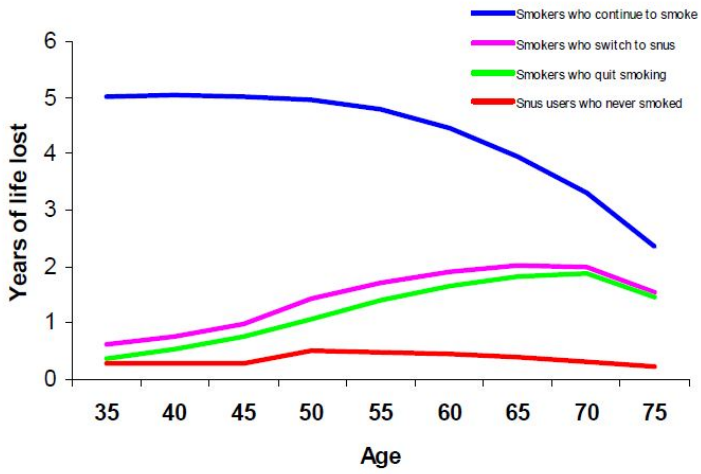
Death by regulation: the EU ban on low-risk oral tobacco



Is it right to ban certain types of smokeless tobacco from sale in the European Union? The short and unequivocal answer is 'no'.

But surely banning any type of tobacco can only reduce the size of the overall tobacco market and therefore be good for health? *No, not at all, it just isn't that simple…*

This post gives my personal take on this important public health issue.

The reason for allowing it on the market is that smokeless tobacco is an effective substitute for smoking, but far less hazardous to health than cigarettes. The chart to the left puts it quite well. It models the effect on life expectancy of switching from smoking to a type of smokeless tobacco ('snus' or Swedish oral snuff) at a given age. These are *dramatic* findings. Given the addictiveness of nicotine and how difficult some smokers find quitting even if they really want to, banning this option amounts to death by regulation. What has gone wrong?

Switching provides a substantial health benefit to smokers who switch, in fact switching is not that much different to quitting smoking altogether. Furthermore, the risks of the product itself (the bottom red line) are quite low (Gartner et al 2007 – see SCENIHR p117). However, *these products are banned* in law the EU (other than in Sweden), and smokers have been denied the option to switch to this much lower risk way of taking nicotine.

A group of us concerned about public health policy set out the arguments for this in 2003 (Bates et al 2003) and the arguments haven't changed since. They have

only strengthened as more evidence has become available. As Gartner et al conclude:

> *Current smokers who switch to using snus rather than continuing to smoke can realise substantial health gains. Snus could produce a net benefit to health at the population level if it is adopted in sufficient numbers by inveterate smokers. Relaxing current restrictions on the sale of snus is more likely to produce a net benefit than harm, with the size of the benefit dependent on how many inveterate smokers switch to snus.*

Despite this, these products are banned in the European Union under Tobacco directive 2001/37/EC article 8 (other than in Sweden). Worse still, and in the face of abundant evidence that supports the lifting of this ban, the EU appears ready to maintain or extend it in a new tobacco directive (see consultation [PDF see p4-6]) and comments from the Commission (here and here).

This is wrong at many different levels. In the sections that follow, I'll address three major policy failings under the following headings:

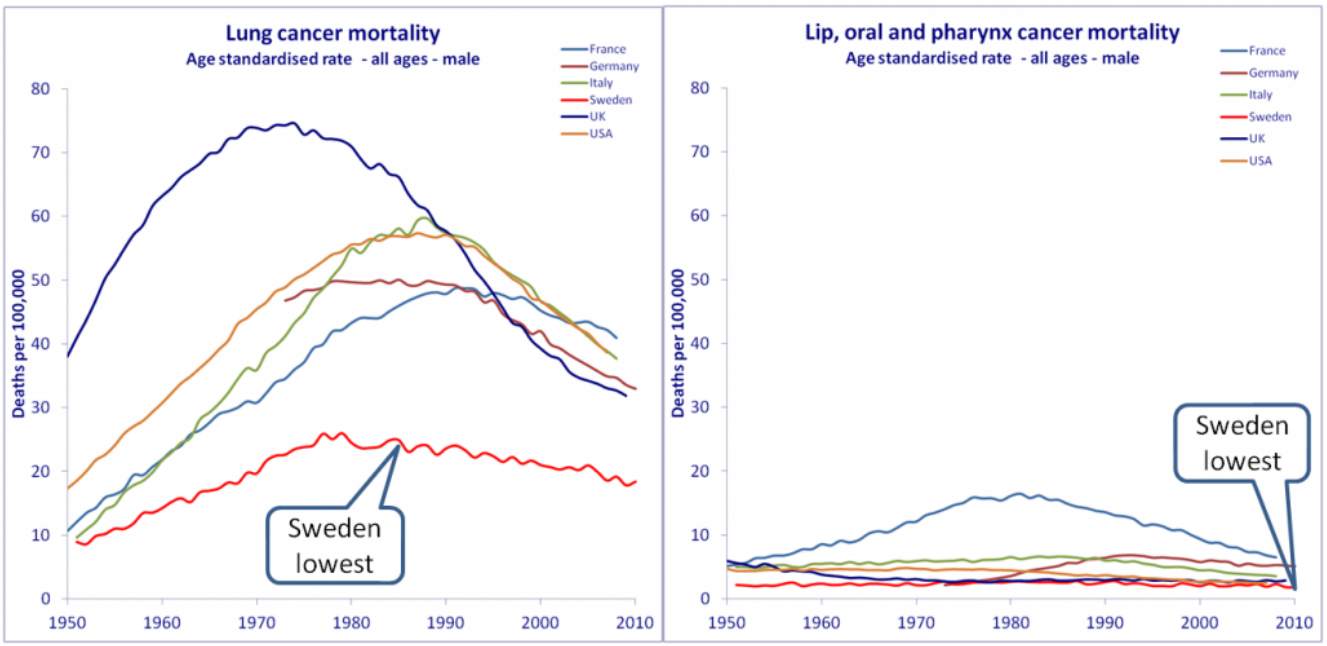
1. Public health science ignored and abused
2. Ethics and consumer rights violated
3. EU legal principles disregarded

But before we get into the substance, some definitions:

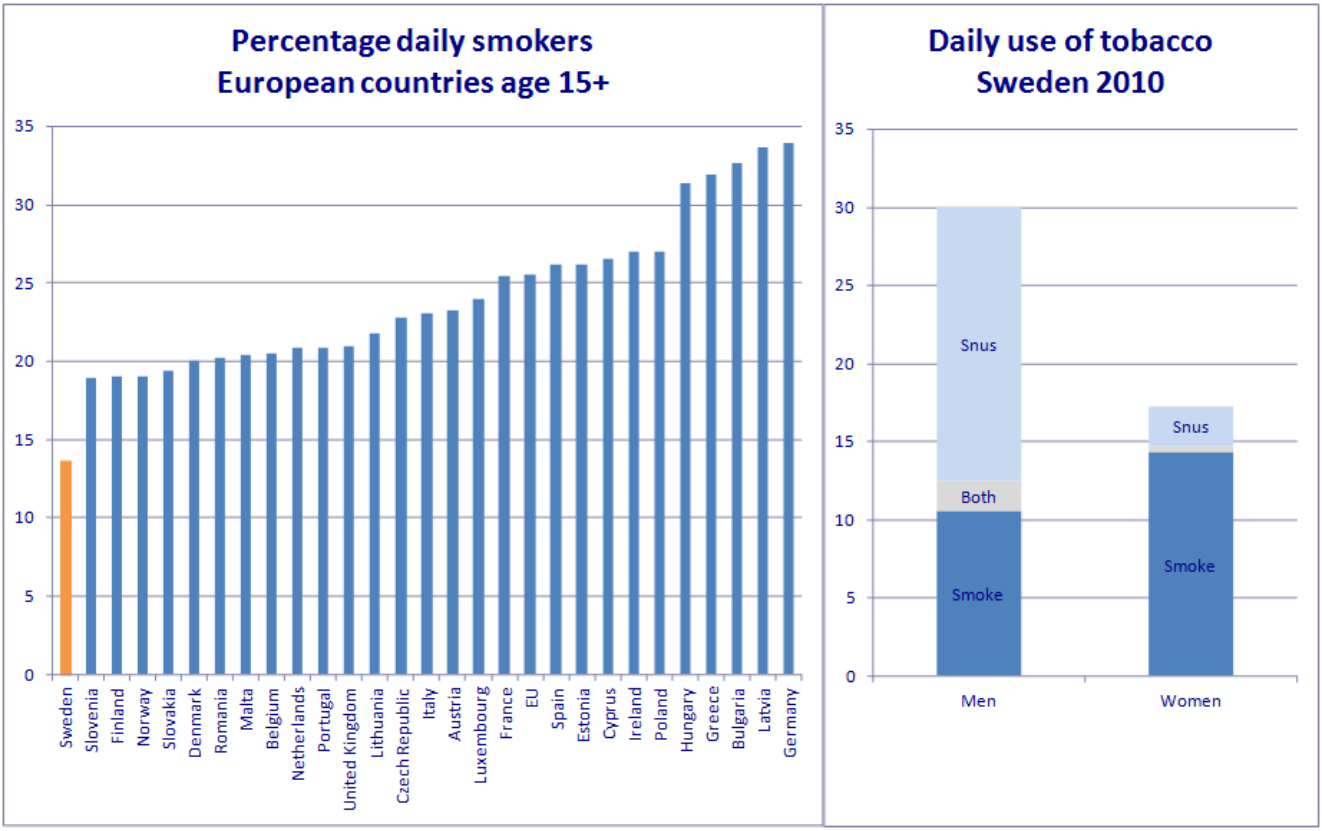
- Smokeless tobacco: any type of tobacco intended to be consumed without burning. Includes snuffs, chewing tobaco, quid, toombak etc [examples].
- Oral tobacco or "tobacco for oral use": definition as in the EU tobacco product directive 2001/37/EC – *all products for oral use, except those intended to 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*;
- Snus: a form of smokeless and oral tobacco, widely used in Scandinavia, but banned under the EU tobacco product directive 2001/37/EC outside Sweden. The largest manufacturer is Swedish Match, which provides information on the product here.

1. Public health science ignored and abused

The data is there for anyone who is prepared to look. The case of Sweden, where the use of smokeless tobacco is highest is striking: Cancer statistics from the World Health Organisation are shown below:



To start with, getting this right matters a great deal. Any credible opportunity to reduce smoking-related cancer, respiratory illnesses and heart disease should be seized on by the public health community and by legislators – even if it involves the idea, uncomfortable to some, of unbanning a tobacco product. The goal, after all, is to deal with tobacco so as to promote public health rather than sacrifice public health in efforts to attack tobacco. Sweden provides a dramatic 'proof of concept' for smokeless tobacco as a population level harm-reduction product, based on the choices made by tobacco users unaided by the state. Sweden has by far the lowest level of tobacco-related mortality in the developed world, the lowest rate of smoking and the highest use of tobacco in smokeless form. See charts below…



Sources: [WHO-Europe Health for All database] and [Swedish Central Bureau of Statistics]

These relationships don't of course prove a causal link between smokeless tobacco use and reduced harm in itself, but you have to take this finding with other evidence drawn from epidemiological studies. And they certainly don't support the case that snus use is anything less than a tiny fraction as hazardous as cigarette smoking – probably comparable with other lifestyle risks widely tolerated.

Given the Commission's official science advice comes from the [Scientific Committee on Emerging and Newly Identified Health Risks] (SCENIHR), let's take this committee's work as our guide to the science. I had many reservations about the way this committee went to great lengths in its interim report to ignore the most important characteristic of snus – its low risk relative to smoking. See my posting: [Useless scientific advice from the EU]. Nevertheless, the committee somewhat redeemed itself in its [final report], though still managed to bury the most important conclusions on harm reduction.

1.1 On respiratory disease

SCENIHR's final report says:

> *Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU (The ASPECT Consortium 2004). There is no consistent evidence that any smokeless tobacco product cause any of these major respiratory diseases. Complete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking.*

1.2 On cardiovascular disease

> *Thus the evidence indicates that if snus use increases the risk of myocardial infarction it does so to a lesser extent than smoking. The reduction in risk is difficult to quantify, but for snus, using the Bolinder study of 1994 (Bolinder et al. 1994) as a conservative estimate, is around 50%. The other studies listed above indicate that the relative risk associated with snus use compared to smoking is probably substantially lower than this. It is therefore reasonable to draw a conservative conclusion that substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%.*

There probably is a heart disease risk associated with smokeless tobacco use, most likely arising from nicotine, but the point is that it is greatly reduced compared to smoking – and so there are potentially significant cardiovascular health gains for those that switch.

1.3 On oral and pancreatic cancer

> *Thus it is evident that the risk of pancreatic cancer associated with snus use is less than that of smoking, and for oral cancer substantially so. Since the numbers of deaths from these diseases is relatively small, the public health impact of this reduced risk, if snus were to replace smoking, would also be modest.*

Both points are important: the risk is comparatively low in absolute terms (also see charts above) and lower than smoking in relative terms. It is also likely that there is a considerable range of risk *within* the smokeless tobacco category, suggesting that regulation may be used to reduce risk further by controlling the levels of carcinogens in the products on sale.

1.4 On passive smoking

> *Since smokeless tobacco products do not produce smoke they will not cause any of the health problems linked to passive smoke exposure in adults or children. Substitution of snus for smoked tobacco would therefore prevent the passive smoke-related diseases.*

1.5 On the risk that smokeless tobacco will lead to more smoking

What about people who start to use smokeless tobacco who would never have smoked? It's difficult to know how many would take this path, and it is indeed a risk that should be offset against the benefit experienced by people who switch from smoking to smokeless. SCENIHR points out:

> *However Gartner and colleagues estimate that the benefits accrued by one person not taking up smoking as a result of the availability of snus will offset the harm experienced by between 14 and 25 people who take up snus but would not otherwise have used any tobacco product (Gartner et al. 2007). According to Gartner's model, the overall effect is therefore likely to be beneficial.*

In fact, other research suggests the patterns of transition imply snus is a net gateway out of smoking – see Foulds et al 2003: *Effect of smokeless tobacco (snus) on smoking and public health in Sweden*.

> *Snus availability in Sweden appears to have contributed to the unusually low rates of smoking among Swedish men by helping them transfer to a notably less harmful form of nicotine dependence.*

Or how about this more recent study examining the same effects in Norway, from Lund et al 2010: *The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies*. The results broadly suggest that snus is used to stop smoking. The authors conclude, with due caution:

> *Consistent with Swedish studies, Norwegian data shows that experience of using snus is associated with an increased probability of being a former smoker. In Scandinavia, snus may play a role in quitting smoking but other explanations, such as greater motivation to stop in snus users, cannot be ruled out.*

In 2010, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA – an agency of the European Union) published a monograph, *Harm reduction: evidence, impacts and challenges* covering harm reduction in drugs, alcohol and tobacco. The chapter on tobacco harm reduction, *Harm reduction policies for tobacco*, concludes:

> *The most promising strategy for reducing harm to tobacco smokers is to encourage smokers who are unable or unwilling to quit to switch to pharmaceutical nicotine or low nitrosamine smokeless tobacco products.*

It is precisely these low-nitrosamine smokeless tobacco products that are banned in the EU outside Sweden. It is the intention of the European Commission and many member states to maintain this ban in a new directive. They are thus obstructing "*the most promising strategy for reducing harm to smokers*". Why?

1.6 Authoritative views from practising scientists and physicians

It isn't just me that thinks a ban on much lower risk products is wrong, or that this is a new idea. If you doubt it, please read this in-depth report by the UK's most eminent medical college: Royal College of Physicians, Tobacco Advisory Group, *Harm reduction in nicotine addiction: helping people who can't quit*, 2007. The College concludes:

> *Low nitrosamine smokeless tobacco products may have a positive role to play in*

> *a coordinated and regulated harm reduction strategy which maximises public health benefit and protects against commercial market exploitation.*

It's worth considering just how striking that conclusions is: the Royal College of Physicians has been at the forefront of doctors battling the health effects of tobacco since its groundbreaking 1962 report, *Smoking and Health*. The Royal College of Physicians would not say something positive about a tobacco product lightly or unless it was strongly convinced of the health rationale. When they speak up, policymakers should listen.

Or if you are concerned that the European Union simply may not understand the argument, have a look at this letter from practising scientists from around the world addressed to the European Commission officials: The advancement of the scientific basis for the EU Tobacco Products Directive.

> *The products with the greatest potential for use in tobacco harm reduction are non-tobacco nicotine products and low-toxicity combustion-free tobacco, such as Swedish Snus.*

Some of the best researchers in the field of tobacco and nicotine dependence are signatories to this letter. When they speak up, policymakers should listen.

1.7 Public health – what to draw from this?

In my view, the abundance of evidence suggesting a likely positive impact from wider introduction of smokeless tobacco shifts the burden of proof. With evidence like this and clear proof of the harm reduction concept in Sweden, it should be up to those who want to ban these products to produce evidence of likely unintended and severe consequences that would outweigh the plausible benefits. I don't wish to overdramatise this, but when a government does something that stops people taking action to reduce their risk, they become culpable for the harm caused – up to and including death.

2. Ethics and consumer rights violated

What is the ethical position of the legislator or campaigner seeking to ban a potential harm reduction product? Impossible to defend in my view. In doing so,

they are denying an option to reduce harm, and so may be causing more harm and possibly premature death through their actions. Pressing for a ban on these products is quite an abusive thing for one person to do to someone facing the risks from long-term smoking. Where is the legitimacy for that?

And remember we are dealing with a powerfully addictive agent. It is absolutely clear that nicotine is addictive and smoking is hard for many to give up. Though 70% of (UK) smokers say they would like to quit and even more say they wish they had never started, quit rates are only 2-3% of smokers per year [see presentation]. Over time, better off smokers are more likely to quit, meaning smoking steadily concentrates in poorer households. Some smokers have greater genetic predisposition to nicotine dependence and others use nicotine to self-medicate to provide relief from psychiatric conditions such as schizophrenia [discussion] – do these people not 'deserve' a low risk alternative? And if so, why would others be denied? Even if smokers are happy or resigned as nicotine users with no intention to quit, why shouldn't they have a choice or temptation to do it differently, even if just some of the time? Those insisting on a ban are deliberately denying access to an option that is used to substitute for cigarettes and reduces risk as a result. If there are health benefits from this switch – and there are and they are significant – then the legislators are deliberately closing a potentially life-saving alternative pathway to a smoking. Lynn Kozlowski dramatises this by imagining what he would say to his brother about this. Before denying someone a life-saving alternative to smoking, I think you need to be very sure indeed that the unintended consequences might outweigh the benefits to individuals that switch. No-one has evidence to support that view – and there isn't any. The SCENIHR report concludes:

> *Conclusion on the comparison of smokeless tobacco with smoking*
>
> *It is possible that introducing snus in EU countries that do not presently allow the product to be marketed would eventually contribute to some or all of the following beneficial outcomes:*
>
> - *Reduced initiation of cigarette smoking*
> - *Increased cessation by switching to smokeless tobacco*
> - *Reduced smoking-associated disease*

Well that's quite an important finding, and it supported by the evidence reviewed

by the Committee, the experience of Sweden and Norway, where these products are available. It is also backed by common sense and the universal practice of not banning safer variants of risky products, whether these be cars, domestic appliances, foods, medicines etc. This view somehow didn't make it into the headline findings and appears almost as an inconvenient truth, buried away at the end of the report. Of course there could be unintended consequences, and the committee feels obliged to state these.

> *It also must be recognised that it is possible that the overall health outcome of introducing smokeless tobacco products could be adverse due to the following possible outcomes:*
>
> - *Increased overall tobacco use without substantial decline in cigarette smoking prevalence*
> - *Impaired tobacco prevention efforts due to 'mixed messages' that attempt to advise against any tobacco use, but favour certain forms over others*
> - *Undermining tobacco cessation efforts*
> - *Uptake of smokeless tobacco in populations who would otherwise have not likely used any tobacco product*

Here's the core of the ethical issue… given the likely population benefits and clear individual benefits of being able to switch from smoking to smokeless tobacco, I would expect those proposing a ban on this option to be supported by strong evidence that these negative effects are real and pronounced (and that they matter). The burden of proof rests with those supporting a ban to show there are overriding reasons to deny people this choice. The truth is that there is no evidence supporting any of the four negative contentions above, and most evidence points in the opposite direction. Let's look at each in turn:

2.1 Increased tobacco use with no decline in smoking?

Sweden and Norway have lower rates of smoking, not higher rates. Tobacco use per se isn't the right goal, the priority is the health impacts associated with tobacco use – and that means doing everything possible to reduce smoking, including allowing addicted smokers to switch to smokeless tobacco.

2.2 Mixed messages on public health?

There are no significant public health messages about smokeless tobacco suggesting its use as a cessation aid. In fact, it is more likely that excessive, alarmist and evidence-free public health messages about smokeless tobacco diminish the role that smokeless tobacco could play in reducing smoking. This study (Wikmans T, Ramström L. 2010) suggests people have been confused about the harm caused by nicotine, NRT and smokeless tobacco. It concludes:

> *Public information about smoking and health should be expanded to include objective and unambiguous information regarding nicotine's part in the harmfulness of smoking and the harmfulness of different nicotine-containing products compared to smoking. This is essential in order to preclude that misperceptions regarding these matters could discourage smokers from adopting effective cessation practices with use of nicotine-containing aids.*

The 'Tobacco Truth' web site, edited by Brad Rodu, meticulously documents misleading propaganda about smokeless tobacco and aims to give smokers reliable evidence-based information about the option to use smokeless tobacco to quit smoking. It reads like a breath of fresh air in a stale debate dominated by unfounded public health dogma. If you want a more complete account of the misleading and, frankly, bent scientific advice used to support the crusade against smokeless tobacco, I recommend a book: *The art of suppression: pleasure panic and prohibition since 1800* by Chris Snowdon – an excellent account of the tactics of prohibitionists, featuring a chapter on snus.

2.3 Undermining tobacco cessation efforts?

It's the other way round in reality. A ban undermines the potential smoking cessation efforts made by individuals through choosing tobacco products with greatly reduced risk, or using these to assist in quitting. Again, the focus should be on the burden of disease and therefore reducing smoking. Even if it meant greater tobacco use in total (and no-one has yet made the case that it does), it would be better if the use of tobacco for smoking was reduced by increased use of smokeless tobacco. Given the relative risks of smoking and smokeless tobacco, the health 'break even point' would require completely implausible levels of smokeless tobacco consumption. Where the product is actually in use, the overall

burdens of tobacco-related disease are significantly lower.

2.4 Uptake of smokeless tobacco in populations who would otherwise have not likely used any tobacco product?

This is sometimes treated as the 'silver bullet' by those favouring a ban. So let's be clear, it is almost certain that someone somewhere will use a product like smokeless tobacco who would never have used tobacco had smokeless tobacco been unavailable. It is also possible that they might go on to smoke rather than never smoke. If that was a large number of people, we should be concerned – but no evidence has ever been presented to suggest that it is. However, we do not (and cannot) conduct consumer or public policy around a protective goal of zero *individual* risk to *all* consumers – if we did, we would start by banning cigarettes, the dominant cause of disease – and ban much else. So we shouldn't take an ultra cautious approach for smokeless whilst maintaining a huge risk appetite for smoked tobacco. At the same time, we should not diminish the health benefits of using smokeless tobacco as an alternative to smoking. It is obviously inherently difficult to determine what a given individual would do differently with the absence or presence of smokeless tobacco, but the available studies do not suggest a significant 'gateway' effect luring potential never smokers into tobacco use or smoking. Ramström and Foulds. (2006) studied *Role of snus in initiation and cessation of tobacco smoking in Sweden*. The authors conclude:

> *Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker and an increased likelihood of stopping smoking.*

And the SCENIHR report states on the basis of Swedish evidence (page 116):

> *These reports suggest that in northern Sweden, the availability of snus and the way in which it has been used may have been beneficial to public health since the harm to health caused by any use of snus as a gateway into smoking may have been more than outweighed numerically by the numbers quitting smoking for snus. This observation is supported by evidence from Galanti (2008) that gateway progression from snus to smoking has not been a significant problem in Swedish young people.*

Despite raising this as a potential problem with a harm reduction approach in its conclusion (page 118), the SCENIHR actually concludes (on page 108):

> *The Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking.*

The overall point is that *no* credible evidence supports the four supposed negative consequences of smokeless tobacco availability set out in SCENIHR report and none was presented in the report. They are more like unsupported hypotheses than actual problems. I must return to the critical point – the ethics of this situation mean that the burden of proof rests with those seeking a ban to show that these effects are real and significant. *They can't show this because the negative consequences simply aren't there to be found.*

2.5 How does the EU justify continuing the ban?

Actually, the Commission doesn't even bother to engage with these arguments. Its logic is simple and astonishingly naive. For the Commission, the SCENIHR has shown that oral tobacco is harmful, therefore the ban is justified. See this 2010 press release Memo/10/220:

> *The opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008 states that snus is a harmful product. This opinion calls for a very cautious approach; there are currently no plans to lift the ban.*

And Commissioner Dalli has answered in similar terms to a question by an MEP:

> *The harmful effects of all smokeless tobacco were confirmed by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in its report of 6 February 2008 (4). In the light of this, the Commission does not see reasons to change the legal status of snus in the EU.*

This reasoning is wholly inadequate. What matters with any product is *how* harmful it is – red meat, cheese, salt, and sugar are all harmful to some extent. In the case of smokeless tobacco, there is an additional factor that doesn't apply to

other products: whether it is a viable substitute for products that are many times more dangerous. In this case it is a viable substitute, so the health impacts are likely to be *positive*. The Commission's flawed reasoning fails to address any of this. And that brings up the question of whether the ban is lawful.

3. European Union legal principles disregarded

Is the EU ban on oral tobacco lawful? No, basically. It is arbitrary, disproportionate, unjustified and violates the principles of the internal market – and therefore it is unlawful.

It may surprise some to know that the European Union cannot just write whatever laws it likes. There are established principles and laws governing law-making. A legally binding ban on oral tobacco must comply with these. The most relevant principles are the following four:

3.1 Non-discrimination or equal treatment

This widely applied principle holds that comparable situations should be treated consistently and different situations shouldn't be treated the same way unless there is a justification for equal treatment.

The existing directive and any proposal to ban oral tobacco is clearly discriminatory. The problem is evident in the definition in 2001/37/EC, which is ludicrously contrived. Oral tobacco (that covered by the ban) is: *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*. Why would you treat a product differently because it is chewed rather than sucked? Surely it's the harm that counts? If your objective was to ensure a high level of health protection, why would you end up banning low-nitrosamine snus but leaving the far more toxic African and Asian smokeless tobaccos on the market? Just to reinforce the point about how discriminatory this measure is, consider this assessment from the 2008 report of the WHO Study Group on Tobacco Regulation:

> *Cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine is the least hazardous. Among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and Asia approach those of smoking.*

The ban is clearly aimed at a contrived limited subset of smokeless tobaccos, it avoids the most hazardous form of tobacco (smoking) altogether and does not apply to the more hazardous form within the smokeless tobacco category, namely the Asian and African chewing products, which remain freely available in Europe. It's hard to design a more discriminatory approach.

3.2 Internal market

The regulation of tobacco products at EU level is primarily a measure to assist the functioning single market. The directive 2001/37/EC is not a health measure *per se* and the same will apply to the new directive. The relevant (current) treaty obligations are Article 26, Article 114, Article 207 of the Treaty on the Functioning of the European Union (previously Articles 14, 95, 133). Internal market measures are always qualified by the need to secure a high level of health protection – see Article 114(3) – and it is this that provides a basis for regulating for health standards, but with the aim of developing the internal market.

If the EU's locus on tobacco regulation is derived from completion of the single market by approximating laws, it is hard to see how banning a product that does not cause exceptional harm achieves any aims regarding the single market. The requirement to achieve a high level of health protection might be invoked, but the ban applies to the least harmful variants and there is a compelling case that the product is *beneficial for health protection* by enabling smokers to switch from cigarettes. In fact, the ban distorts an important market in harm reduction – products that smokers can use as an alternative to smoking that reduces their risk.

3.3 Proportionality

Under the principle of proportionality in Article 5 of the Treaty on European Union, the content and form of European Union action shall not exceed what is

necessary to achieve the objectives of the Treaties. It is not clear to me how a ban is a proportional way to achieve the single market. The obvious, proportional and non-discriminatory way to establish a single market in smokeless tobacco products is to regulate the toxicity of the products. This is exactly the proposal of the WHO Study Group on Tobacco Regulation in its 2009 report

- *All products that deliver nicotine for human consumption should be regulated.*
- *Smokeless tobacco products should be regulated by controlling the contents of the products.*
- *The metric for measuring toxicants in smokeless tobacco should be the amount per gram of dry weight of tobacco.*
- *Initially, upper limits should be set for two nitrosamines N-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and one polycyclic aromatic hydrocarbon, benzo[a]pyrene.*
- *The combined concentration of NNN plus NNK in smokeless tobacco should be limited to 2 µg/g dry weight of tobacco.*
- *The concentration of benzo[a]pyrene in smokeless tobacco should be limited to 5 ng/g dry weight of tobacco.*

Can standards for smokeless tobacco products ever be too tough? I think they can. The approach of regulating for toxic constituents of all smokeless tobacco products would clearly be more in keeping with developing the internal market with a high regard for health, by promoting low risk alternatives to smoking. I don't know if this proposal from WHO's experts is a good regulatory standard. In a harm reduction market, setting a regulatory standard for the lower risk product too tightly risks driving too many products off the market reducing diversity and consumer choice, and therefore uptake. It might also confine the market to a single type of smokeless tobacco, whereas the harm reduction objective may be better served by allowing different categories on the market to meet different tastes, aiming to set standards in each class that remove the worst. This is a case where the perfect can easily be the enemy of the good, and to the detriment of health overall.

3.4 Requirement to give reasons

Article 296 in the Treaty on Functioning of the European Union (previously Article 253) requires that: "*Legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties*". There are three directives addressing regulation of tobacco products: 2001/37/EC, 92/41/EEC and 89/622/EEC . The justification, set out in the 1992 directive is as follows:

> *Whereas it has been proved that smokeless tobacco products are a major risk factor as regards cancer and whereas they should therefore carry a specific warning of that risk;*
>
> *Whereas scientific experts are of the opinion that the addiction caused by tobacco consumption constitutes a danger meriting a specific warning on every tobacco product;*
>
> *Whereas, moreover, new tobacco products for oral use which have appeared on the market in certain Member States are particularly attractive to young people and whereas the Member States most exposed to this problem have already placed total bans on these new tobacco products or intend so to do;*
>
> *Whereas, regarding such products, there are differences between the laws, regulations and administrative provisions of the Member States and whereas these products therefore need to be made subject to common rules;*
>
> *Whereas there is a real risk that the new products for oral use will be used above all by young people, thus leading to nicotine addiction, unless restrictive measures are taken in time;*
>
> *Whereas, in accordance with the conclusions of the studies conducted by the International Agency for Research on Cancer, tobacco for oral use contains particularly large quantities of carcinogenic substances; whereas these new products cause cancer of the mouth in particular;*
>
> *Whereas, the sales bans on such tobacco already adopted by three Member States have a direct impact on the establishment and operation of the internal market; whereas it is therefore necessary to approximate Member States' laws, regulations and administrative provisions in this area, taking as a base a high*

> *level of health protection; whereas the only appropriate measure is a total ban; whereas, however, such a ban should not affect traditional tobacco products for oral use, which will remain subject to the provisions of Directive 89/622/EEC, as amended by this Directive, applicable to smokeless tobacco products;*

These reasons were, at best, speculative in 1992, and were asserted rather than proven. 20 years of science and insights suggest much of this is wrong (A major risk for cancer? Particularly attractive to younger people? No evidence supports either assertion). In fact the position is much more subtle than this, yet this remains the only official justification made so far. In directive 2001/37/EC, no reasons are given to support the ban in article 8, either in the preamble or anywhere else. No effort was made to check whether the arguments used in 1992 are actually right or acceptable. At no point do they reflect the reality harm reduction and the use of smokeless tobacco by smokers to quit. Nor do they reflect the experience of Sweden where smoking rates are low, and so is the burden of tobacco-related disease.

3.5 The 2004 case brought to the European Court of Justice

Some of the legal arguments above were tested in 2004 in a case (C-210/03) heard by the European Court of Justice. The snus manufacturer, Swedish Match, challenged the legality of the ban by bringing a case against the UK Secretary of State for Health, who referred the case to the ECJ. The court rejected the challenge. I don't wish to go through the judgement line by line, but there are two main reasons to believe this judgement would be different now. First, the body of new formal scientific advice and evidence discussed above would destroy much of the ECJ's 2004 reasoning. Second, the ECJ went to extreme lengths in applying a highly precautionary approach to absolute health risks without recognising the importance of relative risks and harm reduction strategies. In fact it misapplied the precautionary approach. What much of the subsequent evidence shows is that precaution actually favour lifting a ban and allowing smokers to switch to these products. It is the ban that adds risk and harm, and obstructs the functioning of the single market in tobacco with a high level of health protection.

4. What now?

The Commission, European governments and major health charities have largely been in denial about tobacco harm reduction – apparently seeing a ban on any tobacco product as progress, irrespective of the body of evidence that suggests otherwise. They have been unwilling to face the idea that banning a low-risk tobacco product might actually be a bad idea and end up killing many more people than it saves by denying them an option to reduce risk. I do not know whether it is negligence, incompetence or cynicism that leads them to do this, but I hope they will look again at the evidence and reconsider their position. Decisions like this do have lethal consequences, those advancing them are morally obliged to take a truly evidence-based approach, not the approach that is most comfortable from a PR point of view. There is an abundance of science and carefully argued reasoning for lifting the ban on smokeless oral tobacco in the EU. This is the most serious of all public health issues and most insidious driver of health inequalities – the lives of real European citizens are at stake.

Here's what I think should happen:

- The ban on smokeless oral tobacco is unjustified, illegal, harmful to health and represents a denial of consumer and human rights. It should be lifted without delay.
- The Commission, member states and elements of the public health community should not misuse the science of smokeless tobacco and harm reduction or use the SCENIHR report to justify a ban on a sub-category of smokeless tobacco. The science does not justify any ban on these products while cigarettes remain widely available and while more hazardous forms of smokeless tobacco is sold freely.
- Smokeless tobacco forms part of a 'harm reduction' market for lower risk alternatives to smoking – this could be an important market commercially in future, and if it does become sizeable, it will have considerable health benefits by reducing smoking. The EU could facilitate development of this market by setting standards for toxins present in smokeless tobacco placed on the market in the EU.
- To balance the market in favour of reduced risk products, governments should consider favourable excise tax treatment, relative to smoked tobacco, for nicotine products with greatly reduced risk, and allow

meaningful risk communication through product marketing.

- The public health community should be honest about the relative risks of smokeless tobacco and smoking, take an evidence-based approach to policy, and adjust its posture towards harm reduction strategies accordingly. It is lethally irresponsible to mislead smokers about less hazardous alternatives to smoking.

I was going to finish with my own conclusions, but I can do no better than set out the Royal College of Physicians conclusions at the end of the excellent chapter 11, *Ethics, human rights and harm reduction for tobacco users,* in its 2007 report, Harm reduction in nicotine addiction:

- *Although stopping tobacco use is the ideal outcome for individual and public health, this is often difficult to achieve. Making a wider range of safer products available would be a harm reduction approach to tobacco control.*
- *Harm reduction approaches in public health are sometimes criticised for condoning the activity they are trying to make safer. The Royal College of Physicians takes no position on the morality of smoking. However, since smoking is dangerous to health, and is hard to give up, the College wants to see a range of effective methods to help smokers quit or to reduce the harm they sustain.*
- *The present status quo, in which cigarettes are freely available, medicinal nicotine products are available but under regulations that restrict availability and effectiveness, and some smokeless tobacco products are prohibited, denies smokers the right to choose safer nicotine products.*
- *Balancing the nicotine market, so that all nicotine products are equally available and comparably priced, would provide smokers with choice but would not encourage change from high risk to lower risk products.*
- *Rebalancing the market in favour of the safest nicotine products would provide choice, encourage safer nicotine use, and reduce morbidity and mortality.*
- *The ethical aspects of regulating alternatives to smoking tobacco are complex, and three positions can be defended: maintaining the status quo, making alternatives to smoking tobacco as easily available as smoking tobacco now is, or making them more easily available than*

smoking tobacco now is.

- *Each alternative represents a balance of consumer rights, consumer protection, fairness and general policy considerations.*
- *The Royal College of Physicians favours an approach which would make smoking easier to give up, while discouraging people from starting to smoke in the first place, by making alternatives to smoking tobacco more widely available and by regulating smoking products more tightly through pricing, marketing controls and formal regulation of the production and sale of tobacco products.*

Personal statement

I don't smoke and I have never tried smokeless tobacco – I doubt I would like it or wish to be addicted to nicotine. I am not in any way affiliated with the tobacco industry and have no competing interests or hidden motives for writing this. My concern is for those who do like or need tobacco or those who continue to use it and would like to quit but find it hard. In my view, they should have all possible options available to them to reduce risks to their health from smoking. From 1997 to 2003 I was Director of the UK public health charity Action on Smoking and Health, but I have no association with the organisation now and work in an unrelated field. These are my own views and not the views of any organisation or government.