BRYAN CAVE

May 9, 2003

VIA **HAND DELIVERY**

The Honorable Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

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Re: Recent Developments : The Role of Smokeless Tobacco as a Reduced Risk Alternative to Cigarette Smoking

Dear Secretary Clark:

I am writing on behalf of U.S. Smokeless Tobacco Company ("USSTC") to submit new information regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative as compared to cigarette smoking, and that for smokers who do not quit and do not use medicinal nicotine products, a growing number of researchers advocate switching to smokeless tobacco products.

In August 2002, USSTC withdrew its February 5, 2002 Request for Advisory Opinion so that it would have the opportunity to provide the Commission with additional information from the proceedings of two upcoming scientific conferences: the *3rd International Conference on Smokeless Tobacco: Advancing Science & Protecting Public Health,* in Stockholm, Sweden; and the *4th European Conference of the Society for Research on Nicotine and Tobacco: Improving Knowledge and Treatments of Nicotine Addiction,* in Santander, Spain. In addition, several scientific articles and reports have been published since August that are relevant to a discussion of tobacco harm reduction, and specifically the role of smokeless tobacco in a comprehensive public health program. Two such publications are expected to have a major impact on the tobacco harm reduction debate. Attached is a discussion of significant new information from the scientific conferences, as well as these additional reports and other recent publications. We have also attached copies of the referenced materials.

Hong Kong
Irvine
Jefferson City
Kansas City
Kuwait
Los Angeles
New York
Overland Park
Phoenix
Riyadh
Shanghai
St. Louis
United Arab Emirates
Abu Dhabi
Dubai
Washington, DC

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Chicago

and Bryan Cave, A Multinational Partnership
London

USSTC continues to believe that a public forum would facilitate further discussion of these important issues and help to inform the public about tobacco harm reduction options. USSTC would be pleased to participate in any such forum.

We respectfully request that this letter and the attachments be placed on the public record relating to USSTC's Request for Advisory Opinion. Please feel free to contact me at (202) 508-6025, or Dana Rosenfeld at (202) 508-6032, if you have any questions concerning these matters.

Sincerely,

Daniel C. Schwartz

Attachment

cc: Chairman Timothy J. Muris
Commissioner Sheila F. Anthony
Commissioner Orson Swindle
Commissioner Mozelle W. Thompson
Commissioner Thomas B. Leary

J. Howard Beales, III, Director, Bureau of Consumer Protection
C. Lee Peeler, Deputy Director, Bureau of Consumer Protection
Joseph Mulholland, Bureau of Economics
Mary Engle, Associate Director, Division of Advertising Practices
Thomas Pahl, Assistant Director, Division of Advertising Practices
Michael Ostheimer, Division of Advertising Practices

May 9, 2003

Review of Significant New Information From Recent Scientific Conferences and Publications Relevant to USSTC's February 5, 2002 Request for Guidance from the Federal Trade Commission

I. Introduction

On February 5, 2002, U.S. Smokeless Tobacco Company ("USSTC") filed a request for an Advisory Opinion with the Federal Trade Commission ("FTC") seeking guidance regarding the acceptability of communicating in advertising that smokeless tobacco products are a significantly reduced risk alternative as compared to cigarette smoking. USSTC urged the FTC to hold a workshop, or similar public forum, to facilitate public discussion of tobacco harm reduction benefits and the appropriateness of cross-category comparative risk statements in tobacco advertising. Reacting to USSTC's request, a substantial number of comments were filed with the FTC from the public health, public policy and academic communities. During the same time period, forums and discussions on the subject were held by academic and public policy groups in several cities.

In anticipation of two scientific conferences scheduled for September 2002 in Stockholm, Sweden, and October 2002 in Santander, Spain, USSTC temporarily withdrew its request on August 12, 2002, so that USSTC could provide to the FTC additional information from those conferences.

As expected, the Stockholm and Santander conferences produced important new information relevant to USSTC's request. More meaningfully, however, two significant publications have appeared over the past few months which will have a major impact on the public debate regarding smokeless tobacco in the context of tobacco harm reduction. Those publications are a report from London's Royal College of Physicians entitled "Protecting Smokers, Saving Lives," and a white paper prepared by a group of tobacco and health

researchers and public health advocates from the United Kingdom, Sweden and Austria entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.* Also, a World Health Organization–related scientific advisory committee issued a set of recommendations relating to smokeless tobacco products in the context of tobacco harm reduction. Finally, several additional scientific publications have appeared that are relevant to USSTC's request.

Significant new information from the above-referenced scientific conferences and publications is reviewed below and copies of relevant materials are attached.

II. The Stockholm Conference

The *3rd International Conference on Smokeless Tobacco: Advancing Science & Protecting Public Health* was held in Stockholm, Sweden from September 22 through September 25, 2002. The Conference was sponsored, in part, by the Centers for Disease Control and Prevention, the National Cancer Institute, and the National Institute on Drug Abuse. Presentations were made by medical professionals, scientists and public health officials who provided participants with their perspectives on smokeless tobacco and health issues, including tobacco harm reduction. The official agenda from the Conference is attached at Tab A.

Among the presentations of particular interest were those by Professor Lynn Kozlowski of the Department of Biobehavioral Health at Pennsylvania State University, Dr. Lars M. Ramström, Director of Stockholm's Institute for Tobacco Studies, and Professor Dorothy Hatsukami of the Tobacco Use Research Center at the University of Minnesota.

A. *Ethical Issues in Using Smokeless Tobacco As a Substitute for Cigarettes; Presentation by Professor Lynn T. Kozlowski*

Professor Kozlowski's conference abstract noted his concern over ethical conflicts in the public health community. Specifically, he pointed to the tension generated by scientists' "ethical standards to not be deceptive in their representation of research findings," the "well-established human right for individuals to be provided honest health-relevant information," and "paternalistic concerns to protect the public from increased use of smokeless tobacco products, even though they are less dangerous than cigarettes to individuals." Professor Kozlowski warned that "[d]eception has arisen in claims that smokeless tobacco is just as dangerous as cigarettes (which is not true) . . . ."

The main portion of Professor Kozlowski's presentation involved a fictional conversation between "a physician and member of a leading smoking policy committee" and "a scientist with interest in human rights ethics." A transcript of the conversation was made available by Professor Kozlowski at the conference. It is entitled "First Tell the Truth: A dialogue on human rights, deception, and the use of smokeless tobacco as a substitute for cigarettes." A copy of the transcript is attached at Tab B, together with a revised version of the transcript which was recently published in *Tobacco Control*.[1] Professor Kozlowski's conference abstract, which is also attached as part of Tab B, states in part:

> Deception has arisen in claims that smokeless tobacco is just as dangerous as cigarettes (which is not true), offered in part to reduce potential, causal gateway effects, whereby youth start with smokeless products and switch to cigarettes. Public health ethics holds that clear and convincing public health risks are needed to override individual rights to honest information. Given the much reduced health risks from smokeless tobacco products in comparison with cigarettes in the United States and Sweden, it is doubtful that the public health is jeopardized by promoting these

[1] Kozlowski LT. First, tell the truth: a dialogue on human rights, deception, and the use of smokeless tobacco as a substitute for cigarettes. *Tob Control* 2003 **12**: 34-36.

products or nicotine replacement products as substitutes for cigarettes in adult smokers. Deception in public health communications should be required to meet the same ethical standards as deception in research. That is, it should not be done, no matter how well intended, if these four conditions cannot be met: (a) the deception causes no more than minimal harm, (b) rights are not violated, (c) there are no alternatives that are not deceptive, and (d) debriefing is done."

B. ***Snus as a Substitution for Smoking – The Swedish Experience; Presentation by Dr. Lars M. Ramström***

Dr. Ramström reported on a recent nationwide survey of a representative sample of 6,700 adults in Sweden sponsored by the Swedish National Institute of Public Health. According to the press summary of Dr. Ramström's presentation, the survey "has made it possible to study more in depth than before to what extent and in which ways snus (the particular kind of oral snuff manufactured and used in Sweden) serves as a substitution for smoking."[2] Copies of Dr. Ramström's press summary and conference abstract are attached at Tab C.

Dr. Ramström reports the following in his press summary:

- Prevalence of daily smoking among adult males in Sweden was 20% in 1996 and is now 15%, while the prevalence of daily use of snus among adult males was 15% in 1996 and is now 20%.

- "Primary snus users have lower rate of starting daily smoking." In support of this conclusion, Dr. Ramström cites survey data indicating that "[i]n males the overall rate of onset of daily smoking is 40%. In the rather small subgroup of males (14% of all) who have started daily snus use without previous daily smoking (primary snus users), the rate of onset of daily smoking was just half as large, 20%. This finding suggests that snus use does keep down rather than promote start of daily smoking."

- "Smoking cessation rates are higher among those (males and females) with a history of daily snus use." In support of this conclusion, Dr. Ramström cites survey data indicating that "[a]mong Ever Daily Smokers the overall rate of quitting smoking completely is 59% for males and 49% for females. Among those 'with a history of daily use of snus' 71% (same for males and females) have quit smoking completely."

[2] Ramstrom L. Press summary. Snus as a substitution for smoking – the Swedish Experience. September 25, 2002.

- "Among males snus is the most commonly used and most effective smoking cessation aid." In support of this conclusion, Dr. Ramström cites survey data indicating that "76% of male Ever Daily Smokers have made at least one attempt to quit smoking. Around 40% of the 'triers' report that at their latest attempt they have used some kind of smoking cessation aid. 36% of these males have used nicotine gum, 20% nicotine patch and 55% have used snus as a smoking cessation aid. No other kind of cessation aid has been used by as much as 10%.[3] The proportion of those who have succeeded to quit smoking completely is 50% for gum users, 34% for patch users, 65% for snus users."

C. *Smokeless Tobacco as Cesssation for Smoking; Presentation by Professor Dorothy Hatsukami*

Copies of Professor Hatsukami's conference abstract and presentation slides are attached at Tab D. Professor Hatsukami's abstract states, in part:

> Smokeless tobacco (ST) can be used in several ways as a potential harm reduction tool for cigarette smokers. These tools include ST use as a method of cessation, as a means to reduce the number of cigarettes smoked, and as a product to be used in situations where smoking is prohibited. The impact of using ST in these ways is relatively unknown. The toxicity of the product itself varies by brand of smokeless tobacco and across countries. Of the existing studies, comparisons of consequences between cigarettes and smokeless tobacco show that cigarette smoking produces more negative health effects, is likely to have a higher addiction potential and more severe withdrawal, and leads to higher rate of relapse than ST use (Hatsukami & Severson, 1999). Differences in the characteristics of ST users vs. cigarette smokers may account for some of the propensity for nicotine addiction as well as inability to sustain abstinence. Nonetheless, in general, when examining the actual user of the products, there is less potential harm associated with smokeless tobacco compared to cigarette smoking. Thus, superficially the use of ST as a cessation tool does not seem unreasonable.

[3] Dr. Ramström noted that the total exceeds 100% because some smokers used more than one aid.

III. The Santander Conference

The *4th European Conference of the Society for Research on Nicotine and Tobacco: Improving Knowledge And Treatments of Nicotine Addiction* was held in Santander, Spain from October 3 through October 5, 2002. This Conference also involved presentations by medical professionals, scientists and public health officials who discussed current research involving nicotine, tobacco cessation and prevention efforts and tobacco harm reduction. The official agenda from this Conference is attached at Tab E.

Of particular note was the presentation by Clive Bates, the former Director of the UK Action on Smoking and Health, entitled "Harm Reduction and Smokeless Tobacco." A copy of his presentation slides is attached at Tab F.

Among the points made or conclusions drawn by Clive Bates during his presentation, were the following:

- "The type of tobacco (nicotine) used can and should be a factor in controlling health impact on the individual and the population." (Original emphasis)
- "The smokeless tobacco used in U.S. and Scandinavia is one to two orders of magnitude less hazardous than cigarettes."
- "Smokeless tobacco is a credible alternative system for nicotine administration. It has several advantages over the current generation of NRT [nicotine replacement therapies]."
- "Snus is an important factor in the low smoking prevalence in Sweden. It is used for cessation and as an alternative to smoking." He cited data from a 2001 survey commissioned by the Swedish Cancer Society reporting that, among 1,000 ex-smokers, 33% used snus as a smoking cessation aid, compared to 17% who used nicotine replacement therapies.
- He also presented data from another 2001 Swedish survey which contradicts the 'gateway' hypothesis. The survey indicated that among Swedish men who were daily cigarette smokers, only 11% started with smokeless tobacco, while 48% of daily smokeless tobacco consumers started with cigarettes. Among daily users of

both smokeless tobacco and cigarettes (3% of the study population), only 23% started with smokeless tobacco.

IV. Royal College of Physicians Report

In December 2002, the Royal College of Physicians ("RCP") issued a landmark report entitled *Protecting Smokers, Saving Lives*,[4] which assessed various issues relating to future tobacco regulation in the United Kingdom.[5] A copy of the Report is attached at Tab G. The RCP is England's oldest medical institution; among its main functions is to advise the government, the public and the medical profession on health care issues.

The 2002 RCP Report recognized that tobacco harm reduction must be an essential element of any tobacco regulation program:

> A tobacco and nicotine regulatory authority should have a clear objective:
>
> *…to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users."* (Original emphasis)

The 2002 RCP Report also recognized that smokeless tobacco would be a key component of any tobacco harm reduction strategy:

> Smokeless Tobacco:
>
> As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.

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[4] Tobacco Advisory Group of the Royal College of Physicians. *Protecting smokers, saving lives*. Royal College of Physicians of London, 2002.

[5] The issuance of the RCP's 2002 Report does not mark the first time that the RCP has led the way on tobacco and health issues. In March 1962, the RCP issued a report on smoking and health which concluded that cigarette smoking caused lung cancer. Shortly after the issuance of that report, the U.S. Surgeon General, Dr. Luther L. Terry, established the Surgeon General's Advisory Committee on Smoking and Health to produce a similar report for the United States. That report was released in January 1964 and is generally referred to as the 1964 Surgeon General's Report. Its conclusions were similar to those of the 1962 RCP Report.

V. White Paper on European Union Smokeless Tobacco Policy

In February 2003, a group of tobacco and health researchers and public health advocates from the United Kingdom, Sweden and Austria published a white paper entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.*[6] A copy of the white paper is attached at Tab H. The authors recommend that the current European Union ban of smokeless tobacco be replaced with a regulatory program based on the recognition that smokeless tobacco is substantially less harmful than cigarette smoking and could play a significant role in tobacco harm reduction. The group summarized the "public health case" favoring smokeless tobacco as follows:

> We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union 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. (Original emphasis)

Among other points made in the white paper are the following:

> 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 COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If

[6] Bates C, Fagerstrom K, Jarvis M, Kunze M, McNeill A, Ramstrom L. *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health*. February 2003.

> 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.
>
> * * *
>
> 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 suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking.* In a spectrum of risk, snus is *much* closer to NRT [nicotine replacement therapy] than it is to cigarette smoking. (Original emphasis)

VI. WHO Scientific Advisory Committee Recommendation

In February 2003, the World Health Organization–related Scientific Advisory Committee on Tobacco Product Regulation ("SAC") voiced a dissenting view on the use of smokeless tobacco as a means of tobacco harm reduction when it issued a document entitled *Recommendation on Smokeless Tobacco Products*[7] (the "SAC Recommendation"). A copy of the SAC Recommendation is attached at Tab I. It is interesting to note that, unlike the authors of the RCP report and the European Union white paper discussed above, the authors of the SAC Recommendation do not identify themselves in their publication.

The SAC Recommendation acknowledges that "[t]here is an ongoing debate in the public health community about the potential for smokeless tobacco, especially snus manufactured in

[7] WHO Scientific Advisory Committee on Tobacco Product Regulation. *SACTob Recommendation on Smokeless Tobacco Products*. World Health Organization, Geneva, 2003.

Sweden, to be used as a substitute for smoking as part of a harm reduction strategy." The SAC recommendation goes on to state that "[t]his is being advocated by some on the premise that the range of health conditions potentially caused by smokeless tobacco is smaller than that caused by smoked tobacco." Although it never disputes the view that smokeless tobacco products used in the United States and Sweden involve substantially less risk of adverse health effects than cigarette smoking, the SAC Recommendation states that:

> There are several reasons that argue against endorsing the use of smokeless tobacco products for the purpose of harm reduction. They are as follows:
>
> *Benefits have not been demonstrated*
>
> - Smokeless tobacco products have not been shown to be more effective smoking cessation aids than other cessation strategies
> - It has not been shown that people substitute smokeless tobacco for smoking or that they will not relapse to smoking
> - Smoking prevalence has not been shown to be decreased by substitution of smokeless tobacco for smoking
>
> *Potential for harm exists*
>
> - Promoting smokeless tobacco products may encourage individuals to adopt smokeless tobacco use in addition to continuing smoking
> - Use of smokeless tobacco products has been reported to increase the chances of subsequent initiation of smoking
> - People who may have quit tobacco use altogether will not do so
> - Children who might not have started smoking may start smokeless tobacco use
> - Health effects from the use of smokeless tobacco products remain unclear, and the potential for long term harm cannot be ruled out
> - All smokeless tobacco products are addictive

These assertions are either contradicted by empirical data, are totally unsupported, or (in the case of the last two points made under the heading "Potential for harm exists"), even if accepted as accurate, they do not negate the conclusion supported by a growing body of scientific literature that smokeless tobacco use involves substantially less risk of adverse health effects than cigarette smoking.

With respect to the three assertions made under the caption "Benefits have not been demonstrated," each of these points is refuted by empirical evidence, including the survey data from Sweden presented by Dr. Lars Ramström at the Stockholm Conference which is discussed above. That data provide evidence that smokeless tobacco products have been shown to be more effective smoking cessation aids than medicinal nicotine products, that Swedish adults have substituted smokeless tobacco for cigarette smoking and have not relapsed to smoking, and that smoking prevalence in Sweden decreased as a result of the substitution of smokeless tobacco for cigarette smoking. Additional empirical evidence refuting these assertions is contained in Clive Bates' Santander Conference presentation referenced above, and in the recent publications by Rodu, et al. and Ault and Ekelund discussed below. With respect to the first four assertions made under the caption "Potential for harm exists," these are the type of statements that Clive Bates has stated amount to "what ifs" about possible unintended consequences that "are a possibility – but easily overstated" (see slides from Clive Bates' presentation at the Santander Conference in Tab F).

Two of the actual "recommendations" contained in the SAC Recommendation require comment. They are as follows:

> 1. Current evidence does not indicate that use of any smokeless tobacco is free of health risks. Therefore, any such health claim is presently untenable and should not be permitted.

2. There is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy. Marketing of smokeless tobacco products with harm reduction claims should not be permitted unless validated by an independent regulatory authority on review of evidence to be submitted by the manufacturer.

The first "recommendation" obfuscates the real issue. Neither USSTC, nor any member of the public health community, seeks to assert that the use of smokeless tobacco is "safe." As Professor Kozlowski stated at the *8th Annual Meeting of the Society for Research on Nicotine and Tobacco* in February 2002, "it's a nonsequitor to say 'the truth is that smokeless tobacco use is connected with all sorts of problems.' To charge a safer product is 'not safe' evades the question. The question is, 'how much safer is it?'"

As to the second "recommendation," the assertion that "there is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy" is belied by the substantial number of scientific publications referenced in USSTC's February 5, 2002 submission and in subsequent submissions. As to the need for "an independent regulatory authority" to validate harm reduction claims relating to smokeless tobacco products, USSTC addressed that issue in its submission to the FTC dated July 26, 2002 (see pp. 8-9). In short, the FTC has the authority to deal with this issue.

VII. Other Significant Scientific Publications

In addition to the scientific conference presentations and publications discussed above, four other significant scientific publications have appeared recently that are relevant to USSTC's request. Those publications are summarized below.

Drs. Richard W. Ault and Robert B. Ekelund, Jr., economists from Auburn University, published an analysis in 2002 of the personal costs and benefits of smoking cessation entitled

The Personal Economics of Smoking Cessation.[8] A copy of their article is attached at Tab J. The authors assessed the costs and benefits of six "smoking cessation techniques": self-help, behavioral modification, nicotine gum, nicotine patches, Zyban (an anti-depressant medication) and smokeless tobacco. Among the conclusions reached by Drs. Ault and Ekelund, were the following:

> The central conclusion is that beyond any health benefits, peace of mind, or greater quality of life, *it pays to quit smoking*! This is true whether benefits are considered in the short run or in the long run. Manifestly, an enormous effort has been undertaken to reduce smoking in the United States. The U.S. Surgeon General's extensive report *Reducing Tobacco Use* (2000) is symptomatic of this effort among public health officials. The report, which presents its own estimates of quit rates (2000: Table 4.3: 114) from a multiplicity of studies (Fiore et al., 2000), suggests that the war on smoking has not been won, especially with hard-core cases.
>
> * * *
>
> As noted in this study, smokeless tobacco shows a high quit rate (bested only by Zyban in Table 2) and a high net benefit vis-à-vis other techniques both in the short and in longer runs. For heavily addicted smokers, moreover, it is not clear that further progress will be made with more standard techniques. For these and other smokers, smokeless tobacco should clearly be considered as a viable alternative. The failure to present smokeless tobacco and long-term use of nicotine replacement therapies as alternatives to smoking comes from a fear of recommending any therapy that has any harmful health consequences. However, there is no logic for arguing against a therapy that results in a net reduction in harm and economic costs.

Rodu, et al., published a paper in late 2002 entitled *Impact of smokeless tobacco use on smoking in northern Sweden*,[9] in which they examined the prevalence and interaction of cigarette smoking and smokeless tobacco use in northern Sweden. A copy of the paper is attached at Tab K. Rodu, et al. analyzed data on a cohort of approximately 6,000 men and women, aged 25 to

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[8] Ault RW, Ekelund RB. The personal economics of smoking cessation. *J Family Consumer Sci* 2002; 94: 41-49.

64, in northern Sweden derived from population surveys conducted in 1986, 1990, 1994 and 1999. The authors reported the following results and conclusions:

> **Results**. Amongst men ever-tobacco use was stable in all survey years at about 65%, but the prevalence of smoking declined from 23% in 1986 to 14% in 1999, whilst snus use increased from 22% to 30%. In women the prevalence of smoking was more stable in the first three surveys (~27%) but was 22% in 1999, when snus use was 6%. In all years men showed higher prevalence of ex-smoking than women. A dominant factor was a history of snus (PR = 6.18. CI = 4.96-7.70), which was more prevalent at younger ages. **Conclusions**. The recent transition from smoking to snus use amongst men, and incipiently amongst women, in northern Sweden is remarkable and relevant to the global discussion on strategies to reduce smoking.

Also in late 2002, Dr. K. Michael Cummings of the Roswell Park Cancer Institute published an analysis entitled *Programs and policies to discourage the use of tobacco products.*[10] A copy of the paper is attached at Tab L. One conclusion reached by Dr. Cummings is that the regulation of "nicotine delivery products" on the basis of comparative health risk would lead to a rapid reduction in the health toll caused by cigarette smoking:

> Up to now, government policies have actually hindered the development and marketing of less harmful alternatives to conventional cigarettes (Warner *et al.*, 1997; Jha *et al.*, 2000). If all nicotine products were regulated on the basis of their risk of causing health problems, nicotine medications would be the least regulated while cigarettes would be the most heavily regulated. Ironically, just the opposite has occurred with nicotine medications carefully regulated by governments while cigarettes have escaped regulatory control (Warner *et al.*, 1997; Sweanor, 2000; Stratton, *et al.*, 2001). Developing a rational basis for regulating nicotine delivery products on the basis of harm would appear to hold great promise for achieving a rapid reduction in the health toll caused by cigarettes (Kozlowski *et al.*, 2001).

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[9] Rodu B, Stegmayr B, Nasic S, Asplund K. Impact of smokeless tobacco use on smoking in northern Sweden. *J Intern Med* 2002; **252**: 398-404.

[10] Cummings KM. Programs and policies to discourage the use of tobacco products. *Oncogene* 2002; **21**: 7349-7364.

With respect to smokeless tobacco in the context of tobacco harm reduction, Dr. Cummings had the following to say:

> Amazingly, many smokers don't perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes (Cummings, 2002). Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as pretty minor compared to the difference in disease risk between smoked and smokeless products. Until smokers are given enough information to allow them to chose [sic] products because of lower health risks, then the status quo will likely remain (Wilkenfeld *et al.*, 2000; Cummings 2002c).

Finally, in its July 26, 2002 submission to the FTC, USSTC provided a copy of a commentary by Professor Kozlowski, which was then "in press," entitled *Harm reduction, public health and human rights: Smokers have a right to be informed of significant harm reduction options*.[11] That commentary has now appeared in published form in *Nicotine and Tobacco Research*, and a copy is attached at Tab M.

[11] Kozlowski LT. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Res* 2002; **4 Suppl 2**: 55-60.

VIII. Conclusion

The scientific conference presentations and publications summarized above provide significant additional support for the conclusions reached in Attachment A to USSTC's February 5, 2002 request for an advisory opinion. In particular:

1. Smokeless tobacco products have a significant and legitimate role to play in a public health strategy aimed at tobacco harm reduction.

2. There is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

3. There is growing support in the public health community for including smokeless tobacco as a component of a comprehensive tobacco harm reduction strategy by encouraging those cigarette smokers who do not quit and do not use medicinal nicotine products to switch to smokeless tobacco products.

Tab A

Stockholm • Sweden

September 22-25, 2002

3rd International Conference on Smokeless Tobacco

Advancing Science & Protecting Public Health

Agenda

(Subject to Change)

Sunday, September 22, 2002

1300 hrs (1:00 p.m.)	Registration	*Auditorium Foyer*
1400 hrs (2:00 p.m.)	Exhibit Session Setup	*Gallerian*
	Poster Session Setup	*Platon-Sokrates*
1800 hrs (6:00 p.m.)	Informal Icebreaker Social	*Panorama*

Sponsored by: *Centre for Tobacco Prevention*
GlaxoSmithKline
Novartis
Pharmacia

Hans Gilljam
Centre for Tobacco Prevention
Stockholm, Sweden

Sponsoring Organization Exhibits/Materials Display — *Gallerian*
(open for viewing for the duration of the conference)

Centers for Disease Control and Prevention
FDI World Dental Federation
GlaxoSmithKline
National Cancer Institute
National Institute on Drug Abuse
Novartis
Oral Health America
Pharmacia

Monday, September 23, 2002

0730 hrs (7:30 a.m.) — Registration Desk — *Auditorium Foyer*

0830 hrs (8:30 a.m.) — Opening Remarks — *Auditorium*

Samira Asma
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Hans Gilljam
Centre for Tobacco Prevention
Stockholm, Sweden

Scott Leischow
National Cancer Institute
Bethesda, Maryland, USA

Keynote Address

Gunnar Ägren
Director General
Swedish National Institute of Public Health
Stockholm, Sweden

Outline of the Conference

Cathy Backinger
National Cancer Institute
Bethesda, Maryland, USA

Michelle Roland
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

0930 hrs (9:30 a.m.) — *Break*

1000 hrs (10:00 a.m.) — Global Perspective of Smokeless Tobacco Use — *Auditorium*

Moderator:

Prakash Gupta
Tata Institute of Fundamental Research
Mumbai, Maharashtra, India

European Experience

Seppo Wickholm
Centre for Tobacco Prevention
Stockholm, Sweden

Africa and the Middle East

Ahmed E.O. Ogwell
Oral and Craniofacial Research Associates
Nairobi, Kenya

Asia and the Pacific

Mihir N. Shah
Government Dental College and Hospital
Gujarat State, India

Americas

Ricardo Granero
ASCARDIO
Barquisimeto, Venezuela

Alaska and the Arctic Region

To Be Determined

Migrant Populations

Shahid Anwar
Leeds Dental Institute
Leeds, England

Discussant:

Saman Warnakulasuriya
King's College London
London, England

1200 hrs (12:00 noon) — *Lunch Buffet* — *Panorama*

Poster Session — *Platon-Sokrates*
(1200 – 1245 presentations; 1245 – 1330 viewing only)

1330 hrs (1:30 p.m.) — Smokeless Tobacco Addictions — *Auditorium*

Moderator:

Karl-Olov Fagerström
Fagerström Consulting AB
Smokers Information Centre
Helsingborg, Sweden

Dynamics of Nicotine Addictions

Jack Henningfield
Pinney Associates
Bethesda, Maryland, USA

Addiction at the Micro Level

Torgny Svensson
Karolinska Institutet
Stockholm, Sweden

"Snus" Uptake In Youths: Trajectories and Determinants

Maria Rosaria Galanti
Centre for Tobacco Prevention
Stockholm, Sweden

Behavioral "Toxicology" of Chronic Nicotine: Consequences of Nicotine-Induced Behavioral Disinhibition

Bo Söderpalm
Göteborg University
Göteborg, Sweden

Discussant:

William Corrigall
National Institute on Drug Abuse
Bethesda, Maryland, USA

Monday, September 23, 2002 (continued)

1500 hrs (3:00 p.m.) — *Break* — *Auditorium Foyer*

1530 hrs (3:30 p.m.) — Health Effects of Smokeless Tobacco Use — *Auditorium*

Session Sponsored by: The Swedish Heart Lung Foundation

Moderator:

Newell Johnson
GKT Dental Institute
London, England

Neoplasms and Cancer

Olof Nyren
Karolinska Institutet
Stockholm, Sweden

Cardiovascular Health Effects of Smokeless Tobacco Use

Gunilla Bolinder
Karolinska Hospital
Stockholm, Sweden

Pregnancy and Reproductive Outcomes

Prakash Gupta
Tata Institute of Fundamental Research
Mumbai, Maharashtra, India

Oral Health Effects of Smokeless Tobacco Use

Maria Teresa Canto
National Institute of Dental and
Craniofacial Research
Bethesda, Maryland, USA

Moist Snuff Use and Risk of Type 2 Diabetes

Claes-Göran Östenson
Karolinska Hospital
Stockholm, Sweden

Discussant:

Deborah Winn
National Cancer Institute
Bethesda, Maryland, USA

1700 hrs (5:00 p.m.) — *Recess*

1800 hrs (6:00 p.m.) — Evening Event — *Auditorium*

Stockholm City Hall Reception and Dinner

Björn Klinge
Karolinska Institutet
Huddinge, Sweden

Hosted by: *City of Stockholm*
Stockholm County Council

Tuesday, September 24, 2002

0730 hrs (7:30 a.m.) — Registration Desk — *Auditorium Foyer*

0830 hrs (8:30 a.m.) — Worldwide Marketing of Smokeless Tobacco — *Auditorium*

Michelle Roland
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Industry Marketing and Public Perceptions

Moderator:

Örjan Åkerberg
Region Västra Götaland
Mariestad, Sweden

Swedish Snus

Paul Nordgren
Swedish National Institute of Public Health
Stockholm, Sweden

Smokeless Tobacco Marketing and Public Perception In India

Surendra Shastri
Tata Memorial Hospital
Mumbai, India

A Safer Form of Arsenic?
The Dynamic Marketing History of Smokeless Tobacco

Alan Blum
Center for the Study of Tobacco and Society
University of Alabama
Tuscaloosa, Alabama, USA

Traditional Products Versus Tobacco Industry Products

Ali M. Idris
Toombak and Smoking Research Centre
Khartoum, Sudan

Discussant:

Gregory Connolly
Massachusetts Department of Public Health
Boston, Massachusetts, USA

1000 hrs (10:00 a.m.) — *Break* — *Auditorium Foyer*

1030 hrs (10:30 a.m.) — Concurrent Sessions

I. Smokeless Tobacco Surveillance — *Auditorium*

Moderator:

Terry Pechacek
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

1. #### Global Youth Tobacco Surveillance–Office on Smoking and Health, Centers for Disease Control and Prevention

   Wick Warren
   Centers for Disease Control and Prevention
   Atlanta, Georgia, USA

2. School Students: Global Youth Tobacco Survey

Ricardo Granero
ASCARDIO
Barquisimeto, Venezuela

3. Youth Tobacco Surveillance of Northeastern States of India, 2001

Dhirendra Sinha
School of Preventative Oncology
Patna, India

4. Smoking Prevalence and Tobacco/Swedish "Snus" Sales in Sweden, Norway, Denmark, and Finland, 1970 to 2000

Brian Wicklin
Statistical Bureau, VECA
Hässelby-Stockholm, Sweden

5. A Prospective Longitudinal Study of Tobacco Habits Among Ice-Hockey Playing Boys

Margot Rolandsson
Karlstad University
Karlstad, Sweden

6. Patterns of Tobacco Use in Northern Sweden: Interaction Between Smoking and Snus Use in Northern Sweden

Brad Rodu
University of Alabama at Birmingham
Birmingham, Alabama, USA

II. Health Effects — *Platon*

Moderator:

Anja Ainamo
University of Helsinki
Helsinki, Finland

1. Epstein-Barr and Human Papilloma Virus in Snuff-Induced Lesions of the Oral Mucosa

Lars Sand
Uppsala Adademiska Sjukhus
Uppsala, Sweden

2. Snuff-Induced Cancer in Sweden

Jan M. Hirsch
Uppsala University and Public Dental Health
Uppsala, Sweden

3. Habit of Chewing or Smokeless Tobacco Habits in Pakistan and Associated Oral Lesions

Rehana Maher
Sinah Post-Graduate Medical Centre
Karachi, Pakistan

4. Lung Cancer in Europe: The Polish and Swedish Experiences

Witold Zatonski
The Maria Sklodowska-Curie Memorial
Cancer Center and Institute of Oncology
Warsaw, Poland

5. How One Smokeless Tobacco Manufacturer Designed Their Products To Cause Addiction Among Youth

Gregory Connolly
Massachusetts Department of Public Health
Boston, Massachusetts, USA

III. Interventions/Health Promotion — *Sokrates*

Moderator:

Karl-Olov Fagerström
Fagerström Consulting AB
Smokers Information Center
Helsingborg, Sweden

1. Sports Venues as a Tool for Spit Tobacco Education and Public Awareness

Paul Turner
National Spit Tobacco Education Program
Oral Health America
Chicago, Illinois, USA

2. Smokeless Tobacco and Children In India: Prevention Through Entertainment

Padmini Somani
Salaam Bombay Foundation
Nariman Point, Mumbai, India

3. Tobacco Knowledge–Smoking and Snuff Cessation: A Part of the New Curriculum in Dental Hygienist Education, at The Karolinska Institutet

Birgitta Söder
Karolinska Institutet
Huddinge, Sweden

4. Intervention in Smokeless Tobacco Use Among the Rural Indian Population

Mira Aghi
Independent Consultant
New Delhi, India

5. Tobacco Use–Economic Consequences on Vulnerable Populations

   Shoba John
   CPAA, King George V Memorial
   Mumbai, Maharashtra, India

6. A Snuff-Dipping Cessation Program for Snuff Dippers With Long and Extensive Snuff Exposure

   Mats Wallström
   Göteborg University
   Göteborg, Sweden

1200 hrs (12:00 noon) — *Lunch Buffet* — *Panorama*

Exhibits and Poster Session Displays (viewing only) — *Gallerian*

1330 hrs (1:30 p.m.) — Regional and Global Policy Interventions — *Auditorium*

Moderator:

Anja Ainamo
University of Helsinki
Helsinki, Finland

European Legislation and Smokeless Tobacco

Kari Paaso
Commission Europeenne
Plateau de Kirchberg, Luxembourg

The Irish Legislative Precedent

Cathy Backinger
National Cancer Institute
Bethesda, Maryland, USA

(Presenting for Bernard McCartan, Trinity College, Dublin, Ireland)

Framework Convention on Tobacco Control (FCTC)

Vera Luiza da Costa e Silva
World Health Organization
Geneva, Switzerland

Regulatory Issues – Who Gets To Call The Shots: The Case of the United States Smokeless Tobacco Company and the Federal Trade Commission

Judith Wilkenfeld
Campaign for Tobacco-Free Kids
Washington, D.C., USA

Discussant:

Mitch Zeller
Consultant
Olney, Maryland, USA

1500 hrs (3:00 p.m.) — *Break* — *Auditorium Foyer*

1530 hrs (3:30 p.m.) — Smokeless Tobacco Cessation — *Auditorium*

Moderator:

Margaret Walsh
University of California, San Francisco
San Francisco, California, USA

Economic Interventions

Ayda Yurekli
World Bank
Washington, D.C., USA

Pharmacotherapy

Elbert D. Glover
West Virginia University School of Medicine
Morgantown, West Virginia, USA

Smokeless Tobacco Cessation for Adults: A Review and Research Agenda

Herbert Severson
Oregon Research Institute
Eugene, Oregon, USA

Youth Cessation

Aira Lahtinen
Finnish Dental Association
Espoo, Finland

Telephone Interventions: Snus Not A Significant Contributor to Abstinence from Smoking Amongst Quit-Line Callers in Sweden

Asgeir R. Helgason
Centre for Tobacco Prevention
Stockholm, Sweden

Discussant:

Jon O. Ebbert
Mayo Clinic
Rochester, Minnesota, USA

1700 hrs (5:00 p.m.) *Recess*

1800 hrs (6:00 p.m.) Evening Events *Auditorium*

Stockholm Tobacco and Match Museum Tour and Dinner at the Vasa Museum

Sponsored by: *Centre for Tobacco Prevention*
GlaxoSmithKline
Novartis
Pharmacia

Wednesday, September 25, 2002

0730 hrs (7:30 a.m.) — Registration Desk — *Auditorium Foyer*

0830 hrs (8:30 a.m.) — Smokeless Tobacco Products Chemistry and Constituents — *Auditorium*

Moderator:

Mirjana Djordjevic
National Cancer Institute
Bethesda, Maryland, USA

Overview

Mirjana Djordjevic
National Cancer Institute
Bethesda, Maryland, USA

Toombak and Snus

Ali Idris
Toombak and Smoking Research Center
Khartoum, Sudan

Smokeless Tobacco Prevalence Among School Personnel in India

Prakash Gupta
Tata Institute of Fundamental Research
Mumbai, Maharashtra, India

New Smokeless Tobacco Products

Gregory Connolly
Massachusetts Department of Public Health
Boston, Massachusetts, USA

Carcinogenicity of Smokeless Tobacco

Joseph Guttenplan
New York University Dental and Medical Schools
New York, New York, USA

Discussant:

Scott Tomar
University of Florida College of Dentistry
Gainesville, Florida, USA

1000 hrs (10:00 a.m.) — *Break* — *Auditorium Foyer*

1030 hrs (10:30 a.m.) — Reducing Risk/Harm? Science, Ethics, and Public Health — *Auditorium*

Moderator:

Harri Vainio
International Agency for Research on Cancer
Lyon, France

Swedish Snus and U.S. Moist Snuff: Oral Health Effects

Scott Tomar
University of Florida College of Dentistry
Gainesville, Florida, USA

Swedish Snus and U.S. Smokeless Tobacco Relationship to Cancer

Deborah Winn
National Cancer Institute
Bethesda, Maryland, USA

Smokeless Tobacco in Harm Reduction Strategies

Clive Bates
Action on Smoking and Health
London, England

Smokeless Tobacco as a Substitute for Cigarettes

Gregory Connolly
Massachusetts Department of Public Health
Boston, Massachusetts, USA

Ethical Issues in Using Smokeless Tobacco as a Substitute for Cigarettes

Lynn Kozlowski
Penn State University
University Park, Pennsylvania, USA

Snus as a Substitution for Smoking: The Swedish Experience

Lars Ramström
Institute for Tobacco Studies
Stockholm, Sweden

Smokeless Tobacco as Cessation for Smoking

Dorothy Hatsukami
University of Minnesota
Minneapolis, Minnesota, USA

1200 hrs (12:00 noon) — *Lunch (on your own)* — *(See venues)*

1330 hrs (1:30 p.m.) — *Auditorium*

Discussants' Responses to Reducing Risk/Harm Presentations

Moderator:

Scott Leischow
National Cancer Institute
Bethesda, Maryland, USA

Discussants:

Gunilla Bolinder
Karolinska Hospital
Stockholm, Sweden

Prakash Gupta
Tata Institute of Fundamental Research
Mumbai, Maharashtra, India

David Sweanor
Non-Smokers' Rights Association
Ottawa, Ontario, Canada

Wednesday, September 25, 2002 (continued)

1500 hrs (3:00 p.m.)

Where Do We Go From Here? Developing a Research Agenda

Moderator:

Hans Gilljam
Centre for Tobacco Prevention
Stockholm, Sweden

Smokeless Tobacco Use and Terminology

Ali Idris
Toombak and Smoking Research Center
Khartoum, Sudan

Smokeless Tobacco Health Effects

Maria Teresa Canto
National Institute of Dental and Craniofacial Research
Bethesda, Maryland, USA

Smokeless Tobacco Cessation Methods

Karl-Olov Fagerström
Fagerström Consulting AB
Smokers Information Center
Helsingborg, Sweden

Smokeless Tobacco and Risk/Harm Reduction Strategies

Dorothy Hatsukami
University of Minnesota
Minneapolis, Minnesota, USA

Smokeless Tobacco and Public Health Measures

Robert Mecklenburg
Consultant
Potomac, Maryland, USA

Smokeless Tobacco Chemistry and Constituents

Scott Tomar
University of Florida College of Dentistry
Gainesville, Florida, USA

Smokeless Tobacco Surveillance and Epidemiology

Witold Zatonski
The Maria Sklodowska-Curie Memorial Cancer Centre and Institute of Oncology
Warsaw, Poland

1645 hrs (4:45 p.m.)

Closing Remarks

Robert Mecklenburg
Consultant
Potomac, Maryland, USA

1715 hrs (5:15 p.m.)

Next Steps for the 12th WCTOH

Cathy Backinger
National Cancer Institute
Bethesda, Maryland, USA

1730 hrs (5:30 p.m.)

Adjournment

Tab B

First Tell the Truth:

A dialogue on human rights, deception, and the use of smokeless tobacco as a substitute for cigarettes

By: Lynn T. Kozlowski, Ph. D.
Department of Biobehavioral Health
Penn State University

Cast: **1:** A physician and member of a leading smoking policy committee
2: A scientist with interest in human rights ethics

Setting: Private room at a conference. These two colleagues have been allied for many years. Today they have been arguing in public. Neither is at ease. The argument starts up again.

1: You don't know what you're doing. You need to stop. We need one message. The industry just loves the public display you put on today.

2: You're too full of yourself. Too secure in your opinions of what should and shouldn't be done.

1: You don't understand how your position can be used against us.

2: Science without scientific integrity is propaganda--public relations. You're so caught up in trying to be a "policy" hero that you forget your scientific roots. We must never censor or manipulate results. In your policy world, scientists are dishonest when they don't conform to the prevailing policy.

1: Science is not our only context. Far from it . . . . Don't imagine that any part of the tobacco industry is committed to public science or fair play with us or their victims. The tobacco industry as a whole are paid killers. They kill for money. They know there is no such thing as a safe tobacco product that will sell well. Their secret documents--the ones we have seen--show an industry that is no friend of the public health.

2: I'll say openly to anyone—you, the press, a consumer, a legislative committee--that (a) smokeless tobacco products in the U.S. and Sweden are safer than cigarettes to individual users and (b) smokeless could be used to substitute for cigarettes in smokers who won't otherwise quit.

1: I will say openly that the Surgeon-General has determined that "smokeless tobacco is not a safe alternative to cigarettes." That's our message. No tobacco products are safe. Smokeless tobacco is not a safe product, and the companies have not generally done all they might do to reduce toxins.

2: A big Volvo sedan is not a "safe alternative" to a small sports car, but it is "safer." A product can be both safer and not safe. Smokeless does not cause lung cancer or other lung disease (emphysema). Smokeless is certainly at least 60% less deadly than cigarettes and could be 90 to 99% less deadly than cigarettes. These are big differences.

1: Smokeless does cause debilitating oral disease . . . causes deadly oral cancer. I have seen a young man's whole jaw lost to cancer. His complete lower face a shriveled monstrosity. You don't forget that. You don't recommend a product that can do that.

2: Which "product" are you talking about--cigarettes or smokeless? User for user, cigarettes cause even more, deadly oral disease than does smokeless. Public policy should care more for the deaths of the many than for the tragic images of the few.

1: Smokeless is not a safe product! It is addictive! Their intent is not harm reduction. They build smokeless products so that users can progress to stronger and stronger hits of nicotine. It contains known carcinogens! As a physician, my professional ethics say "do no harm." DO NO HARM! As a physician, I could never recommend that someone expose themselves to carcinogens.

2: "Do no harm" is a public relations slogan, not an ethical principle. So, as a physician, you don't prescribe drugs that can kill with their side-effects--liver toxicity, GI bleeding?

1: I would expect the anti-tobacco lawyers would be lining up to sue us, if we made health claims for any dangerous tobacco products. I could get sued! You won't catch me advocating the use of a dangerous product.

2: Advocating a dangerous product? My statement about smokeless being safer than cigarettes is not, in and of itself, "advocating" smokeless for harm reduction. You could have many reasons to be against substituting smokeless for cigarettes--but one reason should not be because the product doesn't reduce risk to individual users.

1: You're saying exactly what the industry wants to hear. You come off sounding like you're in bed with the industry. You're playing into the hands of a sleazy group that prefers profits to public health. These peddlers of addiction and death love your human rights rhetoric. But breathless prose about rights doesn't get the job done to protect the public--protect our children. It's damn naive to wave the banner of personal autonomy, cry out for human rights to honest information and for human rights to "informed consent." We are on a battlefield with a vile, unscrupulous enemy. Your ethical rhetoric is unethical and will kill people.

2: Who likes or dislikes an idea has nothing to do with its truth-value. If smokeless is safer than cigarettes (and it is), our policy should consider that, rather than deny it.

1: If I accept that smokeless may be less dangerous to individuals, then you should also accept that smokeless can be more dangerous to society as a whole. If more people start using a less dangerous product, this product can be worse for public health . . . .We can restrict human rights (quarantine an individual), to protect the public health. Public health experts have a responsibility to protect the public.

2: But just how big are these risks? . . . . the "risk/use equilibrium" shows that once risk is reduced greatly, it is far-fetched to suppose that the numbers of users can ever increase so much that there will be net public health loss. Your knee-jerk concern that there might be greater overall harm is a primitive and partial kind of policy assessment. Effect-size does matter! Another reason to be honest about estimating levels of risk. To defeat individual rights, there must be clear and convincing danger to society. A far-fetched, implausible risk is not "clear and convincing evidence."

1: You talk about "informed consent" and "right to information." But what about the young. Children are below the age of consent. Children become nicotine addicted before the age of consent. Children need our special protection--surely "paternalism" is not a bad word when protecting children. Smokeless is a gateway drug. Smokeless is a known gateway to cigarettes. If we don't say smokeless is just as dangerous as cigarettes, we are not doing all that we can to stop kids from using smokeless.

2: Lying about levels of risk to scare kids in health communication is still lying and deception, no matter how worthy your intent. The Federal rules against deception in research should also apply to public health messages.

1: You can be such a goody-goody. Federal rules against deception?

What are you on about? Do you expect that health educators or physicians--when they tell a caring lie--should go to the Institutional Review Board to get permission?

2: Even a "caring lie" robs individuals of autonomy, steals from them the opportunity to choose. The U.S. Government says that deception in research is not allowed unless four conditions can be met. First, the deception should not add risk.

1: Add risk? How does trying to scare kids away from smokeless add to anyone's risk?

2: Some kids are into high-risk activities. For these kids, your lie removes a reason to not become a smoker! Lying to them about the deadliness of smokeless and cigarettes could encourage the move from smokeless to cigarettes. You don't know if the lie "does no harm."

1: I believe that if we don't tell kids that smokeless is just as dangerous as cigarettes, they will take up smokeless and the gateway effect will move them on to cigarettes. Imagine the righteous complaints from parents if the public health movement doesn't do all it can to protect our children.

2: The scientific evidence for a true causal gateway effect is slight. Most users of smokeless cannot be gateway users: About 3 in 4 of those who use smokeless cannot be "gateway users," in that they either never go beyond smokeless to cigarettes or they started using cigarettes before they started using smokeless.

1: How can you propose we practice science outside of the formal sanctions of science-based governmental regulation? Our drug regulatory systems have helped create modern pharmaceutical products that must have years of testing--at the manufacturer's expense--before they can be sold. And they are subject to post-marketing surveillance and strict controls.

2: A scientist should not first look at what answers the regulatory authorities prefer to see, before making judgments. There is no doubt that smokeless products in Sweden and the U.S. are significantly less deadly than cigarettes. Yet, we have government web-pages mistakenly "educating" the public that cigarettes and smokeless are equally deadly.

1: Approved, tested, and pure medicinal nicotine products might be used for cigarette harm reduction. But we need strong governmental drug regulation to protect the public of all ages, before advocating use of smokeless.

2: Yes, we do need strong regulations to see smokeless products--with required minimum toxicity--marketed in ways that might best benefit the public health.

1: It is not "free choice" or "informed consent" or "personal autonomy" when nicotine addicts are duped by slick ads, product placements, sponsorships, and promotional tricks. These smokeless ads won't care if you quit smoking. They will promote the use of smokeless when it is inconvenient to smoke. They will target children, not just the 50 year-old smoker.

2: You don't have to lie about the basic facts, to be against unethical marketing practices! Being deceptive and evasive about the facts is a twisted way for scientists to try to deal with unethical marketing. Marketing practices need to be controlled.

1: Can you show me one scrap of *scientific* evidence that smokeless tobacco products can even substitute effectively for cigarettes? I can think of only one limited study--and that was industry-funded.

2: I don't expect that you would support NIH funding for such a project .... Do you really believe that studies are needed to show that traditional smokeless tobacco products can substitute for cigarettes? Smokeless users say so. The phenomenon of nicotine addiction says so. There are many "cases"--workplaces--where smokeless has been used when cigarettes cannot be. If cigarettes can substitute for smokeless in your gateway model, why not vice versa?

1: You call for human rights. I call for scientific evidence. We need effective, science-based, governmental drug regulation or I am not going to say one positive word about any tobacco products. We don't even know if consumers will really use these products as we would intend.

2: You are so sanctimonious about governmental regulation ... when cigarettes--by far the deadliest tobacco product--are free from proper governmental regulation.

1: There can be no real progress without governmental regulation. I believe governmental regulation is required.

2: I do too, ... but I see no connection between this belief and the reluctance to be honest about what is known to all interested parties. Your insistence on governmental regulation may represent a Utopian solution--it may never happen--not effective regulation!

1: If we permit smokeless to be promoted as a substitute for cigarettes, some smokers will use it to keep on smoking and avoid quitting--they will use smokeless to cope with smoking restrictions at work.

2: Who do you think you are? That point is over-the-top. Even we public-health-loving advocates should have limits on how much we control others! If an adult smoker chooses to use smokeless, or for that matter, medicinal nicotine, as a bridging product, to cope with restrictions, that is their business--their decision. You want to ban Viagra too, if you learned it contributed to philandering and marriage break-up? You go too far!

1: You don't get it. "Choice" is not a word to be used for addicts. You are sabotaging the policies that most of your closest colleagues have been working toward. You can carefully speak a scientific truth and the companies will grab a fragment of what you say and squeeze it to their advantage. Be careful where your "scientific assessments" and your "scientific integrity" take you, because you can be sure that it will be at most one small step forward, and, more likely, several big steps back.

2: I hope these principles will have small, constructive effects on the dialogue. That we will move closer to true science-based policy and that human rights will be respected.

Imagine a smoking patient with a long-standing relationship with a physician. They have tried everything--even tried medicinal nicotine as a substitute. This adult patient has a right to know that a switch to smokeless tobacco might help him stop smoking completely and could reduce disease risks substantially. I think the ethical physician--practiced in the real world of dealing with real patients--should be able to discuss smokeless as an option. And I don't think he should fear that the army of anti-tobacco litigators will swoop down on him as an object of their lawsuits--because to inform that smokeless is much less deadly than smoking is honest, health-relevant information.

1: You don't get it. You are sabotaging the policies that most of your closest colleagues support. You don't know what you're doing.

2. How about instead of "First, do no harm," you try, "First, tell the truth." Just who do you think you are, to be deciding so much for so many? Who do you think you are?

Readings

Bok S. Lying: Moral choice in public and private life. New York: Pantheon, 1978.
Callahan D (Ed.). Promoting Health Behavior: How Much Freedom? Whose Responsibility? Washington, DC: Georgetown University Press, 2000.
Department of Health and Human Services. Title 45 CFR Part 46: Protection of Human Subjects. Available at: http://ohsr.od.nih.gov/mpa/45cfr46.php3.
Johnson GK, & Slach NA (2001). Impact of tobacco use on periodontal status. *J.of Dental Education, 65(4): 313-21.*
Kozlowski LT. Harm reduction, public health and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Research*, in press.
Kozlowski LT & O'Connor RJ. Apply federal research rules on deception to misleading health information: An example on smokeless tobacco and cigarettes. *unpublished manuscript.*
Kozlowski LT, Strasser AA, Giovino GA, Eriksen PA, Terza JV. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tob Control 2001; 10:* 201-203.
Mann JM, Gruskin S, Grodin MA, & Annas GJ (Eds.). *Health and Human Rights.* New York: Routledge, 1999.
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Washington, DC: Department of Health, Education, and Welfare, 1979. Available at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm.
Mill, John Stuart. *On Liberty.* London: Longman, Roberts & Green, 1869; Bartleby.com, 1999. www.bartleby.com/130/.
Ramström, L. (1990) Smokeless tobacco - A potential gateway to smoking? *Proceedings of the 7th World Conference on Tobacco or Health, Perth, Australia,* 451-452.
Rodu, B. & Cole ,P. (1999) Nicotine maintenance for inveterate smokers. *Technology* 6, 17-21.
Rodu B, & Cole P. (2002). Smokeless tobacco use and cancer of the upper respiratory tract. *Oral Surgery Oral Medicine Oral Pathology and Oral Radiology Endodontics, 93(5):* 511-5.
Toebes BCA. *The Right to Health as a Human Right in International Law.* Antwerp: Intersentia, 1999.

Notes Thanks to Kate Wagner, Richard O' Connor, Spring Cooper, Beth Ann Quinio, and Lisa Grove for assistance. Both characters are fictitious and do not represent any individuals, living or dead.

SPECIAL COMMUNICATION

First, tell the truth: a dialogue on human rights, deception, and the use of smokeless tobacco as a substitute for cigarettes

L T Kozlowski

Tobacco Control 2003;**12**:34–36

The use of smokeless tobacco as a substitute for cigarettes raises many scientific and ethical issues, as the fictitious discussion below reveals

Cast: Dr Acton—a physician and member of a leading smoking policy committee; Dr Wright—a scientist with interest in human rights ethics (both characters are fictitious and do not represent any individuals, living or dead).

Setting: Private room at a conference. These two colleagues have been allies for many years. Today they have been arguing in public. The argument starts up again.

Dr A: You don't know what you're doing. You need to stop.

Dr W: *You're* too secure in your opinions of what should and shouldn't be done.

Dr A: You don't understand how your position can be used against us.

Dr W: Science without scientific integrity is propaganda—public relations. You're so caught up in trying to be a "policy" hero that you forget your scientific roots. We must never censor or manipulate results. In your policy world, scientists are dishonest when they don't conform to the prevailing policy.

Dr A: Science is not our only context. Far from it . . .Don't imagine that any part of the tobacco industry is committed to public science or fair play with us or their victims. The tobacco industry as a whole are paid killers. They know there is no such thing as a safe tobacco product that will sell well. Their secret documents—the ones we have seen—show an industry that is no friend of the public health.

Dr W: I'll say openly to anyone—you, the press, a consumer, a legislative committee—that (a) smokeless tobacco products in the US and Sweden are safer than cigarettes to individual users and (b) smokeless could be used to substitute for cigarettes in smokers who won't otherwise quit.

Dr A: I will say openly that the Surgeon General has determined that "smokeless tobacco is not a safe alternative to cigarettes". That's our message. No tobacco products are safe. Smokeless tobacco is not a safe product, and the companies have not generally done all they might do to reduce toxins.

Dr W: A big Volvo sedan is not a "safe alternative" to a small sports car, but it is "safer". A product can be both safer and not safe. Smokeless does not cause lung cancer or other lung disease (emphysema). Smokeless is certainly at least 60% less deadly than cigarettes and could be 90–99% less deadly than cigarettes.

Dr A: Smokeless causes deadly oral cancer. I have seen a young man's whole jaw lost to cancer. His complete lower face a shrivelled monstrosity. You don't forget that. You don't recommend a product that can do that.

Dr W: Which "product" are you talking about—cigarettes or smokeless? User for user, cigarettes cause even more, deadly oral disease than does smokeless. Public policy should care more for the deaths of the many than for the tragic images of the few.

Dr A: Smokeless is not a safe product! It is addictive! Their intent is not harm reduction. They build smokeless products so that users can progress to stronger and stronger hits of nicotine. As a physician, *my* professional ethics say "do no harm". DO NO HARM! As a physician, I could never recommend that someone expose themselves to carcinogens.

Dr W: "Do no harm" is a public relations slogan, not an ethical principle. As a physician, you prescribe drugs that kill with their side effects—liver toxicity, GI bleeding.

Dr A: Anti-tobacco lawyers would be lining up to sue us, if we made health claims for any dangerous tobacco products. I could get sued! You won't catch me advocating the use of a dangerous product.

Dr W: Advocating a dangerous product? My statement about smokeless being safer than cigarettes *is not* "advocating" smokeless for harm reduction. You could have many reasons to be against substituting smokeless for cigarettes—but one reason should *not* be because the product doesn't reduce risk to individual users.

Dr A: You come off sounding like you're in bed with the industry. These peddlers of addiction and death love your human rights rhetoric. It's damn naive to wave the banner of personal autonomy, cry out for human rights to honest information and for human rights to "informed consent". We are on a battlefield with a vile, unscrupulous enemy. Your ethical rhetoric is unethical and will kill people.

Dr W: Who *likes* or *dislikes* an idea has nothing to do with its truth value. If smokeless is safer than cigarettes (and it is), our policy should consider that, rather than deny it.

Dr A: If I accept that smokeless *may* be less dangerous to *individuals*, then you should also accept that smokeless can be more dangerous to *society as a whole*. If more people start using a less dangerous product, this product can be worse for

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public health . . . We can restrict human rights (quarantine an individual), to protect the public health.

Dr W: But just how big are these risks? . . .the "risk/use equilibrium" shows that once risk is reduced greatly, it is far-fetched to suppose that the numbers of users can ever increase so much that there will be net public health loss. Your knee-jerk concern that there *might* be greater overall harm is a primitive and partial kind of policy assessment. Effect-size does matter! Another reason to be honest about estimating levels of risk. To defeat individual rights, there must be *clear and convincing danger* to society. A far-fetched, implausible risk is not "clear and convincing evidence".

Dr A: You talk about "informed consent" and "right to information". But what about the young. Children become nicotine addicted before the age of consent. Children need our special protection—surely "paternalism" is not a bad word when protecting children. Smokeless is a gateway drug. Smokeless is a known gateway to cigarettes. If we don't say smokeless is just as dangerous as cigarettes, we are not doing all that we can to stop kids from using smokeless.

Dr W: Lying about levels of risk to scare kids in health communication is still lying, no matter how worthy your intent. The federal rules against deception in research should also apply to public health messages.

Dr A: You can be such a goody-goody. Federal rules against deception? What are you on about? Do you expect that health educators or physicians—when they tell a caring lie—should go to the Institutional Review Board to get permission?

Dr W: Even a "caring lie" robs individuals of autonomy, steals from them the opportunity to choose. The US government says that deception in research is not allowed unless four conditions can be met. First, the deception should not add risk.

Dr A: Add risk? How does trying to scare kids away from smokeless *add* to anyone's risk?

Dr W: Some kids are into high risk activities. For these kids, your lie *removes* a reason to not become a smoker! You don't know if the lie "does no harm".

Dr A: I believe that if we don't tell kids that smokeless is just as dangerous as cigarettes, they will take up smokeless and the gateway effect will move them on to cigarettes. Imagine the righteous complaints from parents if the public health movement doesn't do all it can to protect our children.

Dr W: The scientific evidence for a true causal gateway effect is slight. About 3 in 4 of those who use smokeless cannot be "gateway users", in that they either never go beyond smokeless to cigarettes or they started using cigarettes *before* they started using smokeless.

Dr A: How can you propose we practise science outside of the formal sanctions of science based governmental regulation? Our drug regulatory systems have helped create modern pharmaceutical products that must have years of testing—at the manufacturer's expense—before they can be sold. And they are subject to post-marketing surveillance and strict controls.

Dr W: A scientist should not first look at what answers the regulatory authorities *prefer* to see, before making judgments.

Dr A: Approved, tested, and pure medicinal nicotine products *might* be used for cigarette harm reduction. But we need strong governmental drug regulation to protect the public of all ages, before advocating use of smokeless.

Dr W: Yes, we do need strong regulations to see smokeless products—with required minimum toxicity—marketed in ways that might best benefit the public health.

Dr A: It is not "free choice" or "informed consent" or "personal autonomy" when nicotine addicts are duped by slick ads, product placements, sponsorships, and promotional tricks. These smokeless ads won't care if you quit smoking. They will promote the use of smokeless when it is inconvenient to smoke. They will target children, not just the 50 year old smoker.

Dr W: You don't have to lie about the basic facts, to be against unethical marketing practices! Being deceptive and evasive about the facts is a twisted way for scientists to try to deal with unethical marketing. Marketing practices need to be controlled.

Dr A: Can you show me one scrap of *scientific* evidence that smokeless tobacco products can even substitute effectively for cigarettes? I can think of only one limited study—and that was industry funded.

Dr W: I don't expect that you would support NIH funding for such a project . . . Do you really believe that studies are needed to show that traditional smokeless tobacco products *can* substitute for cigarettes? Smokeless users say so. The phenomenon of nicotine addiction says so. There are many "cases"—workplaces—where smokeless has been used when cigarettes cannot be. If cigarettes can substitute for smokeless in your gateway model, why not vice versa?

Dr A: You call for human rights. I call for scientific evidence. We need effective, science based, governmental drug regulation or I am not going to say one positive word about any tobacco products. We don't even know if consumers will really use these products as we would intend.

Dr W: You are so sanctimonious about governmental regulation . . .when cigarettes—by far the deadliest tobacco product—are free from proper governmental regulation.

Dr A: I believe governmental regulation is required.

Dr W: I do too, . . .but I see no connection between this belief and the reluctance to be honest about what is known. Your insistence on governmental regulation may represent a utopian solution—it may never happen—not effective regulation!

Dr A: If we permit smokeless to be promoted as a substitute for cigarettes, some smokers will use it to keep on smoking and avoid quitting—they will use smokeless to cope with smoking restrictions at work.

Dr W: Even we public-health-loving advocates should have limits on how much we control others! If an adult smoker chooses to use smokeless, or for that matter, medicinal nicotine, as a bridging product, to cope with restrictions, that is their business—their decision. You want to ban Viagra too, if you learned it contributed to philandering and marriage break-up?

Dr A: "Choice" is not a word to be used for addicts. You are sabotaging the policies that most of your closest colleagues have been working toward. You can carefully speak a scientific truth and the companies will grab a fragment of what you say and squeeze it to their advantage. Be careful where your "scientific assessments" and your "scientific integrity" take you, because you can be sure that it will be at most one small step forward, and, more likely, several big steps back.

Dr W: I hope these principles will have small, constructive effects on the dialogue. That we will move closer to true science based policy and that human rights will be respected.

Imagine a smoking patient with a long standing relationship with a physician. They have tried everything—even tried medicinal nicotine as a substitute. This adult patient has a right to know that a switch to smokeless tobacco might help him stop smoking completely and could reduce disease risks substantially. I think the ethical physician should be able to discuss smokeless as an option. And I don't think he should fear that the army of anti-tobacco litigators will swoop down on him—because to inform that smokeless is much less deadly than smoking is honest, health relevant information.

Dr A: You don't get it. You are sabotaging the policies that most of your closest colleagues support.

Dr W: How about instead of "First, do no harm" you try, "First, tell the truth". Just who do *you* think *you* are, to be deciding so much for so many? Who do you think you are?

ACKNOWLEDGEMENTS

Thanks to Kate Wagner, Richard O'Connor, Spring Cooper, Beth Ann Quinio, and Lisa Grove for assistance.

FURTHER READING

1 **Bok S**. *Lying: moral choice in public and private life*. New York: Pantheon, 1978.
2 **Callahan D**, ed. *Promoting healthy behavior: How much freedom? Whose responsibility?* Washington DC: Georgetown University Press, 2000.
3 **US Department of Health and Human Services**. Title 45 CFR Part 46: Protection of human subjects. Available from: http://ohsr.od.nih.gov/mpa/45cfr46.php3.
4 **Johnson GK**, Slach NA. Impact of tobacco use on periodontal status. *J Dent Educ* 2001;**65**:313–21.
5 **Kozlowski LT**. Harm reduction, public health and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine Tob Res* (in press).
6 **Kozlowski LT**, O'Connor RJ. Apply federal research rules on deception to misleading health information: an example on smokeless tobacco and cigarettes. *Public Health Reports* (in press).
7 **Kozlowski LT**, Strasser AA, Giovino GA, *et al*. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tobacco Control* 2001;**10**:201–3.
8 **Mann JM**, Gruskin S, Grodin MA, *et al*, eds. *Health and human rights*. New York: Routledge, 1999.
9 **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**. *The Belmont report: ethical principles and guidelines for the protection of human subjects of research*. Washington DC: Department of Health, Education, and Welfare, 1979. Available at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm.
10 **Mill JS**. *On liberty*. London: Longman, Roberts & Green, 1869. Available at: Bartleby.com, 1999. www.bartleby.com/130/.
11 **Ramström L**. Smokeless tobacco– a potential gateway to smoking? In: *Proceedings of the 7th World Conference on Tobacco or Health*, Perth, Australia, 1990, 451–2.
12 **Rodu B**, Cole P. Nicotine maintenance for inveterate smokers. *Technology* 1999;**6**:17–21.
13 **Rodu B**, Cole P. Smokeless tobacco use and cancer of the upper respiratory tract. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2002;**93**:511–5.
14 **Toebes BCA**. *The right to health as a human right in international law*. Antwerp: Intersenta, 1999.

For a performance of this dialogue, visit the Tobacco Control website—www.tobaccocontrol.com

"We really need something for people to die of"

2.7. This last point, a brutally realistic one, implies that, with a general lengthening of the expectation of life we really need something for people to die of. In substitution for the effects of war, poverty and starvation, cancer, as the disease of the rich, developed countries, may have some predestined part to play. The argument is obviously not one that the tobacco industry could use publicly. But its weight, as a psychological factor in perpetuating people's taste for smoking as an enjoyable if risky habit, should not be under-estimated.

"Cancer is an essential ingredient of life"!

2.8. There is, furthermore, a certain fatalism about the general public - an acceptance of the presence of adverse factors in life - which is not shared by the medical profession or by scientists whose task it is to find ways of overcoming or countering such factors. The disillusion now being felt, for example in the United States, about the small return achieved by vast expenditure on cancer research, reflects a sense of the inescapable nature of the disease. For smokers or potential smokers, this 'inevitability' runs against the spirit of caution urged by health educators. In this particularly highly-charged area of discussion, both professionals and laymen tend to regard cancer as wholly inimical, a threat which may develop suddenly or slowly, but which is always alien to the body. In reality, of course, though in its controlled and positive aspects, cancer is an essential ingredient of life without which the cells of the human body would be unable to renew themselves.

Proposal prepared for the UK's Tobacco Advisory Council by UK firm Campbell Johnson Ltd in 1978. The whole document can be found at: www.pmdocs.com/getallimg.asp?if=avpidx8DOCID=2501160781/0803.

Ethical Issues in Using Smokeless Tobacco As a Substitute for Cigarettes

Lynn T. Kozlowski, Ph.D., The Pennsylvania State University, University Park, PA, USA

Many scientists are enjoined by their ethical standards to not be deceptive in their representation of research findings. Additionally, there is a well-established human right for individuals to be provided honest health-relevant information. These principles can conflict with paternalistic concerns to protect the public from increased use of smokeless tobacco products, even though they are less dangerous than cigarettes to individuals. These issues will be discussed as they bear on the use of smokeless tobacco as a substitute for cigarettes. Deception has arisen in claims that smokeless tobacco is just as dangerous as cigarettes (which is not true), offered in part to reduce potential, causal gateway effects, whereby youth start with smokeless products and switch to cigarettes. Public health ethics holds that clear and convincing public health risks are needed to override individual rights to honest information. Given the much reduced health risks from smokeless tobacco products in comparison with cigarettes in the United States and Sweden, it is doubtful that the public health is jeopardized by promoting these products or nicotine replacement products as substitutes for cigarettes in adult smokers. Deception in public health communications should be required to meet the same ethical standards as deception in research. That is, it should not be done, no matter how well intended, if these four conditions cannot be met: (a) the deception causes no more than minimal harm, (b) rights are not violated, (c) there are no alternatives that are not deceptive, and (d) debriefing is done.

Biography

Lynn Kozlowski was awarded a Ph.D. in Psychology by Colombia University in 1975. He was an assistant Professor of Psychology at Weslyan University form 1974 to 1979. For 10 years he worked at the Addiction Research Foundation in Toronto, Canada, where he was a Senior Scientist and Head of their behavioral research program on tobacco use. He was also Professor of Prevention Medicine & Biostatistics at the University of Toronto. In 1990, he moved to Penn State University where he is now Professor and Head of Department of Biobehavioral Health. He served on Editorial Boards of Drug and Alcohol Dependence, Journal of Substance Abuse and Psychology and Addictive Behavior. He is an Assistant Editor of Addiction. His research has focused on various aspects of tobacco use (For example, it's epidemiology, treatment with nicotine replacement therapies, the risks of low-tar cigarettes, filter vent blocking, and nicotine addiction). He has over 100 publications and has contributed to four Surgeon General Reports on Smoking and Health. He was a founding member of the Society for Nicotine and Tobacco Research and is a Fellow of the Society of Behavioral Medicine, Academy of Behavioral Medicine Research, and the American Psychological Association.

Financial Interest

No significant financial interest
Organization:
Relationship:

Tab C

PRESS SUMMARY

3rd International Conference on Smokeless Tobacco

Session September 25, 2002, 10.30 - 12.00

Snus as a Substitution for Smoking - the Swedish Experience

By Lars M Ramstrom
Institute for Tobacco Studies, ITS, and, Research Group for Society and Information Studies, FSI
Stockholm, Sweden

A current survey (sponsored by the Swedish National Institute of Public Health) of a nation-wide representative sample of around 6,700 people in Sweden has made it possible to study more in depth than before to what extent and in which ways snus (the particular kind of oral snuff manufactured and used in Sweden) serves as a substitution for smoking.

Swedish males have an internationally record low prevalence of smoking

The following data show an overall picture of the current trends:
- Prevalence of daily smoking among adult males (age 16-79) was 20 % in 1996 and is now 15 %
- Prevalence of daily use of snus among adult males (age 16-79) was 15 % in 1996 and is now 20 %.
- Prevalence of daily smoking among adult females (age 16-79) was 19 % in 1996 and is now 19 %
- Prevalence of daily use of snus among adult females (age 16-79) was 2 % in1996 and is now 2 %.

While the above prevalence data suggest the possibility that snus use does to some extent replace smoking, more in-depth research is needed. Therefore the current study has looked specifically into two aspects, initiation of smoking and cessation of smoking.

Primary snus users have lower rate of starting daily smoking

A unique feature of the current study is that it has identified which started first, daily smoking or daily snus use. This has made it possible to calculate the rate of onset of daily smoking according to the presence or absence of previous daily snus use. In males the overall rate of onset of daily smoking is 40 %. In the rather small subgroup of males (14 % of all) who have started daily snus use without previous daily smoking (primary snus users), the rate of onset of daily smoking was just half as large, 20 %. This finding suggests that snus use does keep down rather than promote start of daily smoking.

Smoking cessation rates are higher among those (males and females) with a history of daily snus use

Among Ever Daily Smokers the overall rate of quitting smoking completely is 59 % for males and 49 % for females. Among those "with a history of daily use of snus" 71 % (same for males and females) have quit smoking completely. Among those "without a history of daily use of snus" the rate of quitting smoking completely is 54 % for males and 51 % for females. Thus, it is interesting to notice that females are equally good at quitting smoking as males when compared under equal conditions.

Among males snus is the most commonly used and most effective smoking cessation aid

76 % of male Ever Daily Smokers have made at least one attempt to quit smoking. Around 40 % of the "triers" report that at their latest attempt they have used some kind of smoking cessation aid. 36 % of these males have used nicotine gum, 20 % nicotine patch and 55 % have used snus as smoking cessation aid. No other kind of cessation aid has been used by as much as 10 %. The proportion of those who have succeeded to quit smoking completely is 50 % for gum users, 34 % for patch users, 65 % for snus users.

Summary conclusion

The low smoking rates in Sweden are obviously the result of a large number of efforts during a long time. For example, Sweden was the first country in the world to establish permanent governmental funding of tobacco education. The above data do, however, suggest that the use of snus as a substitution for smoking is actually one of the factors that have contributed to the current favourable situation in Sweden with low smoking rates and accordingly low rates of tobacco-related diseases.

Snus as a Substitution for Smoking: The Swedish Experience

Lars M. Ramstrom, Ph.D., Institute for Tobacco Studies, Stockholm, Sweden

A current survey (sponsored by the Swedish National Institute of Public Health) of a nation-wide representative sample of around 6,700 people in Sweden has made it possible to study more in depth than before to what extent and in which ways snus (the particular kind of oral snuff manufactured and used in Sweden) serves as a substitution for smoking.

Results

Current patterns of tobacco use: In males (age 16-79) the prevalence of daily smoking is 15 % and the prevalence of daily use of snus is 20 %. The corresponding figures for females are 19 % and 2 %. Combining daily smoking and daily use of snus occurs in 2 % of males and 0 % of females.
Initiation of tobacco use among males: 14 % are "primary snus users" i.e. having started daily use of snus as first kind of daily use of tobacco. 20 % of the "Primary snus users" have then started daily smoking. Among "Non primary snus users" the rate of onset of daily smoking is 45 %.
Patterns of smoking cessation: 59 % of all male "Ever daily smokers" have quit smoking completely and 7 % have stopped smoking daily but smoke occasionally. Corresponding figures for females are 49 % and 6 %. Among "Ever daily smokers with a history of daily use of snus 71 % (same for males and females) have quit smoking completely. Among those "without a history of daily use of snus" the rate of quitting smoking completely is 54 % for males and 51 % for females.
Patterns of cessation of use of snus: 23 % of all "Ever daily users of snus" have quit use of snus completely and 3 % have stopped daily use of snus but use it occasionally. Corresponding figures for females are 32 % and 5 %.

Smoking cessation practices: 76 % of male and 82 % of female "Ever daily smokers" have made at least one attempt to quit smoking. Around 40 % of the "triers" report that at their latest attempt they have used some kind of smoking cessation aid. 36 % of these males have used nicotine gum, 20 % nicotine patch, 55 % snus as smoking cessation aid. Corresponding figures for females are 55 %, 42 %, 15 %. No other kind of cessation aid has been used by as much as 10 % in either gender. Among males the proportion of those who have succeeded to quit smoking completely is 50 % for gum users, 34 % for patch users, 65 % for snus users. Corresponding figures for females are 34 %, 27 %, 56 %.

Conclusions

The above findings suggest that, in Sweden, the use of snus as a substitution for smoking is one of the factors contributing to the country's low smoking rates both by keeping down onset of smoking and by serving as a commonly used and effective smoking cessation aid.

Biography

Lars M. Ramstrom, Ph.D., has been working with Smoking or Health matters for more than 35 years, 1967 – 1990 as Director of the Swedish National Smoking and Health Association, from 1991 as Director has of the Institute for Tobacco Studies, Stockholm, Sweden. As researcher he has been adopting a multidisciplinary approach to matters regarding tobacco use and its health consequences trying to contribute to establishing and strengthening links between science and policies. He has been a member of numerous governmental and non-governmental committees working with tobacco matters both in Sweden and on the international level and he has been a member of the WHO Expert Advisory Panel on Tobacco or Health. He has participated actively in all of the World Conferences on Smoking and Health and served as Secretary General of the Fourth one of them (Stockholm, 1997). He is an Honorary Vice President of the International Council on Alcohol and Addictions (ICAA) and Co-chair of the Tobacco Dependence Section of the ICAA and member of the Society for Research on Nicotine and Tobacco.

Tab D

Smokeless Tobacco as Cessation for Smoking

Dorothy Hatsukami, Ph.D., Charlotte Lemmonds, Ph.D., University of Minnesota, Minneapolis, MN, USA

Smokeless tobacco (ST) can be used in several ways as a potential harm reduction tool for cigarette smokers. These tools include ST use as a method of cessation, as a means to reduce the number of cigarettes smoked, and as a product to be used in situations where smoking is prohibited. The impact of using ST in these ways is relatively unknown. The toxicity of the product itself varies by brand of smokeless tobacco and across countries. Of the existing studies, comparisons of consequences between cigarettes and smokeless tobacco show that cigarette smoking produces more negative health effects, is likely to have a higher addiction potential and more severe withdrawal, and leads to higher rate of relapse than ST use (Hatsukami & Severson, 1999). Differences in the characteristics of ST users vs. cigarette smokers may account for some of the propensity for nicotine addiction as well as inability to sustain abstinence. Nonetheless, in general, when examining the actual use of the products, there is less potential harm associated with smokeless tobacco compared to cigarette smoking. Thus, superficially the use of ST as a cessation tool does not seem unreasonable. To date, limited research data is available in addressing the feasibility and impact of this approach. Only one preliminary study has been conducted that shows that ST use as a means for cessation among cigarette smokers led to 25% abstinence at 1 year (Tilashalski et al., 1998). Other research has shown that among smokeless tobacco users, about half reported being former cigarette smokers. In addition, research has shown that this population of ST users has a higher rate of success in achieving abstinence from ST than a population of ST users who never had a history of former use of cigarettes. Data will also be presented on comparing toxicity of smokeless tobacco use with nicotine replacement agents. Future directions in research will be discussed. These directions include further examining the feasibility of using smokeless tobacco as a means of quitting cigarettes. For example, can people successfully stop smoking by using ST and how does this success compare with existing pharmacological treatments or enhancement of these treatments? What population of smokers should be targeted for and can benefit from this approach? What percent of cigarettes smokers persist in using ST alone or in combination with cigarettes? Will these persistent ST users actually experience a reduction in mortality and morbidity as a result of using ST products given their past history of smoking? How difficult would it be for this population to eventually quit using ST? What are the public health and legal implications associated with recommending use of a tobacco product as a cessation aid?

Biography

Dorothy Hatsukami, Ph.D. is currently Professor of Psychiatry and Adjunct Professor of Psychology and Epidemiology and Director of the Tobacco Use Research Center at the University of Minnesota. She has conducted research in examining the characteristics and treatment of nicotine addiction among a general population of adult smokers as well as in women and adolescents. She has also conducted research in the area of smokeless tobacco. More recently, she is the Principal Investigator of a National Institutes of Health Transdisciplinary Tobacco Use Research Center focused on reducing tobacco toxin exposure.

Financial Interest

No significant financial interest
Organization: National Institute on Drug Abuse
Relationship: Grantee
Organization: SmithKlineBeecham
Relationship: Donated nicotine replacement products

Smokeless Tobacco As Cessation for Smoking

Dorothy K. Hatsukami, Ph.D.
Charlotte Lemmonds, Ph.D.
U of MN TTURC
Figures by Robeon Morgan

ST Use for Harm Reduction in Cigarette Smokers

- ST use for cigarette cessation
- ST use to cut down on cigarette smoking
- ST use in situations that restrict cigarette smoking

Rationale for ST Use

- **Fewer health consequences associated with ST use**
- Less potential for addiction and physical dependence
- Higher rate of cessation with ST
- Lower cost

Health Consequences

Cigarettes	Smokeless Tobacco
• Pulmonary disease	• NA
• Cancers	• Oral Cancer
• Cardiovascular disease	• Cardiovascular disease ?
• Fetal toxicity	• Fetal toxicity
• Second-hand smoke exposure	• NA

Rationale for ST use

- Fewer health consequences associated with ST use
- **Less potential for addiction and physical dependence**
- Higher rate of cessation with ST
- Lower cost

Slower Absorption Rate

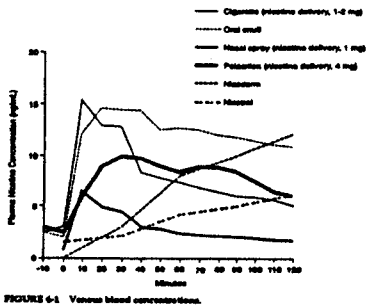
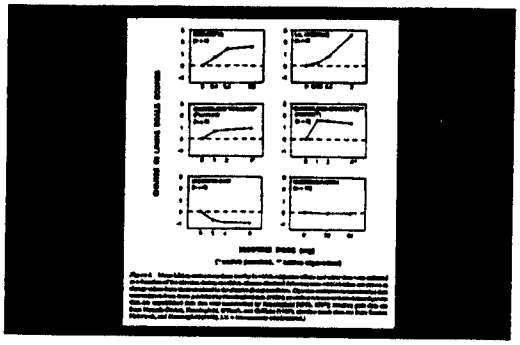


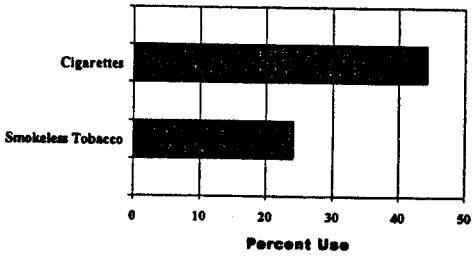
FIGURE 6-1 Venous blood concentrations.

NOTE: Venous blood concentrations in nanograms of nicotine per milliliter (ng/ml) of blood as a function of time for various nicotine delivery systems.
SOURCE: Reprinted with permission from Fant et al., 1999. Copyright 1999 Lippincott, Williams and Wilkins.

Liking Scores Across Tobacco Products

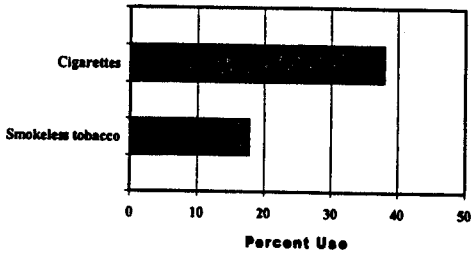


Percent who used tobacco in past year among individuals ever exposed to tobacco



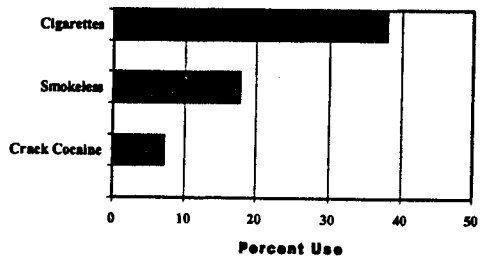
1999 National Household Survey on Drug Abuse
$p < .001$

Percent who used tobacco in past month among individuals ever exposed to tobacco



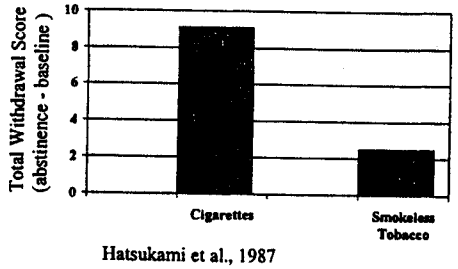
1999 National Household Survey on Drug Abuse
$p < .001$

Percent who used tobacco in past month among individuals ever exposed to tobacco



1999 National Household Survey on Drug Abuse

Withdrawal symptoms: cigarettes vs. smokeless tobacco



Hatsukami et al., 1987

Fewer cues associated with ST use compared to cigarettes

10 dips per day

versus

20-30 cigarettes per day

Rationale for ST use

- Fewer health consequences associated with ST use
- Less potential for addiction and physical dependence
- **Higher rate of cessation with ST**
- Lower cost

Treatment success rates across products at 6 mos follow-up

	NRT	Placebo
TNS		
ST user	41%	35%
Smoker	18%	10%
Gum		
ST user	31%	29%
Smoker	24%	17%

Rationale for ST use

- Fewer health consequences associated with ST use
- Less potential for addiction and physical dependence
- Higher rate of cessation with ST
- **Lower cost**

Cost for ST and FDA-Approved Medications

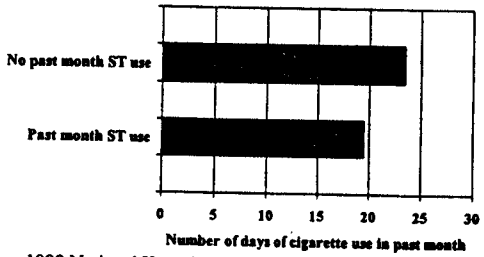
Product	Cost Per Day
ST	$1.88-$2.00
Nicotine Patch	$2.36-$4.50
Nicotine Gum	$4.26-$6.87 (10 2-4 mg)
Nicotine Spray	$4.50-$9.20 for 10-20 doses
Nicotine inhaler	$10.90 for 10 cartridges
Bupropion SR	$3.33-$3.40

IOM, 2001

ST and Cigarette Smoking

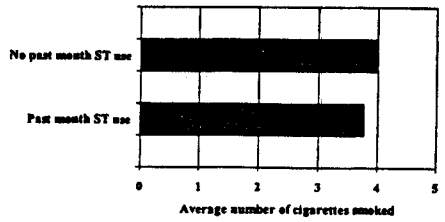
- About 7%-28% of smokers report using ST
- About half of ST users report former use of cigarettes
- Smokers who use ST report fewer number of cigarettes smoked and fewer days smoking than non-ST users

Relationship between past month ST use and frequency of cigarette use



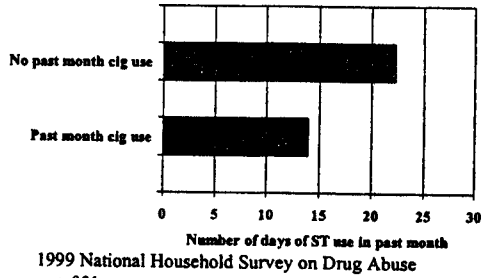
1999 National Household Survey on Drug Abuse
$p < .001$

Relationship between past month ST use and amount of cigarette use



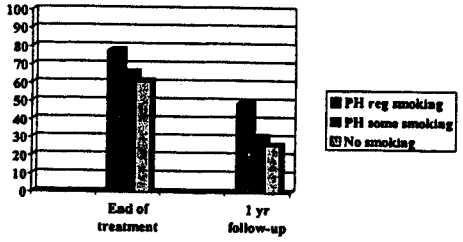
1999 National Household Survey on Drug Abuse
$p < .001$

Relationship between past month cigarette smoking and frequency of ST use



1999 National Household Survey on Drug Abuse
$p < .001$

ST abstinence rates by smoking history



(Hatsukami et al., 2000)
$p < .05$

Pilot Study on Cessation

One-year Follow-up Results

- 25% of 63 smokers quit smoking by using ST, 31% males and 19% women
- 7% reduced cigarette smoking by ≥ 50%
- 13 of the 16 who quit by using ST, continued to use ST

Tilashalski et al., 1998

Future Research Directions

- Feasibility of ST as a means for quitting smoking
  - –Comparison of toxicity of products and biological exposure across products including medications
  - –Treatment outcome success using ST
  - –Comparison with already existing treatments

Future Research Directions

- What percent of cigarette smokers will persist in the use of ST or combined use of cigarettes and ST? What are the consequences of combined use?
- Will smokers who switch to continued ST use reduce mortality and morbidity associated with tobacco use given the past exposure to cigarettes?

Future Research Directions

- Who should be targeted to use ST for cessation?
- What ST products and treatment methods should be used?
- In what context would this treatment method be recommended?

Future Research Directions

- How should the public be informed?
- What are the public health and legal implications of recommending the use of ST as a cessation aid?

Conclusions

- Smokeless tobacco produces less harm than cigarette smoking.
- However, smokeless tobacco is still a harmful product. The extent of the harm varies across countries.

Conclusion

- Whether smokeless tobacco is a viable treatment method is unknown.
- Developing more rapid and acceptable methods of nicotine delivery may be better alternative to using smokeless tobacco.

Tab E

THURSDAY, 3rd October

16:00 h – Secretariat: Distribution of Congress Documentation & New Registrations

17:00 h – 18:30 h - Global Network International Research Symposium *(Room A)*

Chairperson: Ovide F. Pomerleau

Speakers: Sameer Malhotra
Lenora C. Fernandez
João Carlos Dias Da Silva
Samer Jabbour

Objetive: This symposium features presentations by four recipients of SRNT Global Network Travel Awards who will describe their own nicotine or tobacco-control research or review the state of such research in their country or region.

18:30 h - Opening Ceremony(*) *(Paraninfo Room)*

19:00 h - Opening Conference: A discourse on cigarrette smoking(*) *(Paraninfo Room)*

Chairperson: Karl O. Fagerström

Speaker: Ovide F. Pomerleau

Objective: The main objective of this conference is to give an overview of the various aspects of scientific research in smoking.

FRIDAY, 4th October

09:00 h –11:00 h - Round Table Discussion:
Looking for the best treatment for each smoker(*) *(Paraninfo Room)*

Chairperson: Eva Kralikova

Speakers:	Karl O. Fagerström	*What diagnostic characteristics should we look for in smokers?*
	Robert West	*Nicotine Replacement Therapy*
	Martin Jarvis	*Bupropion*
	Peter Hajek	*Behavioural therapy*

Objective: To give some practical information about when and where, to whom and how to use the different pharmacological treatments of smoking.

11:00 h –11:30 h – Coffee Break – Commercial Exhibition

11:30 h –12:30 h - Debate: Harm Reduction(*) *(Paraninfo Room)*

Chairperson: Carlos A. Jiménez-Ruiz

Speakers: *Pros:* Philip Tønnesen
Cons: Richard Hurt

The chair will make a short introduction of the issue. Then each discussant will argue his position, followed by general discussion.

12:30 h –14:00 h - Lunch
Poster Session I *(Magdalena Palace)*

14:15 h –15:15 h - Oral Presentations *(Paraninfo Room)*

EFFECTS OF SMOKING EXPOSURE ON SMOKING RELAPSE
Maxine L. Stitzer, Ph.D. and Laura M. Juliano, Ph.D.
Johns Hopkins University School of Medicine, Baltimore, USA

GENERAL PRACTITIONERS' VIEWS ON THE PROVISION OF NICOTINE REPLACEMENT THERAPY AND BUPROPION
Andy McEwen MSc, BA and Robert West PhD, BSc
St. George's Hospital Medical School, London, U.K.

PATTERNS OF EARLY SMOKING ONSET
Elizabeth McMillan-Davey MEd, Jennifer O'Loughlin PhD, Jill Tarasuk MSc, Garbis Meshefedjian MSc and Joseph DiFranza MD
Direction de santé publique de Montréal-Centre, Montreal, Canada

CHARACTERISATION OF GENETIC VARIATION IN THE HUMAN DOPAMINE TRANSPORTER GENE AND ITS RELEVANCE TO SMOKING BEHAVIOUR
Elaine Johnstone PhD, Louisa Draper, Emma York BA, Robyn Jacob BSc, Siân Griffiths BSc, Mike Murphy MSc, Robert Walton MD
Cancer Research UK General Practice Research Group, Oxford, UK

CESSATION RATES IN A PLACEBO-CONTROLLED TRIAL OF NICOTINE GUM FOR SMOKING REDUCTION
Poul Wennike MD, Tobias Danielsson BSc, Björn Landfeldt MA, Ake Westin MSc and Philip Tønnesen MD
Dept. of Pulm. Medicine, Gentofte University Hospital, Copenhagen, Denmark
Pharmacia AB, Consumer Healthcare, Helsingborg, Sweden

A RE-ASSESSMENT OF CYP2A6 AND RISK FOR SMOKING
R.F. Tyndale PhD, E. Hoffmann MSc, B. Xu MD, C. Xu MD PhD, Y.S. Rao MSc, S. Goodz MSc and E.M. Sellers MD PhD
CAMH and Department of Pharmacology, University of Toronto, Toronto, Canada

15:15 h –17:15 h - Round Table Discussion.- Anti-smoking Activities in Europe *(Room A)*

Chairperson:	Peter Anderson	
Speakers:	Joan R. Villalbí	*Prevention activities: the role of NGOs*
	Esteve Saltó	*The role of local and regional governments*
	Enrique Gil	*Legislative action on tobacco/nicotine in the EU*

Objective: To provide an outline of current tobacco control activities

15:15 h –17:15 h - Round Table Discussion: Vulnerability to tobacco dependence(*) *(Paraninfo Room)*

Chairperson:	Andrew Johnston	
Speakers:	Michael Murphy	*Genetics, nicotine addiction and quitting smoking*
	Allan C. Collins	*Genetics underlying psychopharmacological responses to nicotine*
	David Balfour	*Strain differences in mesoaccumbens dopamine responses to nicotine*
	Martin Jarvis	*Socio-economic influences on tobacco dependence*
	Lirio Covey	*The role of psychopathology in nicotine dependence*

Objective: To provide an outline of innate and acquired factors affecting tobacco dependence.

17:15 h –17:30 h – Coffee Break – Commercial Exhibition

17:30 h –19:00 h - Round table discussion: Preventing and treating relapse(*) *(Room B)*

Chairperson: Gay Sutherland

Speakers:	José Ignacio de Granda-Orive	*Relapsing as a learning process*
	Elisardo Becoña	*Psycho-social relapse prevention*
	Andrew Johnston	*Pharmacologic relapse prevention*

Objective: To provide practical information on relapse and relapse-prevention

17:30 h –19:00 h - Round Table Discussion: Smoking cessation in special populations(*) *(Room A)*

Chairperson: Agneta Nordberg

Speakers:	Peter Hajek	*Treating pregnant smokers*
	Pedro J. Romero	*Treating smokers with CVD*
	Karen Slama	*Treating adolescents and children smokers*

Objective: To provide practical information on approaches to special populations

17:30 h –19:00 h - Symposium: Basic research on nicotine *(Paraninfo Room)*

Chairperson: Fernando Rodríguez de Fonseca

Speakers:	Rafael Maldonado	*Involvement of the endogenous opioid system in nicotine-induced antinociception, rewarding effects and dependence*
	Liana Fattore	*Baclofen as a putative candidate in the pharmacotherapy of nicotine abuse: Pre-clinical behavioural and biochemical evidence*
	Athina Markou	*Group II metabotropic and AMPA/kainate ionotropic glutamate receptors regulate the deficit in brain reward function associated with nicotine withdrawal*
	Sakire Pogun	*Sex differences in the central action of nicotine*

Objetive: To review recent advances in the central effects and mechanisms of action of nicotine.

SATURDAY, 5th October

09:00 h –11:00 h - Round table discussion:
Pharmacological treatments for smokers: What´s new?(*) *(Paraninfo Room)*

Chairperson: Carlos A. Jiménez-Ruiz

Speakers:	Gay Sutherland	*Characteristics of an ideal pharmacological treatment for smokers*
	Lirio Covey	*Antidepressants*
	Torgny H. Svensson	*Development and potential utility of nicotine vaccines*
	Rodrigo Cordoba-García	*Minimal intervention plus pharmacological treatment*

Objective: To give an overview of recent research on pharmacological tools for tobacco dependence.

11:00 h –11:30 h – Coffee Break – Commercial Exhibition

11:30 h –12:30 h -Debate: Higher doses of NRT?(*) *(Paraninfo Room)*

Chairperson: Stefano Nardini

Speakers: *Pros:* Lowell Dale

Cons: F. Javier Ayesta

Objective: To review evidence related to the efficacy of higher doses of nicotine for treating smokers.

12:30 h –14:00 h -Lunch
Poster Session II *(Magdalena Palace)*

14:00 h –15:00 h - Members Meeting *(Paraninfo Room)*

15:00 h –15:15 h – Coffee Break – Commercial Exhibition

15:15 h –17:15 h - Round Table Discussion: Smoke-free tobacco with special emphasis on the Swedish product "snus" *(Room A)*

Chairperson: Ann McNeill

Speakers:	Freddie Lewin	*Swedish non-smoking tobacco (snus), cancer and cardiovascular disease*
	Lars Ramström	*Patterns of use: A gate leading to smoking, or a way to give up?*
	Clive Bates	*How should smoke-free tobacco be regulated?*

Objective: To give an overview of smoke-free tobacco

15:15 h –17:15 h - Symposium: Brain imaging of nicotine/smoking(*) *(Paraninfo Room)*

Chairperson: Edythe D. London

Speakers:	Arthur L. Brody	*Regional brain metabolic changes associated with cue-elicited cigarrette craving*
	Jed E. Rose	*Nicotinic influences on functional brain systems: PET studies with smokers*
	Elliot A. Stein	*Effects of Nicotine on Brain Attention Mechanisms*
	Alexey G. Mukhin	*In vivo imaging of nicotinic receptors in human brain with SPECT and PET*

Objective : To present functional brain imaging studies of responses to cigarette craving and nicotine, along with recent advances in the examination of nicotine receptors in the human brain *in vivo*.

17:15 h – Conclusions(*) *(Paraninfo Room)*
Coordinated by Scott Leischow

(*) Simultaneous translation English-Spanish will be available at these sessions.

Tab F

Harm reduction and smokeless tobacco

Clive Bates
Director
Action on Smoking and Health

ash.

Smokeless-related disease

- Hypertension
- Tachycardia
- Tourette's syndrome
- Disorientation
- Schizophrenia
- Balance disorders
- Paranoia
- Blindness
- Deafness
- Carpal tunnel syndrome
- Stockholm syndrome

ash.

Smokeless-related disease

- Hypertension
- Tachycardia
- Tourette's syndrome
- Disorientation
- Schizophrenia
- Balance disorders
- Paranoia
- Blindness
- Deafness
- Carpal tunnel syndrome
- Stockholm syndrome

…and that's just me!

ash.

Baseline

- Extremely bad…
  - 5.6 Trillion cigarettes per year
  - 1.1 billion smokers and rising @ 80,000/day
  - 4 million deaths/year
  - Rising to 10 million/year in 2020s
  - 1 billion deaths predicted for 21st Century

ash.

“Harm reduction” products

- ‘Lights’
- Modified cigarettes
- Novel smoking devices
- Smokeless tobacco
- Medicinal nicotine
- Other nicotine sources

ash.

Harm reduction behaviours

- Temporary abstinence
- Smoking reduction
- Switching
- Alternative nicotine use
- Cessation

ash.

Proposition 1

The type of tobacco (nicotine) used can and should be a factor in controlling health impact on the individual and the population.

ash.

Harm caused to 46 million users

- Smoking
  - Cancer – 151,000
  - Circulation – 180,000
  - Respiratory – 85,000
  - Other – 3,000
  - ETS – 50,000*
- Smokeless
  - 6,000 (may be less…)
  - 0 – ? uncertain
  - 0
  - 0
  - 0

- ***Adapted from Rodu (1995)*** & *CalEPA (1999)

ash.

Snuff and CHD

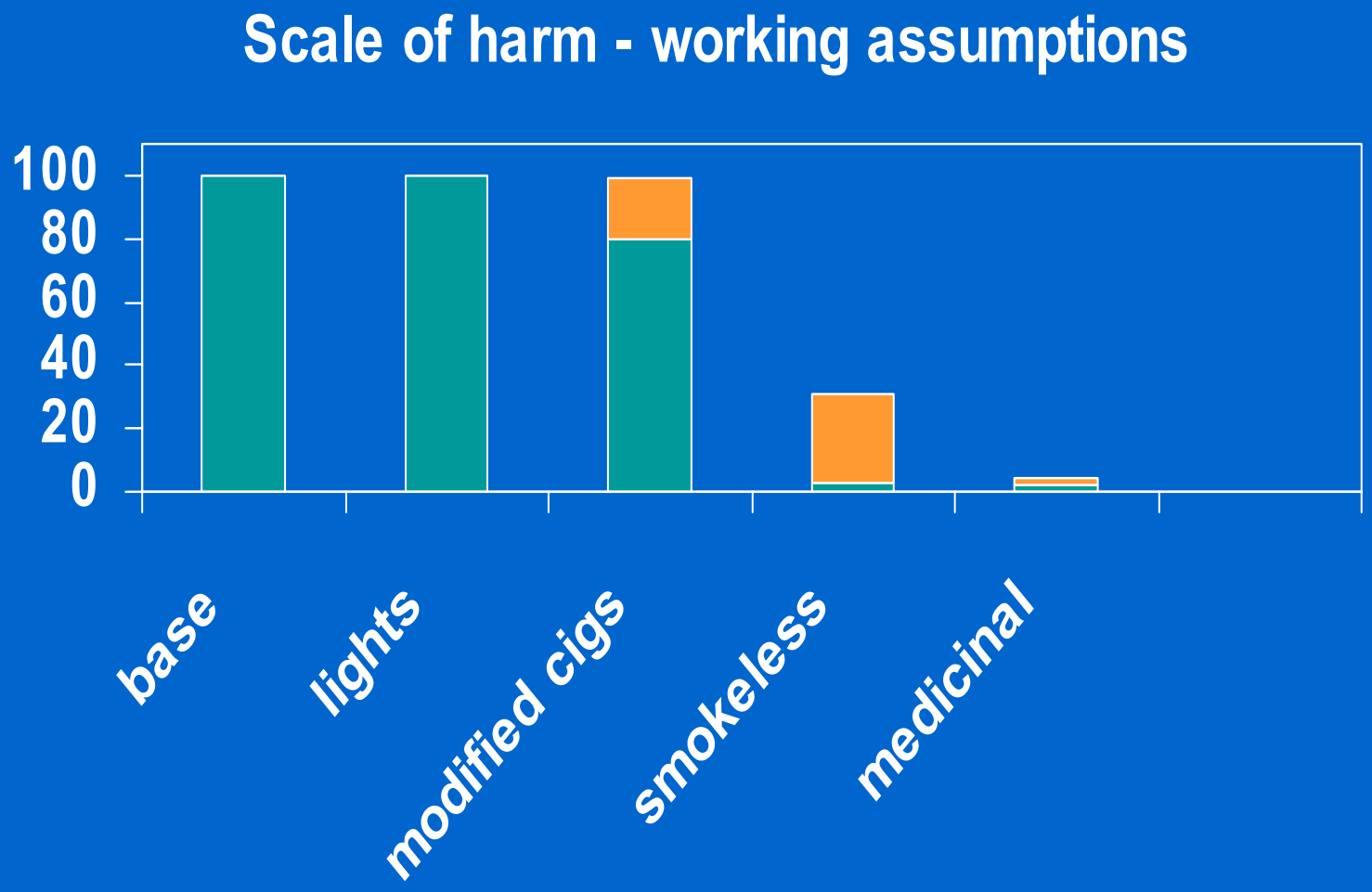
- Smoking increases the risk of myocardial infarction, sudden death, stroke and peripheral artery disease of the legs by 2-4 times.

- 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.

Asplund K. Review of Smokeless and CHD risk for ASH(UK) Sept 2002 (unpublished)

ash.

How much harm reduction?



ash.

Proposition 2

The smokeless tobacco used in US and Scandinavia is one to two orders of magnitude less hazardous than cigarettes

ash.

Nicotine delivery

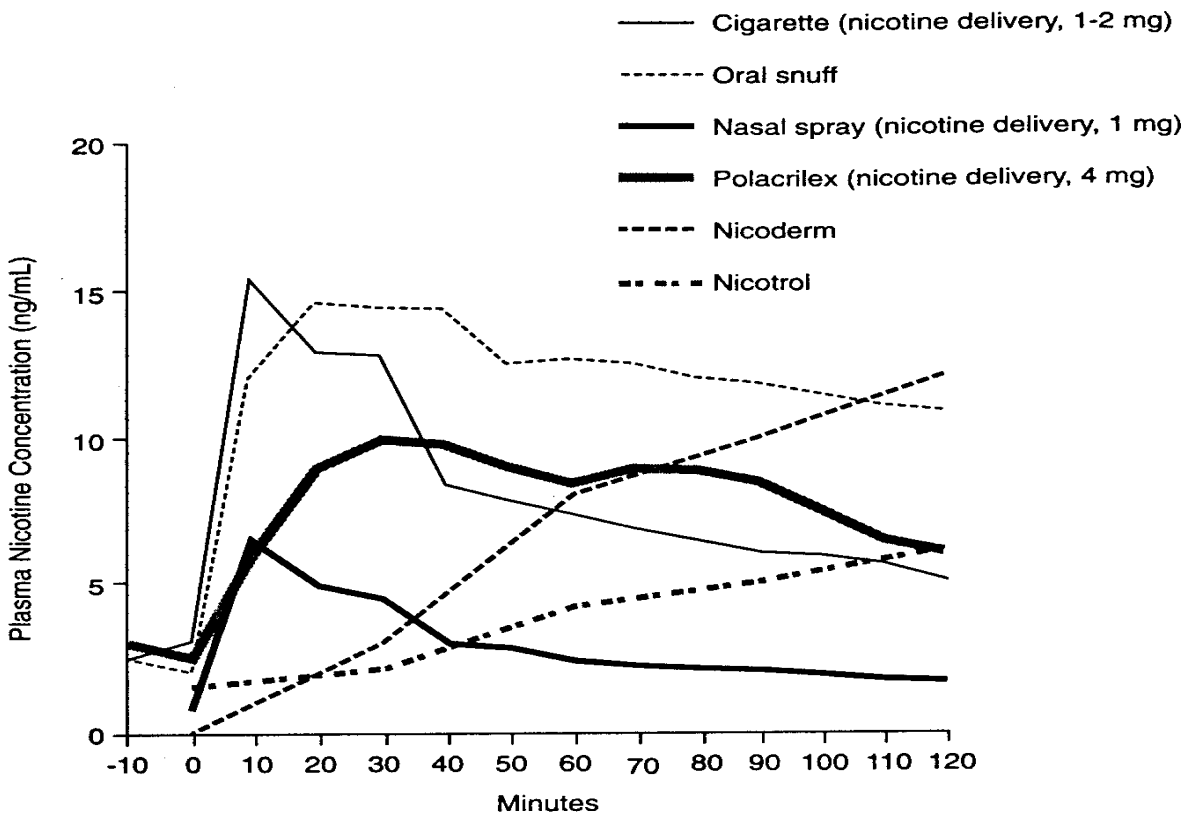


FIGURE 4-1 Venous blood concentrations.

NOTE: Venous blood concentrations in nanograms of nicotine per millimeter (ng/ml) of blood as a function of time for various nicotine delivery systems.
SOURCE: Reprinted with permission from Fant et al., 1999. Copyright 1999 Lippincott, Williams and Wilkins.

ash.

Viable alternative?

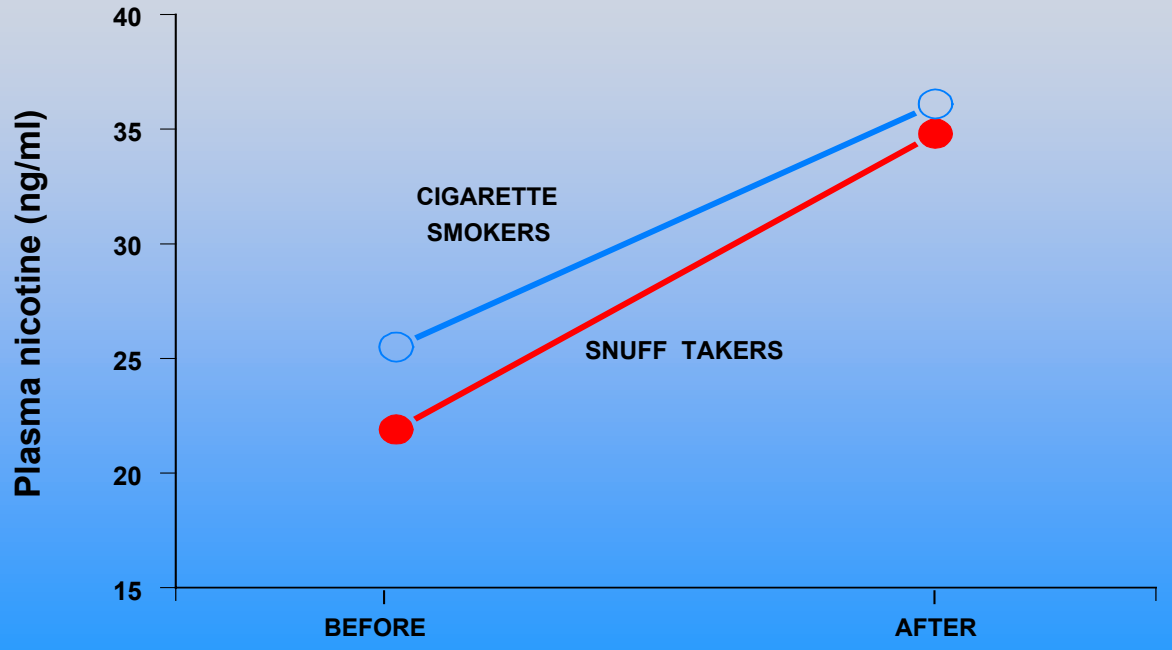
- "Snuff may well be a satisfactory and acceptable substitute for cigarette smoking. In addition to its capacity to deliver nicotine, snuff could provide many other components of the smoking habit, such as ..sensorimotor rituals…

Russell et al (1980) Lancet i: 474-5
A new age for snuff?

ash.

Nicotine uptake

Nicotine uptake from a single cigarette or pinch of snuff in regular users



Russell et al BMJ 1981

ash.

Nicotine dose

Peak plasma nicotine concentrations from cigarettes and snuff from normal daily use

	Plasma Nicotine (ng/ml)
British cigarette smokers	36.7
British nasal snuffers	36.1
Swedish cigarette smokers	36.7
Swedish oral snuffers	36.6

ash.

Proposition 3

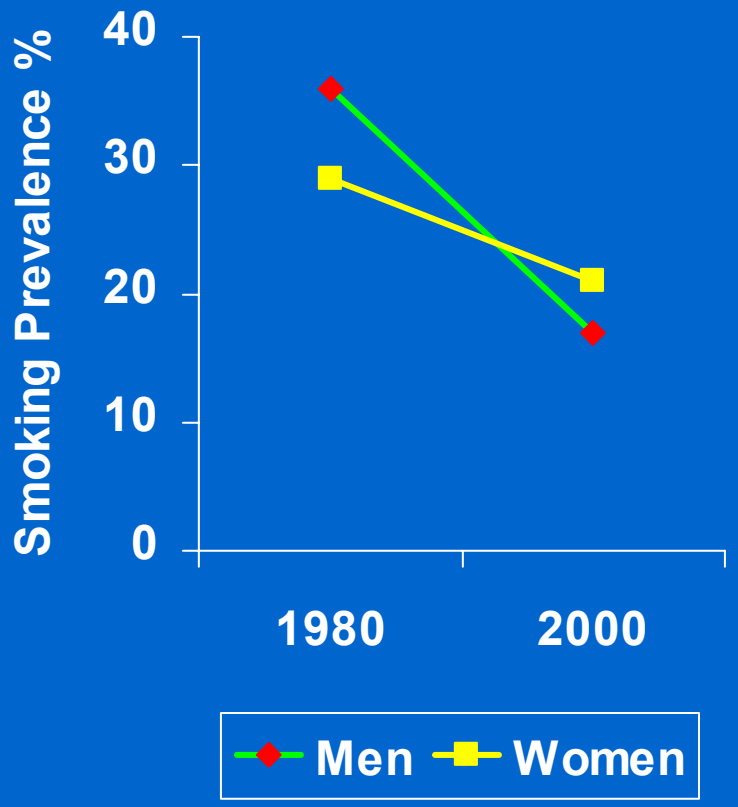
Smokeless tobacco is a credible alternative system for nicotine administration.

It has several advantages over the current generation of NRT

ash.

Sweden

- Similar tobacco consumption to Denmark, Norway
- Lowest smoking prevalence in Europe
- Lowest tobacco-related mortality in Europe
- Rate of reduction in male prevalence = 1% per year



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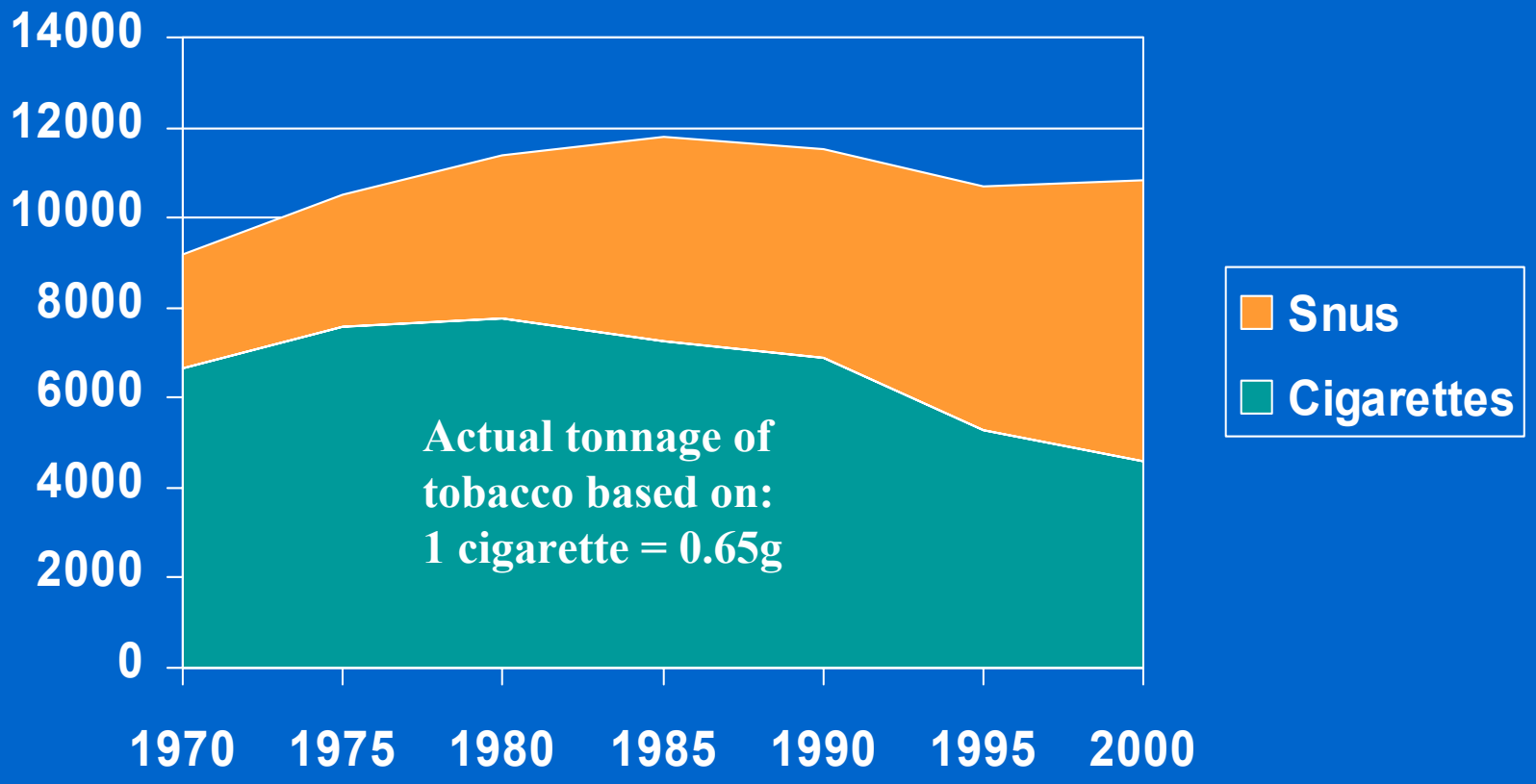
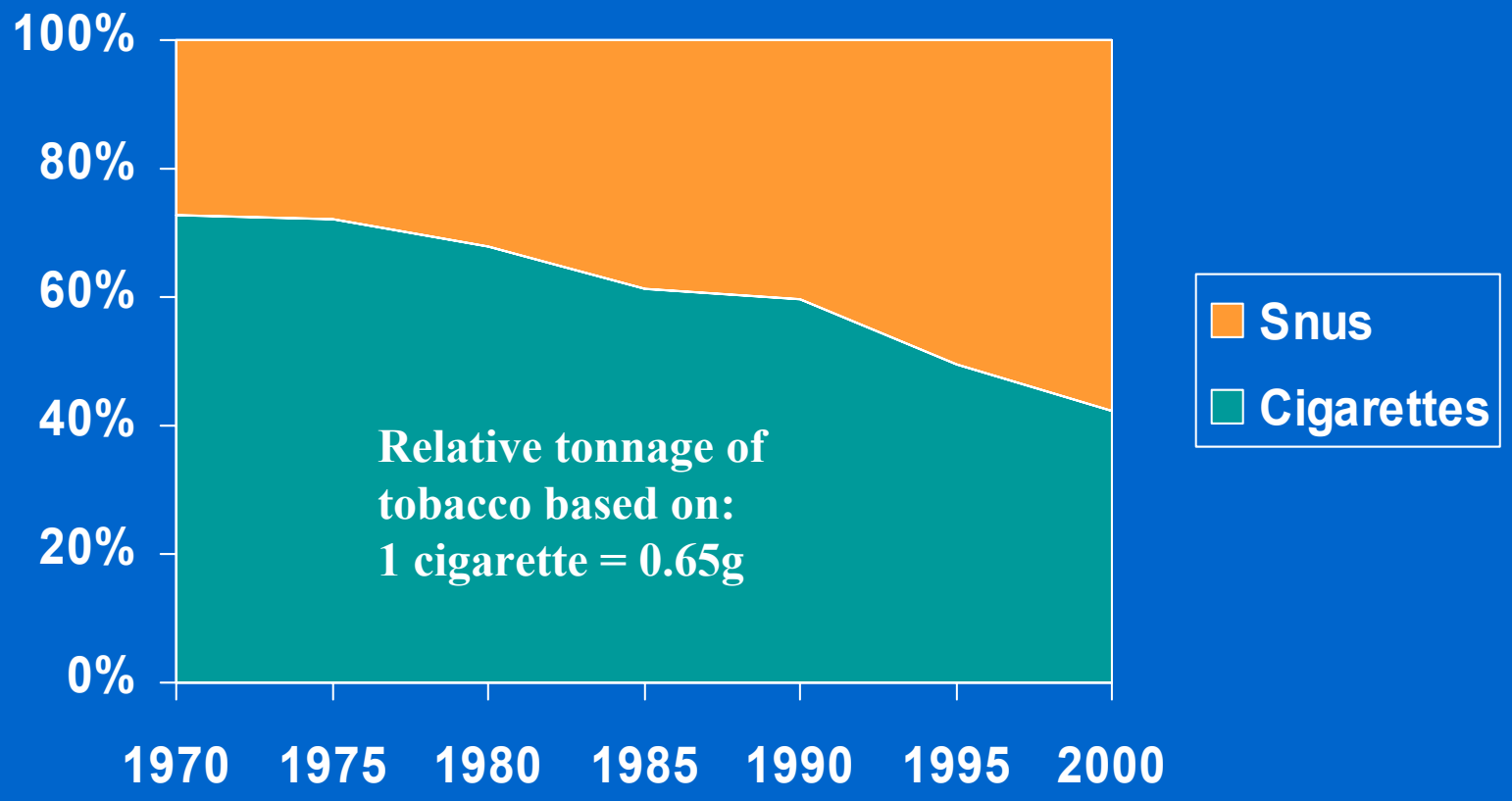
Changing Swedish market



Adapted from Fagerstrom KO, Schildt WB, Snus a smoke-free tobacco product, paper at 5th German nicotine conference May 2002.

ash.

Changing Swedish market



Adapted from Fagerstrom KO, Schildt WB, Snus a smoke-free tobacco product, paper at 5th German nicotine conference May 2002.

ash.

Switching

Swedish men (age 16-75) Poll mid-2001	Prevalence (daily use)	Started on snus	Started on smoking
Snuffers	17%	52%	**48%**

TEMO (polling) 2002. Svenska folkets tobaksvanor 2001. For Swedish Match

ash.

Switching

Swedish men (age 16–75) Poll mid–2001	Prevalence (daily use)	Started on snus	Started on smoking
Snuffers	17%	52%	48%
Smokers	12%	**11%**	89%

TEMO (polling) 2002. Svenska folkets tobaksvanor 2001. For Swedish Match

ash.

Switching

Swedish men (age 16–75) Poll mid–2001	Prevalence (daily use)	Started on snus	Started on smoking
Snuffers	17%	52%	48%
Smokers	12%	11%	89%
Mixed*	**3%**	23%	65%

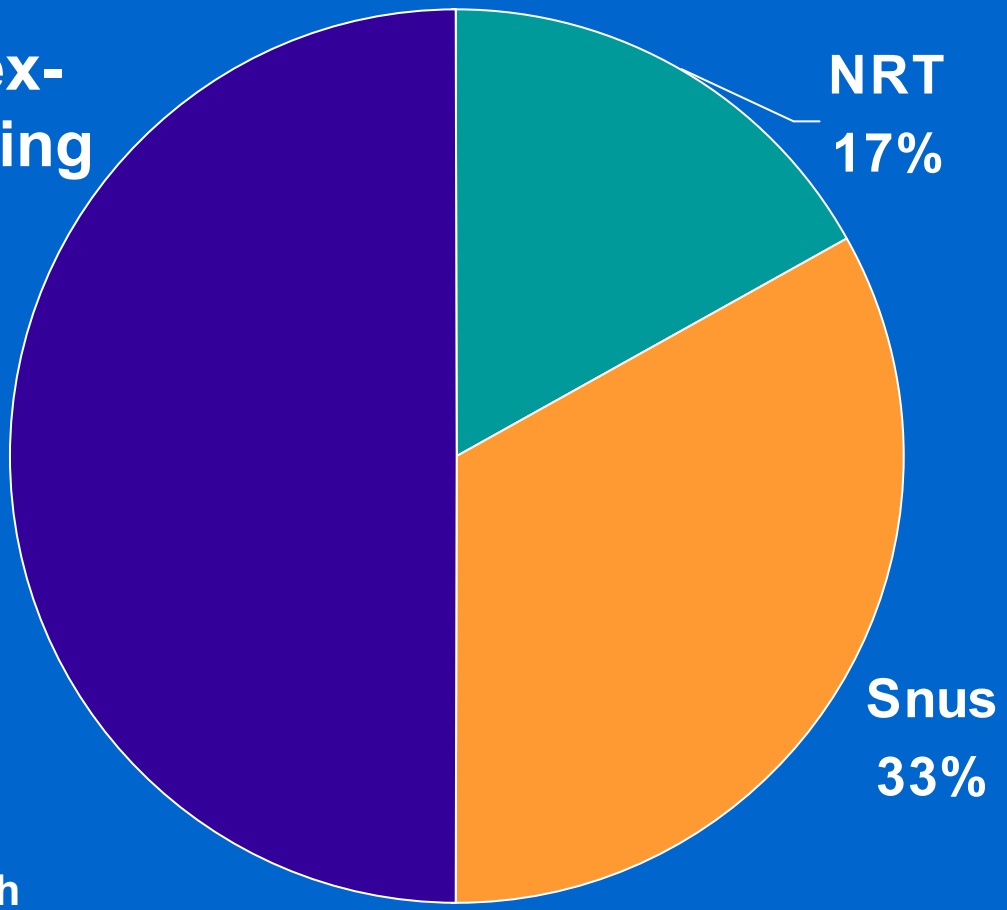
TEMO (polling) 2002. Svenska folkets tobaksvanor 2001. For Swedish Match

* Mixed users starting on both = 12%

ash.

Use in smoking cessation

1000 Swedish ex-smokers reporting use in smoking cessation…



TEMO (polling for Pharmacia and Swedish Cancer Society) 2001

ash.

Swedish snus

- Much less harmful than smoking (>90%)
- Displacing smoking at population level
- Used in cessation, like 'super-NRT'
- Public health value in Sweden
  - Banned in EU
  - Scorned in US
  - Feared in developing countries

But…. **moral imperative for public health community to be open-minded and explore…**

ash.

Proposition 4

Snus is an important factor in the low smoking prevalence in Sweden.

It is used for cessation and as an alternative to smoking.

ash.

Unintended consequences

- "What if young people start, people don't quit, gateway to smoking, adults restart, hidden health effects, the new 'lights ..."
- "What if things stay as they are?"
- How do we weigh fear of unintended consequences and failure to realise potential benefits?

ash.

The new 'lights'…?

"[Ariva] has the same harm as any other tobacco product"

(American Cancer Society, Dallas – 3 January 2002)

ash.

The new 'lights'…?

"[Ariva] has the same harm as any other tobacco product"

(American Cancer Society, Dallas – 3 January 2002)

- Lights
  - Misleading claims by manufacturers
  - No reduction in risk
- Smokeless tobacco
  - Misleading claims by health advocates
  - Substantial reduction in risk

ash.

Gateway to smoking…

- No clear evidence anywhere
  - If anything Swedish data suggests gate is an ***exit*** rather than an ***entry***
- Evidence difficult to gather…
  - Would smokeless starters have smoked anyway?
  - Should see elevated smoking prevalence
- Why doesn't Big Tobacco sell it?

ash.

It isn't safe…

- "Tobacco in any form is not safe to allow non cigarette users to try it and get addicted. In my mind that is what the ban is about." (British academic)

- But for addicted cigarette users 10-100 times *safer*
- Population harm unlikely to increase
- Gateway effect unproven and unlikely

ash.

Smoke-free areas

- Argument
  1. Smoke-free environments drive cessation
  2. Smokers no longer affected by withdrawal
  3. Propensity to quit reduced
  4. Smokeless keeps smokers smoking so very dangerous

ash.

Smoke-free areas

- Argument
  1. Smoke-free environments drive cessation
  2. Smokers no longer affected by withdrawal
  3. Propensity to quit reduced
  4. Smokeless keeps smokers smoking so very dangerous

- But…
  - Contribution of smoke-free policies varies
  - Mechanism unknown – may be denormalisation of smoke
  - Mixed use low (3% men) in Sweden
  - Legitimacy of coercive strategies…

ash.

Primary reason for using snus

% of those giving a reason	Because I can't smoke on certain occasions	To smoke less	Other reason
Mixed users (3% men)	26%	44%	30%

TEMO (polling) 2002. Svenska folkets tobaksvanor 2001. For Swedish Match

ash.

Proposition 5

Unintended consequences are a possibility – but easily overstated.

The EU ban and public health hostility to smokeless may also have unintended consequences

ash.

Market or regulation

- Nothing should happen without full regulation…
- But that has favoured the cigarette makers…
- Is there a workable mix of regulation and liberalisation?
  - Toxicology
  - Marketing claims
  - Sell-by date
  - Labelling
  - Price
  - Other forms of promotion / restraint

ash.

Gothiatek standard

Component	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
Pesticides	SM policy

Based on 50% water content – multiply by 2 for limit in dry matter

ash.

Proposition 6

An regulatory framework for smokeless tobacco could realise health benefits from reduced smoking and manage risks of unintended consequences

ash.

Propositions

1. The type of tobacco product used matters
2. Smokeless can be much less dangerous
3. Smokeless tobacco is a credible alternative to smoking
4. Swedish ‘snus’ has played an important role in reducing disease
5. There may be unintended consequences, but there are also consequences from the ‘do-nothing’ approach
6. There are many options for regulation and ‘promotion’ of smokeless tobacco

ash.

Thank you!

Tab G

Protecting smokers, saving lives

The case for a tobacco and nicotine regulatory authority

Prepared by the Tobacco Advisory Group
of the Royal College of Physicians

Royal College of Physicians
December 2002

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ONE

Introduction

1.1 Tobacco is a uniquely dangerous consumer product, killing 120,000 people per year in the UK and 4 million worldwide when used as intended by the manufacturer. Cigarettes are highly addictive, and are the most toxic and carcinogenic means of delivering nicotine. They are also heavily promoted and widely available.

1.2 In February 2000, the Royal College of Physicians' Tobacco Advisory Group published an extensive, authoritative account of the role of nicotine in British society, *Nicotine addiction in Britain*. The final two recommendations of that report were:

> *14. Tobacco products in Britain should therefore be regulated either by the Medicines Control Agency or by a nicotine regulatory authority similar in concept to the Food Standards Agency.*
>
> *15. We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*

1.3 In June of 2000, the Commons Health Select Committee examined the issue in detail and arrived at a similar conclusion, endorsing the recommendation of the College and adding:

> *189. […] It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*

1.4 The purpose of this report is to take those recommendations forward and to encourage the government to address the strategic issue of how it should regulate the tobacco industry and tobacco and other nicotine products. This report considers the regulatory challenges that lie ahead and are already evident, and examines various institutional and legal structures for regulation, based on three models. These are the Irish Office of Tobacco Control, the Medicines Control Agency (MCA) and the Food Standards Agency (FSA).

1.5 The report examines the options for regulation at European level (the stated preference of the Government) and the options available in UK law to create the necessary regulatory capacity.

TWO

The case for a tobacco and nicotine regulatory authority

2.1 This document argues that considerably more regulatory capacity for tobacco is required and justified in order to protect public health in the UK. The impact of tobacco on British society is quite unprecedented – consider eight aspects:

1 **The scale of the impacts of tobacco use.** 10 million users are addicted to nicotine, and tobacco-related disease kills 120,000 per year (one fifth of all deaths). It is responsible for one third of cancer, one seventh of cardiovascular disease and most chronic lung disease in adults. Tobacco is the single largest cause of social inequalities in health and aggravates poverty among poor smokers. There are multiple impacts on non-smokers and children exposed to tobacco smoke. There are pronounced economic impacts on the public sector (especially the NHS) and on productivity in the economy. It is the largest cause of fires with fatal injury and creates the single largest source of litter.

2 **The challenges of developments in the tobacco market.** Tobacco companies are designing products which claim reduced risk or other benefits, and smokeless tobacco producers are seeking to exploit very large reductions in risk compared to smoking. At the same time, novel nicotine products are coming to market that could greatly reduce harm, but face regulatory barriers far greater than cigarettes – the most harmful means of delivering nicotine.

3 **The complexity of the policy responses.** The policy responses require skilled programme management in order to spend money and expend resources wisely. Some may be scientifically complex, such as regulating the chemistry of smoke and tobacco products. Some policies are highly contentious, such as banning tobacco advertising, raising taxes and securing smoke-free areas. Some responses may give rise to unintended consequences, for example some youth initiatives may encourage smoking. In the area of smoking cessation, strict regulatory systems for pharmaceutical nicotine clash with the much weaker regime for tobacco, causing perverse outcomes that harm smokers.

4 **The current regulatory imbalances.** At present, nicotine replacement therapies are strictly controlled under medicines regulation, and oral tobacco is banned completely under European Union (EU) law – yet both represent much less hazardous ways of administering nicotine than cigarettes and both may be used for smoking cessation. However, cigarettes are subject only to the most cursory regulation and restrictions. This perverse regulatory imbalance favours the most deadly means of delivering nicotine.

5 **The strength of the commercial interests.** The UK industry is highly profitable, achieving profit margins of about 40% on turnover after deduction of duty. There are three FTSE 100 companies and major multinationals such as Philip Morris and Japan Tobacco International are involved at UK, EU and international level.

6 **The money involved.** Tax revenue raised from this sector is £9.3 billion per year in duties and VAT. This exceeds the monies committed in the tobacco white paper, *Smoking Kills*, by 250 times. Closer regulation of this industry in the interests of consumers is a modest return to those who pay their tobacco taxation. The whole enterprise should be funded by levies on the tobacco industry at no net cost to the public purse.

7 **Precedents from other areas of policy.** The government benefits from considerable regulatory capacity in the area of food and pharmaceuticals. Other governments are establishing reasonable regulatory capacity for tobacco.

8 **The 'pitiful' resources currently devoted to regulating tobacco.** No other area of public health policy has such large stakes in health, welfare and the economy, combined with such a complex and contentious policy environment and such large sums of money involved. Against this background, the Health Select Committee described the regulatory capacity for tobacco within government as 'pitiful' and at EU level 'utterly derisory'.

THREE

Forthcoming regulatory issues in tobacco policy

3.1 The following are examples of issues that already arise or are likely to arise in the regulation of tobacco products over the next few years.

The emergence of reduced-risk tobacco products

3.2 Manufacturers have already introduced products in the United States that they claim offer smokers reduced risks. Products include those making false, implied claims, such as 'lights'; products with certain carcinogens or other toxins selectively reduced; novel technologies such as heating rather than burning tobacco; and smokeless tobacco products to be chewed or sucked. In each case there are marketing claims made and applications suggested.

3.3 These present multiple challenges for regulators.

- What reduction in risk does the product achieve and how is this measured? The ISO tar yield measurements are of no use.
- What happens when some risks increase and others decrease?
- What claim may be made for the reduced risk, and who will give approval or regulate such claims?
- At what level of reduced risk would the authorities be negligent in not allowing consumers to be informed about products that do them less harm?
- How should claims that are true but may be misunderstood or understood disproportionately ('reduced cancer risk') be dealt with?
- How should relevant consumer information reach the consumer in a situation where advertising is prohibited?
- How should the market testing of such products be handled?
- What should government policy be in this treacherous area of public health?

The scope for reducing harm caused by mainstream cigarettes

3.4 There are technologies and techniques available that may reduce the harm caused by smoking by reducing hazardous chemicals in the smoke: what scope is there to *impose* technical performance standards on tobacco product manufacturers – what legal basis could be used? How would such standards be set and monitored?

Smokeless tobacco

3.5 As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10–1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.

3.6 This raises many questions.

- Should the ban on oral tobacco (EU Directive 2001/37/EC article 8) be lifted and what kind of regulatory regime should replace it?
- Can product 'purity' standards be used to reduce the toxins in smokeless tobacco?
- What claims could be made about the relative health risk of smokeless tobacco and smoking and how should these be communicated?
- How can the use of smokeless products as a 'starter' product for young smokers be minimised?
- How can the risk of unintended consequences (eg reduced cessation) be minimised?
- How would the government and EU respond to a successful legal challenge to the EU ban on oral tobacco?
- How should 'smokers' rights' to have access to products that do them much less harm be reconciled with possible negative consequences at the population level?
- What options are there to 'promote' smokeless tobacco as a much safer alternative to smoking, without promoting tobacco use per se?

Pharmaceutical regulation of nicotine products: the level playing field

3.7 There may be 'harm reduction' indications for pharmaceutical nicotine, which involve long-term use or use during temporary abstinence from smoking. There are pharmaceutical products in the pipeline that may be branded more like tobacco products with a view to appealing to smokers. How is it possible to avoid letting the far more onerous pharmaceutical regulation keep such products from the market, while the almost non-existent regulation of tobacco allows cigarettes to be widely available with minimal safety restrictions or warnings?

Use of pure nicotine as a consumer alternative to smoking

3.8 There may be a generation of nicotine products that are offered outside the conventional pharmaceutical and medical framework as consumer products. One company has placed nicotine water on the market and another wished to offer a nicotine gum packaged and branded as an alterative to smoking. Such developments offer the potential for competition with cigarettes with much lower health impacts, but may also create new population risks.

Legal challenges

3.9 The tobacco industry has shown that it will challenge any meaningful public health measure on tobacco. Even if the measure cannot be overturned, the effect is to delay implementation, to tie up official time and to 'chill' the government's determination to regulate in this area. All of which means that legislation must be as robust as possible, offer a proper public health benefit and be robustly defended. The legal challenges to tobacco product regulation threaten a precipitous destruction of the government's policy on consumer protection for tobacco products.

3.10 This raises several questions:

- Why was legislation which in places is at variance with best available scientific knowledge written in the first place? For example, the Royal College of Physicians' February 2000 report, *Nicotine Addiction in Britain*, illustrated how tar-yield reductions offer little benefit to contemporary smokers.
- What scientific and public health capacity is available to work with lawyers to defend against legal challenges brought by the tobacco industry?
- How can UK regulation be made consistent with EU law and international trade agreements, while still achieving its aim of protecting public health, and who will gather the evidence?
- Are the trade-related treaties – World Trade Organisation (WTO) agreements, Trade-Related Aspects of International Property Rights (TRIPS) and the EU single market – adequately framed to protect health? Should the UK press for a public health article in the EU treaty?

Warnings on packaging

3.11 The UK will have to decide if it wants to include pictorial warnings on packs following the Commission's specification of how such warnings might be used. A regulatory committee will be established with the power to modify the warnings specified in EU Directive 2001/37/EC, but what are the appropriate warnings for the UK and how would these be determined?

Additives and design features

3.12 The regulation of additives is wholly inadequate in the UK and EU. How can a proper public health assessment be made of the impact of individual tobacco additives and what sort of approval process would be needed? What more could be done to force the introduction of fire-safe cigarettes?

Successor directive

3.13 EU Directive 2001/37/EC contains provisions for a review to be completed by 2004, with new proposals to follow if necessary. How will the UK government address the many areas that will be covered by the review and provide good scientific advice to the Commission?

Research agenda

3.14 Tobacco companies clearly know a great deal more about tobacco products than their regulators. What funds can be justified for research into tobacco products and how should these be spent?

Other areas of tobacco policy

3.15 The items listed above reflect just one aspect of tobacco policy – the regulation of the product and its packaging. There is also government regulatory involvement in a number of other areas of the tobacco market.[1]

- **Advertising, sponsorship and promotion – monitoring, enforcement, and legislative development.** The Tobacco Advertising and Promotion Bill allows for modification of the legislation in response to changes in technology and marketing practices.
- **Smoking in the workplace and public places.** The Health and Safety at Work Act places obligations on employers to protect the health, safety and welfare of employees. How should the scientific evidence on passive smoking be reconciled with the requirements on employers to do what is reasonably practicable to offer protection to workers?
- **NHS treatment of tobacco dependence.** There are several areas in which the Government defines policy and regulation of smoking cessation.
- **Taxation and economic effects.** There is a strong case to gather and analyse much greater data on the impact of tax policy both in shifting patterns of consumption and any unintended consequences.

Knowledge and experience

3.16 In addition to regulation and enforcement, there is a need for authoritative scientific, economic and public health advice and research to inform policy and regulation. Programmes with substantial funding, such as the national tobacco education campaign, also need to draw on best available knowledge of what works and programme experience from elsewhere.

1. See Action on Smoking and Health (ASH), 'Tobacco legislation, regulations and voluntary agreements', http://www.ash.org.uk/html/policy/legislation.html<8 November 2002 (Last accessed 13 November 2002)>

FOUR

Views of Parliament and Government responses

4.1 After an extensive review of the history of tobacco regulation in the UK and the role played by the tobacco industry, the Commons Health Select Committee made the following observations and recommendations:

> *189. The final conclusion of the RCP in its Report* Nicotine Addiction in Britain *was that 'an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain'. We concur. It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*
>
> *190. We have, throughout our report, indicated areas for which we think a Tobacco Regulatory Authority (TRA) could take responsibility. It could look at all aspects of the marketing of tobacco, the product itself and the nature of its health risks and developments in respect of 'safer' cigarettes. […]*
>
> *191. Consequently we would envisage the creation of a TRA with its own scientists, completely independent of the tobacco companies. When considering its function we should like to stress that we do not believe that the TRA could, for example, seek the elimination of nicotine from cigarettes. Its policies would have to recognize the realities of a global market for tobacco products, where any attempt to exclude nicotine – which would in our view be tantamount to prohibition of cigarettes, in that nicotine is, in the words of the RCP, the 'unique selling point' of cigarettes – would be likely to be counter-productive. The proposed TRA could, however, examine nicotine:tar ratios to determine how these could be optimised to minimise exposure to toxins.*
>
> *192. The TRA would, as we have stated, be the ideal objective judge of which additives and flavourings should or should not be permitted to be added to tobacco products, having as its test the overall impact on public health. The TRA could consider the marketing of tobacco products, looking at areas of promotion going beyond advertising into issues such as point of sale displays.*
>
> *194. In a research capacity, the TRA could examine, and offer definitive statements, on the current scientific consensus as to the dangers of smoking, and could examine the most effective ways of persuading people to quit or never to start.*
>
> *195. Assuming there is a will on the part of Government to tackle nicotine addiction in the very fundamental way that we propose, the question remains where should a TRA be located? One possibility would be for the UK to have its own TRA, in a way analogous to the Food Standards Agency or Medicines Control Agency; another would be for a TRA to be located in Europe, the source of much of what currently passes for tobacco regulation. […]*
>
> *198. Turning to the question of how the TRA should operate we think it vital that such a body should be very well resourced to deal with the huge scientific and legal resources of the tobacco*

companies. We think that a proportion of tobacco duty should be hypothecated to finance the regulatory authority. In oral evidence the DoH told us that, to analyse and understand the technical composition of cigarettes, it relied on a scientific adviser, Professor Frank Fairweather, who worked one day a week, another scientific advisor working two days a week, and Mr Tim Baxter who worked full time. Mr Baxter explained that, as head of the Tobacco Research Unit, he had access to a technical advisory group via the Scientific Committee on Tobacco and Health. Finally the DoH provided over £500,000 a year to the Laboratory of the Government Chemist to test tar and nicotine ratings. Mr Baxter recognized there were many calls on the Department's resources, but he admitted that it would be 'very nice' to have more resources since his team were 'highly stretched'. When we put our concerns on this matter to the Secretary of State he agreed that the tobacco team in the Department was 'quite small', but he contended that its work was supplemented by, for example, the professionals working in Health Action Zones and the Scientific Committee on Tobacco and Health. This latter body he described as 'a very useful organisation'.

199. We would have more faith in the Secretary of State's assessment of the added benefit of SCOTH had that organization not been in abeyance for almost two years. We regard the current staff resources devoted to tobacco control, especially in the area of scientific knowledge and advice, to be pitifully weak. Irrespective of whether the Secretary of State accepts our recommendation that root and branch reform is needed in terms of a TRA, we would expect to see a major increase in resources, met out of the enormous income the tobacco companies pay in duties to the Treasury.

200. If UK staff resources are pitiful, those in the EU are utterly derisory. As the Secretary of State informed us, and as we saw for ourselves in Brussels, in Europe 'there is just one official dealing with tobacco', Mr John Ryan. In fact the situation is graver still, in that tobacco forms only one half of Mr Ryan's portfolio. We met Mr Ryan on our visit to Brussels and were extremely impressed by his knowledge and commitment. But we do not see how the Health Commissioner can deliver his objective of reducing tobacco consumption with such scant resources. We recommend that the Secretary of State makes immediate and urgent representations in Brussels to create a far more substantial unit to combat the enormous resources of the tobacco industry. We believe that European policy is already hugely compromised by the CAP subsidy, and that unless appropriate resources go into tobacco control European action in this sphere will lack credibility. [2]

4.2 The government's response dealt with these recommendations in a cursory manner:

The Government agrees with the Select Committee that tobacco products need to be regulated more effectively than at present. We believe that much of this regulation will be most effective if it is done at the European level, which is why we continue to argue strongly for tighter regulation and greater openness in negotiations with our European partners. The Draft European Directive on the manufacture, presentation and sale of tobacco products requires much greater openness, something which the UK has argued for strongly in Europe. Once adopted, we will be implementing the Directive.[3]

4.3 However, there is little sign of effective regulation at the European level, and indeed such regulation may not even be possible without a change to the EU Treaties. At present the treaties

2. House of Commons Select Committee on Health. *The tobacco industry and the health risks of smoking. Second report, session 1999/2000.* London: The Stationery Office, 2000.

3. Department of Health. *Government response to the second report of the Health Committee: the tobacco industry and the health risks of smoking*. London: DH, 2000.

emphasise the operation of the single market and do not allow regulation by qualified majority for health protection. In our view, it would be unduly constraining to require regulation of tobacco to fit within the single market provisions of the treaty – see the discussion in Appendix 2.

4.4 Evidently dissatisfied, the Health Select Committee raised the matter again in its report on public health:

> *248. We would welcome a clear statement of principle by the Government on the desirability of a Tobacco Regulatory Authority. We feel that our report was one of the most comprehensive analyses of the tobacco industry ever undertaken in the UK, had access to documentation that had hitherto been concealed, and got very much to the heart of the behaviour of the tobacco companies. We would like the Government unequivocally to support our recommendation and – when parliamentary time permits – introduce appropriate legislation to support it.*[4]

4.5 In its response, the Government offered a more open-minded view than its previous response to the Committee's report:

> *The Government agrees that there is a need for tighter regulation of tobacco products, and more information about the additives used in them and their effect upon health.*
>
> *It also agrees that there is a need for greater control of the contents of tobacco products and more information about the effects on health of the various ingredients. However, the Government is not convinced that all existing legislative powers have been fully applied and is considering how these might be used to regulate tobacco products more effectively. Wide-ranging powers exist under the Consumer Protection Act 1987 to ensure the safety of consumer goods, and the Government will not hesitate to use these, if necessary, to ensure that changes are made to tobacco products so as to reduce the harm these cause. That said, it is not in principle opposed to the idea of a Tobacco Regulatory Authority, should existing mechanisms prove inadequate, and will keep this whole area under review.*
>
> *The Government continues to believe that work in this area will be most effective at a European level and good progress is being made. The Directive of the European Parliament and Council on the manufacture, presentation and sale of tobacco products (2001/37/EC) came into force on 18 July 2001. This Directive will require Member States to collect thorough details of the contents of tobacco products on the market and to submit these to the European Commission, which in turn will be required to draw up a report on its application. The Directive requires that the Commission will be assisted by the necessary scientific and technical expertise.*[5]

4. House of Commons Select Committee on Health. *Second report, session 2000/1*. London: The Stationery Office, 2001.

5. Department of Health. *Government response to the House of Commons Select Committee on Health's second report on public health.* London: DH, 2001.

FIVE

Resources for tobacco: Department of Health 'regulatory' staff

5.1 A key criticism made by the Health Select Committee was that government resources devoted to regulating tobacco were 'pitiful' at UK level and 'utterly derisory' at EU level. However, since the publication of the Committee's report, the position has not improved and may actually have deteriorated. There has also been a rapid turnover of key staff, leading to loss of continuity and experience.

- At the Department of Health branch head level (civil service grade 5), there have been four senior officials in the last five years.
- At the team leader level (grade 6 or 7) there have been three complete changes of staff in five years. In the most recent change, the team leader has assumed wider responsibilities.
- The science and medical capacity was regarded as inadequate at the time of the Health Committee report in 2000, and has since been reduced. An experienced full-time medical officer has been replaced by a part-timer new to the field.
- The Department was previously able to draw on a pool of experience and expertise at the Health Education Authority – there was a team of ten professionals in 1999, but there are now only two part-time staff devoted to tobacco at its successor, the Health Development Agency. Though there have been some compensating increases in resources in the Department's communications and policy units, the government has lost a substantial body of expertise.
- The Scientific Committee on Tobacco and Health relies on voluntary and unpaid participation by established scientists in the field. After its 1998 report, it was in abeyance for more than two years. The Committee was reformed in late 2000 and has since met approximately quarterly. The Committee itself has registered concerns about its own level of resources, time commitment and expertise in relation to the scale of scientific challenges which lead to problems in its effective functioning.
- The Health Committee spoke highly of the experienced Commission official, Mr John Ryan. Mr Ryan has since been moved. The European Commission does have a slightly larger team now, but comprised of less experienced officials. It also has greater demands on its time due to legal actions by tobacco companies.

5.2 This is not intended to be a criticism of civil service career structures. However, it does suggest that the government needs an institutional solution to the problem of regulating tobacco that may be in some way separate from the Department of Health's Cancer and CVD Prevention branch. This would be similar to the approach taken towards regulating drugs and food, whereby external agencies exercise statutory powers and advise the Secretary of State on the use of his powers.

The Royal College of Physicians' view

5.3 The Royal College of Physicians urges the government to act on its commitment to tighter regulation and at least to follow the recommendation of the College's 2000 report *Nicotine addiction in Britain*:

> *We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*[6]

5.4 The College maintains that the regulation of tobacco and conduct of tobacco policy needs to be addressed at an institutional level – and that this means creating a permanently staffed agency with adequate responsibility and authority to create a proper regulatory environment for tobacco.

6. Royal College of Physicians. *Nicotine addiction in Britain*. London: RCP, 2000.

SIX

Regulating tobacco at the European level

6.1 The Government has argued that tobacco should be regulated at the European level and that any regulatory agency needs to be established at the EU level. There are a number of reasons why this is an insufficient response to the challenge.

- The institutions do not exist at EU level and the government has done little to press for them to be established. The tobacco product directive 2001/37/EC establishes a regulatory committee to deal with three narrow areas of regulation and requires that the Commission takes appropriate scientific advice in reviewing the effect of the directive. However, this does not amount to a proper regulatory authority.
- The government is ultimately responsible to the British electorate for positions adopted in the EU, and needs to place British interests to the fore while EU regulation and legislation is made. Where the regulatory capacity is weak at EU level and in other member states, the UK should not find itself agreeing with weak or inappropriate measures (as happened with 2001/37/EC) simply because it has, as stated by the Health Select Committee, 'pitiful' resources devoted to the issue.
- The competence of the EU to regulate for public health is at best ambiguous and the EU regulations in place governing tobacco are primarily to ensure the operation of the single market and compliance with trade agreements. The government therefore has the scope (and obligation) to introduce tobacco regulation for public health and consumer protection purposes as UK legislation or regulation – this has been the case for the advertising legislation. This will remain the case as long as the EU treaties (eg article 152) do not allow negotiation of binding directives or regulations at EU level for public health reasons.
- Enforcement and operation of EU laws are the responsibility of member states and there are many issues that arise at national level in the practical implementation of EU regulation.
- In the case of food and pharmaceuticals, the regulatory agencies are at both national and EU level, with very substantial agencies (the FSA and MCA respectively) in the UK. A similar structure should apply to tobacco.
- Regulation of tobacco at EU level has not been a conspicuous success so far (see Appendix 2 for a discussion of the limitations of tobacco regulation at EU level). This is mainly because tobacco legislation in this arena has been formulated under *single market* articles of the EU Treaties rather than as *health* legislation. Any regulatory body would also be formulated in the same way. Thus its dominant pre-occupation would be operation of the single market rather than public health.

SEVEN

Comparison: The Office of Tobacco Control, Ireland

7.1 In Ireland, new tobacco control legislation completed its passage on 27 March 2002. Part of the bill was to establish the Office of Tobacco Control (OTC). The legislation gives the following functions to the Office at section 10:

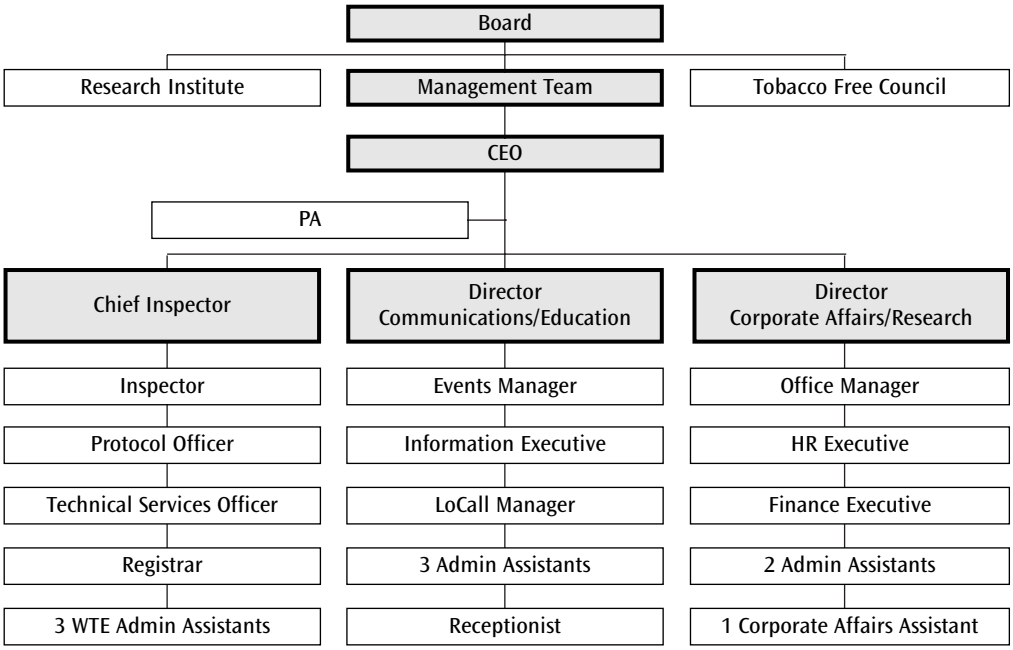
> *10.–(1) The general functions of the Office shall be to –*
>
> *(a) advise the Minister in relation to the formulation, and assist him or her in the implementation, of policies and objectives of the Government concerning the control and regulation of the manufacturing, sale, marketing and smoking of tobacco products,*
>
> *(b) consult with such national or international bodies or agencies having a knowledge or expertise in the field of smoking prevention for the purpose of identifying measures designed to eliminate, reduce the incidence of, or discourage smoking,*
>
> *(c) make such recommendations to the Minister as it deems appropriate in relation to measures that the Office considers should be taken in order to reduce or eliminate smoking or its effects in the State,*
>
> *(d) undertake, sponsor or commission, or provide financial or other assistance for, research aimed at identifying measures that when adopted are likely to reduce the incidence of smoking or its effects,*
>
> *(e) prepare and publish, in such manner as it thinks fit, reports on any research undertaken, sponsored or commissioned, or for which financial or other assistance was given, under paragraph (d),*
>
> *(f) furnish advice to the Minister, whenever he or she so requests, on matters relating to the control and regulation of the manufacture, importation, sale or supply of tobacco products and on measures to reduce, eliminate or discourage smoking,*
>
> *(g) provide, and where appropriate exchange with the Garda Siochana and the Revenue Commissioners, information relating to the control and regulation of the manufacture, sale, supply, importation and distribution of tobacco products,*
>
> *(h) prepare and implement a plan for the coordination nationally of the activities of the Office and of health boards in relation to this Act and the cooperation of the Office and the health boards in the performance of their functions under this Act,*
>
> *(i) furnish advice to the Minister, whenever he or she so requests, on matters relating to –*
>
> > *(i) strategies employed by manufacturers, importers, distributors or retailers of tobacco products in the marketing, sale or promotion of such products,*
> >
> > *(ii) technology used in the manufacture, production or marketing of tobacco products,*
> >
> > *(iii) any innovations on the part of manufacturers, importers, distributors or retailers of tobacco products relating to the manufacture, production or marketing of those products,*

(j) coordinate and implement a programme for the inspection of all premises in which tobacco products are manufactured, stored, subjected to any process or sold by retail, and all premises to which the public have access, either as of right or with the permission of the occupier or person in charge of the premises concerned, for the purposes of ensuring that there is compliance with the provisions of this Act,

(k) collect or disseminate such information as may reasonably be necessary for the effective performance of its functions,

(l) furnish, whenever the Office considers it appropriate or is so requested by the Minister, advice or information to a Minister of the Government (including the Minister) in relation to any matter connected with its functions.[7]

Fig. 1 **Organisation chart of the Office of Tobacco Control, Ireland.**



7.2 The role of the Board is described in section 12 of the Act:

12.–(1) The Office shall consist of the following members, that is to say, a chairperson and 11 ordinary members.

(2) The members of the Office shall be appointed by the Minister.

(3) The chairperson of the Office shall hold office for a period of 5 years from the date of his or her appointment.

(4) An ordinary member of the Office shall hold office for such period not exceeding 5 years as the Minister may determine when appointing him or her.

(5) A member of the Office whose term of office expires by the effluxion of time shall be eligible for reappointment to the Office.

7. Government of the Republic of Ireland. Public Health (Tobacco) Bill 2001. March 2002.

7.3 The role of the Tobacco Free Council is described in section 22 of the Act:

> *22.–(1) The Office shall establish a body to be known as the Tobacco Free Council (hereafter in this section referred to as the 'Council').*
>
> *(2) The Council shall make themselves available to be consulted by the Office in relation to the performance by the Office of functions (of such a class as may be determined by the Office, with the consent of the Minister) and may give advice or an opinion to the Office regarding any matter (of such a class as may, with the consent of the Minister, be determined by the Office) falling to be decided by the Office or the performance by it of such functions.*

Budget

7.4 The OTC is part of a comprehensive programme outlined for Ireland, *Towards a Tobacco-Free Society*.[8] The programme was budgeted at IR£20 million per year (UK£15.6 million) of which IR£600,000 was allocated to the OTC and IR£100,000 to the Tobacco Free Council. The final budget has yet to be settled (in July 2002).

7.5 The population of Ireland is 3.8 million, compared to 56 million for the UK. There are about 7,000 tobacco-related deaths per year in Ireland, compared to 120,000 for the UK. If Britain spent equivalent in per capita terms to Ireland's OTC and Tobacco Free Council, the budget would be £8.8 million.

8. Tobacco-Free Policy Review Group. *Towards a tobacco free society.* Dublin: DoH, 2000.

EIGHT

Comparison: The Food Standards Agency

8.1 The Food Standards Agency is an independent food safety watchdog set up by the Food Standards Act 1999 to protect the public's health and consumer interests in relation to food. The Act sets out the Agency's main objective of protecting public health in relation to food and the functions that it will assume in pursuit of that aim, and gives the Agency the powers necessary to enable it to act in the consumer's interest at any stage in the food production and supply chain. The Act provides for the Agency's main organisational and accountability arrangements. In addition, it provides powers to establish a scheme for the notification of the results of tests for foodborne diseases.

What are the FSA's aims?

8.2 Between 2001 and 2006, the Agency's aims as stated on its web site are to:

- reduce foodborne illness by 20% by improving food safety right through the food chain (it is estimated by the FSA that there could be up to 4.5 million cases of food poisoning every year in the UK);
- help people to eat more healthily;
- promote honest and informative labelling to help consumers;
- promote best practice within the food industry;
- improve the enforcement of food law;
- earn people's trust by what it does and how it does it.

How is the FSA structured?

8.3 The Agency is led by a board that has been appointed to act in the public interest and not to represent particular sectors. Board members have a wide range of relevant skills and experience. The UK headquarters are in London, but the Agency also has national offices in Scotland, Wales and Northern Ireland. The Meat Hygiene Service is an executive agency of the FSA. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

The FSA's responsibilities

8.4 The work of the FSA involves food safety across the whole of the food chain, including:

- food contaminants (defining tolerable levels, risk management and policy);
- food additives, contact materials, and novel foods (including safety assessment and surveillance);

- microbiological safety and food hygiene (including providing advice on the management of food borne outbreaks and prevention of food borne illness);
- inspection and enforcement action to protect consumers;
- local authority enforcement (developing policy, and auditing and improving enforcement);
- pesticides, veterinary medicines and animal feed (assessing food safety implications);
- food labelling and standards (developing policy, improving consumer choice and representing the UK in the EU);
- nutrition (providing advice and guidance on the nutritional composition of food, and providing information on a healthy, balanced diet, so as to promote and protect public health).

The FSA's powers and accountability

8.5 Although the FSA is a Government agency, it works at 'arm's length' from Government because it does not report to a specific minister and is free to publish any advice it issues. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

8.6 The powers and function of the FSA are defined in the Food Standards Act 1999:

- **The Food Standards Agency** (**sections 1–5**), concerns the establishment of the FSA, its main objective and its main organisational arrangements including the establishment of advisory committees (more detailed provisions are contained in Schedules 1 and 2).
- **General functions in relation to food** (**sections 6–8**), confers on the FSA responsibility for developing food policy and advising Ministers and other public authorities, for advising consumers and other interested parties and for keeping abreast of developments relevant to its remit.
- **General functions in relation to animal feedingstuffs** (**section 9**), supplements the FSA's functions in relation to animal feed.
- **Observations with a view to acquiring information** (**sections 10–11**), gives the FSA functions in relation to surveillance and provides powers to enable it to carry them out.
- **Monitoring of enforcement action** (**sections 12–16**), gives the FSA a function of monitoring food and feedingstuffs law enforcement and provides powers to enable it to carry it out.
- **Other functions of the Agency** (**sections 17–21**), describes the Secretary of State and the devolved authorities' powers to delegate the making of emergency orders to the FSA, and the FSA's power to publish its advice.

- **General provisions relating to the functions of the Agency (sections 22–25)**, concerns certain considerations which the FSA must observe in carrying out its functions, provides for directions by ministers and the devolved authorities should the FSA fail to perform its duties, and allows for modification of enactments to allow disclosure of information to the FSA and publication by it.
- **Miscellaneous provisions (sections 26–35)**, sets out the functions no longer to be exercised by the Minister of Agriculture, Fisheries and Food, and the Department of Agriculture for Northern Ireland, and makes various provisions for consultation with other parts of Government or the devolved administrations on aspects of food safety.
- **Final provisions (sections 36–43).**

European dimension

8.7 There is considerable EU regulation in the area of food and food safety, currently managed by the European Commission and several scientific and regulatory committees.[9,10,11] The mission of the Directorate General for Health and Consumer Protection (known as the 'DG Sanco') is to implement the responsibilities entrusted to it by the treaty and derived legislation so as to ensure that a high level of human health and consumer protection is attained throughout the EU. DG Sanco also has prime regulatory responsibility for tobacco.

8.8 In January 2002, the EU agreed to establish the European Food Safety Authority (EFSA).[12] The measures introduced will reinforce existing consumer protection and should help re-establish consumer confidence in the food chain in Europe. The EFSA is an intrinsic part of a more strategic approach to food safety issues across the EU.

Budget

8.9 The net cost of the Westminster funded FSA (ie excluding Wales, Northern Ireland and Scotland) in 2000/1 was £83.7 million. The FSA also raises substantial funds (£48 million) through charges for the meat hygiene service. General food hygiene inspection is outside the remit of the FSA and is undertaken by the local authority's environmental health officers.

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9. DG Sanco, 'Food safety: from the farm to the fork', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

10. DG Sanco, 'Scientific committees', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

11. DG Sanco, 'Regulatory committees', http://europa.eu.int/comm/food/fs/rc/index_en.html <Last accessed 13 November 2002>

12. Regulation 2002/178/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

13. Food Standards Agency. *Food Standards Agency annual report and accounts.* London: The Stationery Office, 2002.

8.10 The FSA divides up its expenditure according to the aims set by Government and Parliament.[13]

Table 1. FSA expenditure and income divided by aim.

Aim	**Expense** (thousands of pounds)	**Income** (thousands of pounds)	**Net** (thousands of pounds)
Aim 1: Measurably improve public confindence in the national food safety and standards arrangements	23,434	(397)	23,037
Aim 2: Reduce foodborne illness by 20% over the next 5 years including reducing salmonella in UK produced chickens on retail sale by at least 50% by the end of 2004/2005	38,910	(2,305)	36,605
Aim 3: To protect consumers through improved food safety and standards	69,447	(45,346)	24,101
Total	**131,791**	**(48,048)**	**83,743**

NINE

Comparison: The Medicines Control Agency

9.1 The MCA's primary objective is to safeguard public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy. Safety aspects cover potential or actual harmful effects; quality relates to development and manufacture; and efficacy is a measure of the beneficial effect of the medicine on patients. The MCA achieves its objectives through:

- a system of licensing before the marketing of medicines;
- monitoring medicines and acting on safety concerns after they have been placed on the market;
- checking standards of pharmaceutical manufacture and wholesaling;
- enforcement of requirements;
- responsibility for medicines control policy;
- representing UK pharmaceutical regulatory interests internationally;
- publishing quality standards for drug substances through the *British Pharmacopoeia*.

History

9.2 The MCA was established in April 1989, taking over the duties of the Medicines Division of the Department of Health. It became an executive agency of the Department in July 1991 and was established as a trading fund on 1st April 1993 by the Medicines Control Agency Trading Fund Order 1993.

9.3 Effectively, a function previously managed within the Department of Health was moved out to become a separate and separately accountable body with autonomous funding. This could be a useful model for a tobacco and nicotine regulatory authority.

Advisory committees

9.4 There are several advisory committees that interact with the MCA. These are established under the Medicines Act 1968 or related regulations and many have functions that could find parallels in the regulation of tobacco.

- **Medicines Commission.** Twenty three members meet five times per year, to advise the Secretary of State on the application of the Medicines Act 1968. The Medicines Commission also advises on setting up other committees under the Act.

- **Committee on the Safety of Medicines (CSM).** This body provides advice on licensing of medicines to the Licensing Authority in conjunction with the MCA. The CSM is comprised of 34 members who are appointed by the UK's health ministers. Members include pharmacists, pharmacologists, toxicologists and physicians from a wide range of disciplines working in general practice, hospitals and universities across the UK. It also includes two lay members. The Committee meets fortnightly (except in August) and its secretariat is provided by the staff of the MCA.
- **The Advisory Board on the Registration of Homoeopathic Products (ABRHP)** gives advice with respect to safety and quality in relation to any homoeopathic medicinal product for human use.
- **Independent review Panel for Advertising.** The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 came into force on 5 April of that year and complete the implementation of EU Directive 92/28/EEC. Regulation 13 and the Schedule contain a procedure for a review of the Health Minister's preliminary decision on whether an advertisement complies with the Medicines (Advertising) Regulations 1994, as amended ('the Regulations').
- **Veterinary Products Committee (VPC).** The VPC was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are to give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance.

European dimension

9.5 The control of medicines in the UK is primarily through the system of licensing and conditional exemptions from licensing laid down in EC legislation, the Medicines Act 1968 and in relevant subordinate legislation. Controls on medicines under the Medicines Act matched or in some cases exceeded those of existing European Directives and the UK played a major part in the development and revision of the EEC Directives in this area. European Community (EC) legislation now takes precedence over the Medicines Act, its Instruments and Orders, which are amended from time to time to align with new EC requirements.

9.6 The MCA plays an active role in negotiations and discussions in Europe and continues to represent the UK at key European meetings, such as Heads of National Regulatory Agencies, the Pharmaceutical Committee and the Committee for Proprietary Medicinal Products (CPMP). In addition, towards the end of 2000 the draft EU directive on good clinical practice and clinical trials reached a critical stage in its progress through the European legislative procedure.

9.7 The MCA continues to contribute to issues on which wider Department of Health and other government departments are in the lead. This has notably included the review of the General Product Safety Directive (that is the responsibility of the Department of Trade and Industry).

9.8 There is also a body operating at EU level; the European Agency for the Evaluation of Medicinal Products (EMEA), which is based in London. This body supervises the operation of the 'mutual recognition procedure' for authorisation of medicines, co-ordinates research, directly authorises biotechnology products and operates a pharmacovigilance network

throughout Europe. EMEA cooperates closely with the MCA – the current Chairman is Dr Keith Jones, who is also Chief Executive of the MCA. The MCA is one of the 'competent authorities' recognised by EMEA.

Budget

9.9 The budget for the MCA for 2000/1 was £38.4 million and it employed 436 people. The MCA raises its funds by charging for licensing and inspections (£18.3 million) and services (£12.4 million).

9.10 The budget for EMEA is EUR 65.9 million for 2001 (£40 million), and roughly equivalent to the budget for the UK regulator.

TEN

Options for a Tobacco and Nicotine Regulatory Authority

Objective

10.1 A tobacco and nicotine regulatory authority should have a clear objective:

> *… to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users.*

Organisational form

10.2 There are several potential models that could be used:

- **Move existing functions to a new agency.** This approach was used with the formation of the Medicines Control Agency which advises the Secretary of State on the exercise of powers that were defined in earlier legislation.
- **Introduce new enabling legislation and powers to create a new agency.** This was how the Food Standards Agency was formed. The FSA has an independent role and powers conferred by its own legislation, the Food Standards Act, 1999. Tobacco could conceivably be included within the definition of food used in the Act (see Appendix 1).
- **Add tobacco regulation to the mandate of an existing body, amending its enabling legislation if necessary.** This could be the FSA or the MCA – or possibly a split between both.
- **Re-examination of existing legislation to create specific powers to regulate tobacco.** For example, the Consumer Protection Act 1987 or the newly adopted General Product Safety Regulations could be used to create a framework for tobacco regulation. The new agency could be created to advise the competent authorities defined in that legislation on the exercise of the relevant powers. The use of consumer protection legislation is discussed in question and answer form in Appendix 1.

Funding

10.3 Funding should, as far as possible, be raised from charges to the regulated industry – tobacco manufacturers, wholesalers, importers and exporters as appropriate. The MCA is entirely funded from external income, the FSA receives about 36% of its total funds from inspections and the Environment Agency earns 38% of its income from fees and levies.[14]

14. Environment Agency, 'Our income', http://www.environment-agency.gov.uk/aboutus/275155/234158/?version=1&lang=_e <Last accessed 13 November 2002>

Mandate for a tobacco and nicotine regulatory authority

10.4 The mandate of a tobacco and nicotine regulatory agency could be as follows:

Product regulation and consumer protection

- enforcing legislation in place – in concert with local enforcement agencies;
- establishing standards for novel tobacco or nicotine products;
- taking test cases on behalf of the Secretary of State where there is ambiguity or contention;
- managing disclosure of additives and publishing of public data;
- managing testing and disclosure of toxicity data for smoke and ingredients;
- formulating proposals for regulation of constituents of tobacco products and smoke;
- representing ministers on EU regulatory committees;
- conducting market surveillance;
- advising on warnings and consumer protection information required on packs;
- advising Secretary of State on risk communication to the public;
- challenging misleading risk communication;
- evaluating, approving or challenging health claims, whether explicit or implicit;

Non-tobacco nicotine products

- to advise the medicines 'licensing authority' (ie ministers) on the public health consequences of licensing particular non-tobacco nicotine products for sale in the UK. The authority would strike a 'concordat' with the MCA over their respective responsibilities.

Research and evidence clearing house

10.5 There is a clear need to have some continuity and experience with the science, law, economics and other policy aspects of tobacco. The authority could 'own' and develop expertise in this field on behalf of the government. For example, it could take responsibility for the following:

- Secretariat for Scientific Committee on Tobacco and Health;
- research and monitoring of wider tobacco control policies;
- gathering data on trends in tobacco use
  - prevalence and consumption
  - brand data
  - tobacco related disease trends
  - use of smuggled or budget cigarettes and switching to hand-rolling tobacco

- impact of new products
- impact of policy measures, including primary and secondary prevention intervention
- passive smoking exposure and indicators of responses.

10.6 Other functions that could be included in the mandate of a nicotine and tobacco regulatory authority are:

Marketing activity

- control and supervision of marketing activities of tobacco companies;
- enforcement of advertising legislation;
- developing regulations in response to technology developments;
- acting as a source of pressure for voluntary restraints on use of tobacco in films, magazines etc;
- contracting effective mass-media advertising campaigns and organising an education campaign;

Counter-marketing

- collating evidence and advise on campaign strategy;
- possibly 'owning' the campaign;
- commissioning evaluation;

Smoking cessation

- developing, disseminatimg, promoting and auditing implementation of best practice;
- offering support infrastructure;
- developing economic analysis and monitoring economic impacts;
- commissioning evaluation;

Passive smoking

- implementing the Approved Code of Practice on passive smoking at work;
- monitoring impact of voluntary agreements; and
- proposing legislation where necessary.

Economic and trade regulation

10.7 The UK tobacco industry is a duopoly and its two main companies earn super-normal profits. A large share of the UK cigarette market is also lost to contraband and counterfeit, and measures such as fiscal markings have been introduced to tackle these. There are a number of

economic and trade-related issues that could be managed by a tobacco regulator, including:

- smuggling;
- under-age sales;
- illegal sales;
- vending machines; and
- budget brands and price ranges in the marketplace.

ELEVEN

Conclusion

11.1 Having considered the issues discussed in this report, the College draws the following conclusions.

1. There are numerous and formidable regulatory challenges in the field of tobacco and nicotine. The approach taken to these challenges will be an important factor in determining the burden of disease caused by tobacco and nicotine use in the future.
2. The current almost-entirely unregulated position enjoyed by tobacco products and tobacco manufacturers should not be allowed to continue. Detailed consideration by Parliament concluded that some regulatory authority was essential to control and contain the tobacco industry and the harm caused by tobacco. The College has already argued the case for a Tobacco and Nicotine Regulatory Authority.
3. The Government has not strengthened its regulatory capacity since the Health Select Committee's report. The scientific capacity has actually been reduced. The practice of leaving tobacco policy and programme implementation to career civil servants who will often stay in post for less than two years will not be adequate to match the regulatory challenges posed by the evolving tobacco market.
4. The harm done by tobacco and nicotine use is to some extent controllable by influencing the design, blending and ingredients of tobacco products. Tobacco manufacturers will introduce new products with the aim of capturing a niche market for smokers concerned about health. Some smokeless tobacco products and pharmaceutical nicotine may offer substantial reductions in harm compared to smoking. Regulators cannot afford to ignore such developments – which are both public health threats and opportunities.
5. The regulatory arrangements for nicotine products apply the toughest controls to the least hazardous forms of delivery and apply minimal controls to cigarettes, the most hazardous form. A new authority should reconfigure this system so as to give the best outcome for public health.
6. We believe that the Government should act on the recommendations of the Health Select Committee and earlier advice of the College and establish a regulatory function for tobacco and nicotine outside the Department of Health. The function of a 'tobacco and nicotine regulatory authority' would be to advise the Secretary of State on how to exercise his regulatory powers, and to assume any responsibilities allocated to it in legislation.
7. Institutional precedents – notably the FSA – already exist. The FSA receives very substantial funding (£83 million p.a.) as well as fee income, yet the impact of food safety on public health is considerably less than the impact of tobacco.

8. Existing consumer protection legislation is available to give an authority the powers to act on behalf of ministers. Food and medicine regulation could also be applied to tobacco. However, the over-riding importance of tobacco in public health means that the Government should develop whatever legislation proves necessary at a later stage.

9. The body should be entirely funded by fees levied on the regulated industry – as is the case with the MCA and to some extent the FSA and Environment Agency. The authority should be established at national level without delay, with a European agency developed later. This is the approach adopted with food: the UK's Food Standards Agency has preceded the emerging European Food Safety Agency.

Appendix 1
Legal Q&A on a Tobacco and Nicotine Regulatory Authority

Given the existing and planned legislation, and experience of consumer protection measures, in the UK, what more could be done to regulate tobacco products, and how could an entity with the functions of the Tobacco and Nicotine Regulatory Authority be created?

Whilst it might be possible to apply the Medicines Act 1968 and Food Safety Act 1990 to tobacco, the Consumer Protection Act 1987 seems a more obvious and less contentious route to regulation. So long as the matter governs safety, that Act has fairly broad regulation-making powers, which should be broad enough to fulfil most European obligations. However, it might seem strange for a tobacco and nicotine regulatory authority to have to use the Consumer Protection Act (CPA) 1987 for tobacco when most of its uses are in relation to consumer products regulated by the Department of Trade and Industry, rather than public health matters. Specific tobacco legislation would be a more desirable basis for developing regulation in this area and would remove any doubt.

What new legislation would we need to achieve the aim of having a tobacco and nicotine regulatory authority with the mandate set out in the Commons Health Select Committee report and by the Royal College of Physicians?

There would need to be primary legislation establishing a tobacco and nicotine regulatory authority. Existing powers of secondary legislation might be able to be invoked by this authority recommending action to the relevant ministries, but equally it might be more desirable to create a new enabling power. The authority's role may well be simply one of supervising enforcement authorities. Such powers could be outlined in the legislation establishing the authority. If it were thought desirable for the authority to have enforcement powers itself these would have to be specified.

What obligations do the CPA 1987, and General Product Safety Regulations 1994 place on tobacco and nicotine manufacturers or vendors? Is there any existing body responsible for enforcing such obligations?

Obligations on manufacturers and vendors

The CPA 1987 Part II, s. 10, makes it an offence for a person to supply or undertake steps preparatory to the supply of defective consumer goods. Unfortunately the definition of consumer goods excluded tobacco from its scope (s. 10(7)(f)). Tobacco was defined as including any tobacco product within the meaning of the Tobacco Products Duty Act 1979 and any article or substance containing tobacco and intended for oral or nasal use.

In 1992 the EC adopted Directive 92/59/EC on general product safety, which also included a general safety requirement. This was implemented by the General Product Safety Regulations

S.I. 1994/2328, which, whilst not formally repealing s.10, disapplied it in most contexts. The important point for this discussion is that the definition of 'product' under these regulations is broader than the definition of consumer goods under the CPA 1987. Of most significance is the fact that tobacco is no longer excluded. The definition covers 'any product intended for consumers or likely to be used by consumers' (reg. 2(1)) and tobacco products seem to fall squarely within this definition. Thus there would seem to be no need to pass any measure to bring tobacco within the CPA's general safety requirement since this has effectively been done by the 1994 regulations.

Product safety

The main obligation is placed on producers only to place on the market products that are safe (reg.7). A safe product is,

> *any product, which under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular –*
>
> *a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;*
>
> *b) the effect on other products, where it is reasonably foreseeable that it will be used with other products.*

Whilst this would not seem to provide the means to condemn tobacco products as a class, given that the risk only has to be the minimum compatible with the product's use, nevertheless the risk must be an acceptable one consistent with a high level of protection. The wording of the definition seems rather strict: 'does not present any risk or only minimum risks compatible with product's use'.

The question of what constitutes minimum risk is a thorny one. There have been recent product innovations that may reduce risk, but it is extremely difficult to measure with confidence. There is also the problem that it may be possible to make genuinely 'safer' products but such products may differ so much from the existing product line that consumers would not find them acceptable.

Warnings

As packaging can be taken into account it might be possible to argue that inadequate warnings render a product unsafe, but this is unlikely, especially given the statutory prescriptions on warnings. Although one might find a court reluctant to condemn a product which complies with regulations this is not an automatic defence. Reg. 10(1) merely provides that where a product conforms to specific rules of UK law laying down health and safety requirements there shall be a presumption that the product is safe, until the contrary is proved. However, reg. 10(2) states assessment of conformity with the general safety requirement will take into account (in what is not expressly stated to be a hierarchy, but probably should be treated as such):

(i) UK voluntary standards giving effect to a European standard;

(ii) Community technical specifications and then if none of them exist;

(iii) UK standards, codes of good practice or the state of art and technology and finally;

(iv) the safety which consumers may reasonably expect.

The general safety requirement found in reg. 7 is fleshed out for producers in reg. 8. These may be of some use in connection with tobacco. Reg. 8(1)(a) concerns risks which are not immediately obvious without adequate warnings. Consumers must be provided with relevant information to enable them to assess inherent risks and to take precautions against them. Thus this would seem to require tobacco manufacturers to have clean hands as regards disclosing potential dangers. Of course it may not always be possible to take precautions against inherent risks, save by not using the product, but disclosure of risks would seem to be adequate.

Research into risks

Reg. 8(b) is also of interest because it requires producers to adopt measures commensurate with the characteristics of their products to enable them to be informed of the risks the products might present. This is normally seen as requiring a strategy to be in place to learn about problems presented by the product in the market place. However, this can also be read as requiring the industry to have a research strategy adequate to learn more about the risks posed by its products. One problem with reg. 8 is that there is no specific offence for breaching it, the offence is for breach of reg. 7, the general safety requirement. It might of course be possible to argue that failure to undertake the activities required by reg. 8 would make the product less safe than it otherwise might be and therefore constitute evidence of a breach of the general safety requirement, but this is by no means self-evident, especially where the problem is lack of a strategy to be informed of risks.

Under reg. 9 distributors are under an obligation to act with due care to ensure compliance with the general safety requirement. In particular reg. 9(a) requires that they shall not supply products they know or should have presumed to be dangerous. Reg. 9(b) requires that within the limit of their activities they participate in the monitoring of products, particularly by passing on information and co-operating in action taken to avoid those risks. Breach of reg. 9(a) is an offence.

Enforcement powers

The 1994 Regulations share the same enforcement powers as the CPA 1987 (reg. 11). Some of these are granted to the Secretary of State and are exercised by the Consumer Safety Unit of the Department of Trade and Industry. In practice these powers are used very sparingly. Prohibition notices can be served on individuals by the Secretary of State to prevent them from supplying the goods specified in the notice (s. 13(1)(a)). They are used for rogue products and only a handful of such notices have been issued. A notice to warn issued by the Secretary of State can require a person to publish a warning about goods considered to be unsafe (s. 13(1)(b)). This power has never been used and is unlikely to be used as the procedures are very cumbersome.

The majority of enforcement action is taken by trading standards officers at the local level. Their main weapon is the suspension notice (s. 14) which can prohibit a person from taking a variety of measures related to the sale of the product for a period of up to six months. They can also apply to the magistrates' court for a forfeiture order (s. 16). A major impediment to the effective use of these powers is the requirement that authorities pay compensation if it turns out their suspicions were not well founded (s. 14(7)).

What are the powers to regulate tobacco and nicotine available in the CPA 1987 and General Product Safety Regulations 1994?

The CPA 1987 provides specific enabling powers to permit the enactment of safety regulations. These powers are broader than that act's general safety requirement, for it applies to all goods rather than just consumer goods, and whilst some products are excluded these do not include tobacco. One of the exclusions does relate to controlled drugs and licensed medicinal products (s. 11(7)(d)) and so if tobacco or nicotine was deemed to fall under the medicinal products regime the regulation making powers in the CPA 1987 would not be available.

The regulation making power in s. 11(1) of CPA 1987 is very broad and covers securing that the goods are safe, preventing products from falling into the hands of persons for whom they would be unsafe, and making sure that appropriate information is, and inappropriate information is not, provided. The section is thus very wide-ranging and would seem to be broad enough to do many of the things one might wish to do, ie ban constituents/toxins/additives or demand reductions in them, set upper limits to emissions, demand product modifications, demand that cigarettes meet common performance standard on constituents or by-products, demand changes to cigarette paper/filter etc. To this extent the advice of the Government solicitor seems correct. S. 11(1) is developed in s. 11(2) where certain specific provisions that safety regulations may contain are listed. It should be borne in mind that this list is expressly stated to be without prejudice to subsection (1), but that the overall objective listed in s.11(1) must guide the content of the regulations, ie safety must be to the fore. One might imagine some debate as to whether, for example, passive smoking was a safety or a discomfort issue.

There does not seem to be any express power which would require the licensing of manufacturers and importers. The rules on approvals seem to relate to the goods rather than the person controlling them. Indeed the overarching power in s. 11(1) seems to be related to the goods, and so controls on who can deal in the goods might well be deemed to fall outside its scope.

The safety regulations themselves cannot provide that any contravention of them will be an offence (s. 11(4)), but s. 12 provides for various offences against safety regulations.

What are the implications of the exemption of tobacco from the consumer safety part of the CPA 1987 at s. 10(7)(f) – and, by extension, what would be the implications and feasibility of amending the Act to remove this?

The exemption of tobacco in s. 10(7)(f) of the CPA 1987 would seem to be of little relevance now. It had the effect of not making the general safety requirement in s. 10 applicable to

tobacco, but this has now been superseded by general safety requirements in the General Product Safety Regulations, which do not exclude tobacco. The other powers in the CPA 1987 relating to safety refer to 'goods', which has a broader meaning than 'consumer goods' and would include tobacco, unless tobacco was deemed to be a licensed medicinal product.

What are the implications of the section 3(c) (application and revocation) of the 1994 regulations? Given that tobacco is to be regulated under the new tobacco product directive (and previously under 90/239/EEC on tar yields, and 89/622/EEC and 43/92/EC on labelling) would the directive mean these regulations did not apply to tobacco?

The relationship between the general safety requirement and specific sectoral directives is problematic. The best approach from a consumer protection point would be to have both sectoral rules and the general safety requirement apply. This is clearly not the approach of the General Product Safety Directive. At the other extreme one might wish the general safety rules to be disapplied whenever there were any sectoral safety rules in directives that were intended to be total harmonisation directives dealing with all safety aspects. Slightly less extreme would be to argue that if sectoral rules covered safety then the general product safety directive only applied as regards its post-marketing notification obligations. In fact the United Kingdom seems to have adopted the sensible approach of retaining the controls afforded by the general safety requirement whenever the specialist legislation does not cover a specific aspect of safety. This seems to be the effect of the Regulations, for although reg. 3(c) excludes any product for which there are specific community rules, this exclusion only applies where the specific provisions govern all safety aspects of the product. Furthermore reg. 4 makes it clear that the regulations do apply where the product is subject to Community law provisions in so far as those provisions do not make specific provision governing an aspect of the safety of the product. However, the matter is not entirely free of ambiguity. There may still be some situations where producers may try to argue that all safety aspects are covered by the Community law and the authorities are then forced to show that some novel or distinct aspect has not been included in the specific EC law, even if it had been intended to be a total harmonisation directive.

It should be noted that the General Product Safety Directive is in the process of being revised. There has not been time to make a detailed study of the proposed changes, but of interest is the fact that one issue to be reformed is the relationship between sectoral legislation and the general safety requirement. The procedure for assessing conformity is also to be reworked with it being likely that a greater role will be given to standards implementing European standards.

Going beyond the issue of exclusion from the general safety requirement where sectoral directives exist, it should be noted that there is a more general issue concerning the relationship between EC internal market law and domestic law. As confirmed by the tobacco advertising decision internal market law is an area of exclusive Community competence. This means that, at least once the Community has enacted laws in this area, member states cannot regulate, except as provided for by EC laws. This is an important issue, which may prevent national activity in areas such as tobacco products that have been regulated at the EC level and needs exploring in more detail. In particular art. 13(2) of the Tobacco Products Directive needs consideration because it does seem to permit member states to keep or introduce more

stringent rules, but only in so far as they do not prejudice the rules laid down in the Directive. The scope this gives member states to derogate from the directive needs to be assessed.

What are the powers to regulate tobacco and nicotine available in the Medicines Act 1968?

If tobacco (or nicotine) fall within the definition of a 'medicinal product' then they would be subjected to the licensing regime of the Medicines Act 1968. To fall within this definition they would have to fulfil a 'medicinal purpose' and the most relevant test would seem to be that found in s. 130(2)(e) of 'otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way'.

There does not seem to be any express exclusion for tobacco. In deciding whether tobacco products fall within this definition some assistance might be gleaned from the US Supreme Court case of *Food and Drug Administration v Brown & Williamson* where the Food and Drug Administration (FDA) was denied authority. Some aspects of this case turn upon particular US issues. Under the US legislation 'drugs' are defined to include 'articles (other than food) intended to affect the structure or any function of the body' and a 'device' is 'an instrument, apparatus, implement, machine, contrivance … or other similar or related article… intended to affect the structure or any function of the body'. The FDA considered nicotine a drug, and cigarettes and smokeless tobacco products 'drug delivery devices'. The issue of intent does not seem to be a factor in the UK. Moreover the majority in Supreme Court were clearly influenced by the FDA having previously denied authority and Congress having created a special regime to regulate tobacco products. However, what is perhaps of most interest is the view of the majority that because of the need for any approved drug device to have a 'reasonable assurance of safety and effectiveness' the result would have to be a ban and that it could not have been intended to give a regulatory agency the power to ban a product which is so central to American society. The FDA and the minority argued that they would have power to take less drastic steps than banning the product, particularly as they could take into account the harm caused from the sudden withdrawal of the product.

The wording of the UK Medicines Act 1968 would appear to be more favourable to tobacco regulation. The concepts of 'safety', 'quality' and 'efficacy' that underpin the regulation of medicine are not easily applied to tobacco, and these are stated to be the three factors the licensing authority shall take into consideration. However, they are simply that – factors to be taken into consideration. It seems quite striking that in the US there was little dispute that nicotine and tobacco products fell within the literal interpretation of drug or device. Thus it would seem to be feasible to argue that tobacco products should be regulated under the medicines regime. Indeed the irony has been noted that whilst tobacco is not regulated in such a manner, many of the products (nicotine replacement treatment) used to treat the effects of nicotine addiction do have to go through the medicine licensing process. However, one suspects there will also be a deal of popular resistance to tobacco being equated with a drug and it must also be recognised that tobacco would then fall outside the regulation-making powers of the CPA 1987 (s. 11(7)(d)). Furthermore one might wonder whether a licensing regime was an adequate means of implementing Community obligations. This matter would have to be looked into further if this avenue was to be seriously explored.

What are the powers to regulate tobacco and nicotine under the Food Safety Act 1990?

The Food Safety Act 1990 might cover tobacco products. There is certainly no express exclusion for tobacco (again there is an exclusion for licensed medicinal products, unless excepted by Ministerial order). Food is said to include 'articles and substances of no nutritional value which are used for human consumption' (s. 1(1)(b)). It would seem that tobacco products fall within the definition of articles or substances (s. 53(1)). The only debate might be whether they are consumed. If this was seen as being a crucial point then more research could be undertaken.

There are wide ranging regulation-making powers under s. 16 and schedule 1 of the 1990 Act. These include regulation on composition, governing processes and treatment in the preparation of food, regulating the labelling, marking, presentation and advertising. There is also a general power for regulations to secure that food complies with food safety requirements, the interests of public health or to protect or promote the interests of consumers. S. 25 also allows the minister to require persons to furnish specified information about the food.

Could the new tobacco product directive be introduced as regulations under the CPA s. 11?

The tar yield (90/239/EEC) and labelling (89/622/EEC etc) directives are implemented in regulations under the CPA, and the new directive 2001/37/EC is a consolidation of these directives with a few new but related provisions. It will be obvious from the above that there would seem to be a sufficient basis in s. 11 of CPA 1987 to use this to implement most safety measures relating to tobacco. However a future project might take the directive and assess whether every provision can be validly adopted on this basis. The preference would clearly be for specific enabling powers geared to tobacco and supervised by a tobacco and nicotine regulatory authority.

For products other than tobacco, what kind of institutional arrangements have been used to enforce the CPA 1987 and GPS Regulations 1994?

As outlined above the main enforcement authorities are the local government trading standards departments. Central government, through the Consumer Safety Unit of the Department of Trade and Industry, does have some enforcement powers but uses these infrequently and tends to act more as a supervisory body, handling data collection and the development of any regulations or standards.

Appendix 2
Review of European Union tobacco regulation

Product regulation and consumer protection

Though the 1989 labelling directive (89/622/EEC) was welcomed at the time, it normalised warning labels that are too small, with weak messages using contrasting colours that can be almost impossible to read. Although a member state can impose more substantial warnings on its domestic manufacturers, it cannot block the import of products conforming to this directive.

The 1992 update to labelling directive (92/41/EC) provided new warnings and banned oral tobacco outside Sweden. This form of tobacco is substantially lower risk than cigarettes and is one reason why there is a lower cancer rate in Sweden.

The 1990 'tar' directive (90/239/EEC) wrote into law and established as a legitimate public health measure the strategy of reducing tar yields – and lending credibility to the concept of light and mild branding. This approach is now discredited in public health terms – however, this mistake was perpetuated in Article 3 and 5 of 2001/37/EC (the new directive superseding 90/239/EEC).

The new tobacco product directive (2001/37/EC) contains some good provisions (larger and bolder warning labels, ingredients disclosure, removal of misleading branding, review and update provisions) and some bad provisions (tar reduction, labelling with tar yield numbers). This is subject to challenge by tobacco companies (see British American Tobacco release, 24 August 2001).

Tobacco advertising

The 1989 'Television without frontiers' directive (89/552/EEC) banned advertising on TV but did not deal with the dominant form of TV advertising – televised sponsored events. The 1998 tobacco advertising directive (98/43/EC) was struck down by the European Court of Justice in October 2000 on account of its legal base (Case C-376/98) – the court argued that the Directive must contribute to 'eliminating appreciable distortions of competition' and 'eliminating obstacles to the free movement of goods and to the freedom to provide services'. The Court found the directive failed these tests.

In 2001, the Commission proposed a new advertising directive (COM/2001/0283 final) and this is formulated to act within the Commission's conservative view of the narrow boundaries of EU competence established by the treaty as interpreted by the European Court of Justice. The directive covers four areas of cross-border advertising (printed publications, Internet, radio and sponsorship), but does not include indirect advertising and will be easily circumvented by modern promotional techniques or moving promotional activity – such as

sports sponsorship – outside the EU. The German government has already threatened to challenge this directive if it has the effect of banning tobacco advertising in newspapers whose main circulation is within Germany.

Tobacco subsidies and public health funding

The European Union provides almost €1 billion to tobacco farmers through the Common Agricultural Policy (98/2848/EC). In contrast, expenditure on tobacco and public health is about 2-3% of this – the 'Europe Against Cancer' programme (see 646/96/EC) and the Tobacco Fund (see Regulation 2000/1648/EC which elaborates the operation of the fund established in Article 13 of 92/2075/EC – the tobacco subsidy regime).

Excise duties

The EU has applied limits governing the structure of tobacco duties (see directives 92/79/EEC on cigarettes, 92/80/EEC on products other than cigarettes and 95/59/EC). These may have had some effect in raising minimum duties, but their prime purpose is to stop the use of the excise tax system acting as a protectionist barrier to trade. A new proposal to restructure and raise minimum excise duties (COM/2001/0133 final) has been proposed by the Commission.

Weakness of health and consumer protection in the treaty

The fundamental weakness in EU tobacco policy is that the treaty article on public health (art. 152) does not allow binding EU legislation – directives or regulations. Public health legislation on tobacco has been shoehorned in as 'single market' legislation under art. 95. Consumer protection legislation is similarly constrained: art. 153 on consumer protection requires the use of art. 95 on the single market.

Dominance of free trade

Art. 95 of the treaty establishes the single market and does require 'a high level of health and consumer protection'. However, the ECJ emphasised that the primary purpose must be to remove barriers to trade.

A particular concern is the possible use of treaty provisions on the free movement of goods and services (art. 28) to undo national public health legislation. For example, national advertising legislation could be challenged as a barrier to entry.

Art. 30 allows a public health defence but the burden of proof is on the public health authority to show the measure is 'proportionate'; 'such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

This is not hypothetical – there are developments in this area:

- Complaints to the Commission about the French 'Loi Evan' and other national legislation.

- Swedish alcohol case (Case C-405/98) (a challenge to Sweden's ban on alcohol legislation). This appears to leave the matter to the Swedish courts to decide if the ban is justified in health terms.
- A potential Commission challenge to UK Customs over border controls designed to stop cross-Channel bootlegging. This could open the way for increased bootlegging and make the UK's tax policy harder to defend.

International negotiating positions: the EU forces the lowest common denominator

The position of the EU in the Framework Convention on Tobacco Control (FCTC) negotiations has been obstructive. For two reasons, the EU tends to drag its position down to the level of the least progressive member state. First, the member states *must* negotiate common EU positions where there is EU legislation in force. In the FCTC the EU has simply put forward positions that are already agreed within the EU, though it could agree more progressive positions if member states could agree them. Second, art. 300 of the treaty requires co-ordinated positions, even where there is no Community competence. In both cases, the EU negotiators have been drawn down to a position acceptable to the least progressive country – Germany.

Tab H

European Union policy on smokeless tobacco

A statement in favour of evidence-based regulation for public health

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February 2003

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Summary

1. **Public health case**. We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union 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 European Union but is often highly toxic, and our proposal would be likely to remove more products from the market than it permitted.

2. **Regulatory options**. We believe that the European Union 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 regimes 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 view if its action fails.

Public health arguments

3. **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, cardio-vascular disease 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:

    a) Where the use of a tobacco product is substantially less hazardous than cigarettes;

    b) 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 European Union because of legal challenges to EU regulation in this area, and a commitment to review policy by the end of 2004.

4. **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 European Union 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.

5. **Harm caused by smokeless tobacco**. Smokeless tobacco is *not* harmless. For example, smokeless tobacco products used on the Indian sub-continent and some products in the United States 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[1] [2]. The largest review, Nilson (1998)[3], 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 cardiovascular disease, though the evidence is contradictory and far from clear. A literature review commissioned by ASH[4], 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.*

   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 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 pubic 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.

6. **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.

7. **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*

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1 Schildt E-B, Eriksson M, Hardell L, Magnuson A. Oral snuff, smoking habits and alcohol consumption in relation to oral cancer in a Swedish case-control study. *Int J Cancer* 1998;**77**:341-6.

2 Lewin F, Norell SE, Johansson H, Gustavsson P, Wennerberg J, Biörklund A, *et al*. Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck. A population-based case-referent study in Sweden. *Cancer* 1998;**82**:1367-75.

3 Nilsson R. A qualitative and quantitative risk assessment of snuff dipping. *Regul Toxicol Pharmacol* 1998;28:1-16

4 Asplund, K. Snuffing, smoking and the risk for heart disease and other vascular diseases. Department of Medicine, University Hospital, Umeå, Sweden, 2002 [PDF]

the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or 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.

8. **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 European Union policy represents an optimum public health outcome or that the policy does not increase tobacco-related harm.

9. **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[5].
   - Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (c. 22%) prevalence.
   - 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 1970s.
   - 33% of ex-smokers report use of snus - almost twice the number that report use of a pharmaceutical treatment (17%). Among males who have used a single aid to stop daily smoking, and succeeded to do so, some 70% had used snus and some 30% had used some kind of NRT.
   - There are far more ex-smokers among snus users, than ex-snus users among smokers - a substantial population study has been conducted by Lars Ramstrom with funding from the National Institute of Public Health in Sweden and the data has been presented at conferences and is in the public domain, though not yet published[6]. A published study by Rodu also showed similar results[7].
   - 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.

10. **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

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5 Peto R. et al. Mortality from smoking in developed countries 1950-2000. Oxford. 1994.

6 Ramström LM, Snus, the Swedish oral smokefree tobacco - patterns of use: a gate leading to smoking or a way out. Paper presented at the 4th European Conference of Society for Research on Nicotine and Tobacco, Santander, October 5, 2002.

7 Rodu B et al. Impact of smokeless tobacco use on smoking in northern Sweden, Journal of Internal Medicine, 2002:252 398-404.

high tobacco use. The population data from Sweden is much clearer now than when the ban was introduced and again justifies a reconsideration of policy at the European level.

11. **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[8]. 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.

12. **How would smokeless tobacco be used outside Sweden?** There is legitimate doubt about whether snus or similar 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.

13. **Gateway effects.** There is concern that smokeless tobacco will function as a lead-in to smoking for people that 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 US 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.

14. **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 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[6]. 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 United States that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users. 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

[8] Kozlowski L. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. Nicotine and Tobacco Research 2002:4;4 suppl 2. 55-60 [PDF]

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[9] [10].

15. **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 smoke-free policies?. For snus to be shown to be dissipating the pressure to quit caused by smoke-free policies (and therefore have a negative impact on public health) we would need to assess the following contributory factors:

    a) How much combined daily snus and smoking use is there? (Only 3% among men in Sweden compared to 17% using snus only daily). If the combined use is not daily, it is unlikely to be used in overcoming smoke-free restrictions.

    b) How much does smoke-free contribute to smoking cessation? There is clearly an effect. One estimate suggests that completely smoke-free workplaces in the UK would reduce consumption by eight percent. 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.

    c) 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 smoke-free 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.

    d) Is it right to deny people products so that they are forced to feel discomfort in smoke-free areas because this makes them more likely to quit - the ethical point is important.

16. **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 regime would create some safeguards.

17. **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

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[9] O'Connor RJ, Flaherty BP, Kozlowski LT and Quinio BA, Regular smokeless tobacco use is not a predictor of smoking onset when psychosocial predictors are included in the model: an analysis of the TAPS Longitudinal Survey. Poster for Annual Conference of Society for Research on Nicotine and Tobacco, New Orleans, February 22, 2003

[10] Kozlowski LT, O'Connor RJ, Quinio BA, and Flaherty BP, Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluation causation in a national US sample. Paper for Annual Conference of Society for Research on Nicotine and Tobacco, New Orleans, February 22, 2003.

and invoke the precautionary principle on the basis of what is known about Sweden as a reason to act to remove the ban.

18. **Why not use NRT?** It is sometimes claimed that anything that can be done with smokeless 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[11] 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.

19. **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" but 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.

20. **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.

Regulation of smokeless tobacco in Europe and the legal challenge

21. **Regulation of smokeless tobacco in the EU**. Smokeless tobacco in the European Union is now regulated under directive 2001/37/EC[12]. 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].*

22. **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:

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[11] Holm H, Jarvis MJ, Russell MAH, Feyerabend C. Nicotine intake and dependence in Swedish snuff takers. *Psychopharmacology* 1992;108(4):507-511.

[12] Directive 2001/37/EC Official Journal L 194, 18/07/2001 P. 0026 – 0035 [EURLEX]

a) Inadequate legal base because the ban is a public health measure with no single market justification;
b) Total prohibition is disproportionate to achieving single market or public health aims It draws on the case of the advertising directive Case C-376/98 in which a complete ban was imposed as a single market measure. The successful defence of 2001/37/EC (see Case 491/01) was in part because this regulated but does not prohibit trade;
c) The ban is arbitrary and discriminatory as it does not include chewing tobacco;
d) No reasons have been given for the ban and this breaches a general duty in breach of Article 253 of the treaty;
e) The ban violates the company's property rights under European Convention on Human Rights and European Charter of Fundamental Rights of the European Union;
f) The ban violates the EU treaty provisions on free movement of goods (Article 28/29);
g) The EU has not considered new scientific evidence.

23. **Has Swedish Match got a case?** We believe the regulation of smokeless tobacco products in the European Union *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.

24. **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 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.

25. **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 are like snus are banned. A rational regulatory approach would reverse this situation, and effectively ban the most toxic smokeless tobacco products.

26. **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 regime for all tobacco products[13], including smokeless, and this requires extensive testing of tobacco product constituents. The methodologies available for measuring tobacco constituents are appended to this paper at Annex 1. 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.

27. **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

[13] Health Canada. *Tobacco Reporting Regulations*. June 2000. [Health Canada]

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.

28. **Example of a standard**. Voluntary, market-based, toxicity standards do exist. For example, this is the Gothiatek standard (used by Swedish Match – see table)[14]

Toxin	Limit
Nitrite	3.5 mg/kg
TSNA	5 mg/kg
NDMA	5 ug/kg
BaP	10 ug/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
ug = microgram or 10^{-6}g. mg/kg ~ parts per million (ppm). ug/kg is equivalent to parts per billion (ppb). Limits based on 50% water content - double the limits for dry weight equivalents.	

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 would certainly take more tobacco products off the market in the EU than it allows on. Many of these products 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.

30. **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 sub-continent, 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 Annex 1.

31. **European Commission review of policy will happen anyway**. The 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 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.

[14] See www.gothiatek.com - the full standard available here [Gothiatek].

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…

32. **Is the European Union's current position based on scientific advice**? To our knowledge, the EU did not revisit the scientific advice for Article 8 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[15]. 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.

33. **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 European Court of Justice, 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.

34. **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 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

35. **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:
    a) It would create a legally defensible, fair and rational policy – in which public health is given primacy consistent within the framework of EU law.
    b) It could create public health benefits through smoking cessation and smoking substitution.
    c) It gives smokers an extra strategy for controlling their risk and eliminating ETS risk, and thereby respects their consumer and human rights.
    d) It would apply toxicity controls to the currently unregulated chewing products such as gutkha and paan available in the European Union and currently unregulated.
    e) 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 WHO Framework Convention on Tobacco Control.
    f) It opens the dominant cigarette makers to competition from tobacco products that do far less harm.

[15] Europe Against Cancer Programme High Level Cancer Experts Committee Consensus Conference on Tobacco Helsinki, 2 October 1996 [Europa]

Annex 1. 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*
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*

Tab I

SACTob

Recommendation

on Smokeless Tobacco Products

Scientific Advisory
Committee on Tobacco
Product Regulation
(SACTob)

World Health Organization
Tobacco Free Initiative

WHO Library Cataloguing-in-Publication Data

WHO Scientific Advisory Committee on Tobacco Product Regulation.
Scientific Advisory Committee on Tobacco Product Regulation (SACTob)
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1.Tobacco, Smokeless - adverse effects 2.Tobacco industry - legislation 3.Guidelines I.Title

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Preface

The Scientific Advisory Committee on Tobacco Product Regulation (SACTob), established by the World Health Organization, held its first meeting in October 2000. The committee is composed of national and international scientific experts on product regulation, smoking cessation and laboratory analysis. SACTob advises WHO about scientifically sound recommendations to Member States addressing the most effective and evidence-based means to achieve a co-ordinated regulatory framework for tobacco products. The work of the committee is based on recent leading edge research on tobacco product issues and aims to fill the regulatory gaps in tobacco control.

The present recommendation was finalized by SACTob during its Fifth Meeting in 25-27 November 2002 held in Brisbane, Australia.

Scientific Advisory Committee on Tobacco Products Regulation

Recommendation on Smokeless Tobacco Products

Background

Smokeless tobacco use is a significant part of the overall world tobacco problem. Smokeless tobacco products are tobacco products without combustion or pyrolysis at the time of use. The prevalence of use is relatively high in many countries especially in South Asia (1). There is a great diversity of smokeless tobacco products and smokeless tobacco use patterns across the globe (1, 2). Oral use is by far the most common behaviour. Nasal use is very rare.

Different smokeless tobacco products have a range of health hazards that differ in magnitude. Many of the products have not been studied for ingredients and health effects.

Many studies of health risks did not classify smokeless tobacco by specific product characteristics. Many of the tobacco products include multiple ingredients. Most human studies have been case-control studies, although there is some evidence about health risks from a few cohort studies (3, 4, 5).

Health effects that have been studied to date are: oral cancer, other cancers, oral diseases (dental caries, gingival recession, tooth attrition, oral mucosal lesions), cardiovascular risk factors and disease, diabetes, reproductive health effects, and overall mortality.

There is conclusive evidence that certain smokeless tobacco products increase risk of oral cancer, specifically betel quid with tobacco, tobacco with lime, and other tobacco mixtures in South Asia, and smokeless tobacco in the United States (4). The few available studies on certain other smokeless tobacco products, such as toombak in Sudan and other African countries (6), shammah in Saudi Arabia (7, 8), nass and nasswar in Central Asia republics indicate their use increases oral cancer risk (9). Evidence for associations between smokeless tobacco use and other cancers is inconclusive (10).

There are several studies that do not demonstrate a significantly increased risk of oral cancer, possibly due to design problems or lack of power (11, 12, 13). Two studies from Sweden that were well-designed and controlled for smoking showed no association between smokeless tobacco use overall, specifically ever use of snus, and oral cancer (14, 15). However, an increased risk was observed in one study among those who used only smokeless tobacco (14). In both studies ex-users of smokeless tobacco had increased risks, but the increased risk estimates did not reach statistical significance.

There are a few cohort studies from India that demonstrate significant excess all cause mortality among smokeless tobacco users (16, 17) whereas one from the U.S. does not (18).

The few studies of cardiovascular disease provide conflicting findings (19, 20, 21, 22).

One study from Sweden reported that smokeless tobacco use was associated with presence of diabetes and increased insulin resistance (23).

Several studies of smokeless tobacco use by pregnant women in India demonstrate adverse reproductive outcomes, especially low birth weight (24, 25, 26, 27, 28).

There is strong evidence that smokeless tobacco use leads to oral mucosal lesions (29), including oral pre-cancerous lesions, and gingival recession (30).

Most smokeless tobacco products have constituents that are known to be hazardous, such as tobacco-specific nitrosamines, cadmium, and nicotine (31, 32, 33, 34). Products which have not been studied or products for which no hazard has yet been demonstrated cannot be claimed to be free of harm. Products with reductions in some hazardous components, such as nitrosamines, have not been studied adequately for the range of potential health hazards.

All smokeless tobacco products have nicotine as a major constituent and are potentially addictive (35). Persons who experiment with smokeless tobacco often develop a pattern of regular daily use (35). Over time, many users increase amounts they consume (36). Cessation is difficult, as it is for smoking tobacco. Users of both smokeless and smoking products find tobacco cessation even more difficult to achieve than those who use only smokeless tobacco or only smoke (36, 37). Tobacco manufacturers encourage use of smokeless tobacco products by smokers on occasions when they are not permitted to smoke (38) and thereby promote individuals to adopt smokeless tobacco use in conjunction with continued smoking.

Youth are especially vulnerable to initiating smokeless tobacco use. In many cultures, particularly in South East Asia and increasingly in Sweden, smokeless tobacco use is more socially acceptable than smoking (39), and it is usually easy to practice without detection. There is evidence that some advertising of smokeless tobacco products targets children (40, 41, 42, 43).

Tobacco manufacturers sell “starter” products that are milder or sweeter for initiating users (44, 45). Smokeless tobacco products are usually cheaper than cigarettes. At present smokeless tobacco use is common among youth globally (46).

There is an ongoing debate in the public health community about the potential for smokeless tobacco, especially snus manufactured in Sweden, to be used as a substitute for smoking as part of a harm reduction strategy. This is being advocated by some on the premise that the range of health conditions potentially caused by smokeless tobacco is smaller than that caused by smoked tobacco (47, 48).

There are several reasons that argue against endorsing the use of smokeless tobacco products for the purpose of harm reduction. They are as follows:

Benefits have not been demonstrated

- Smokeless tobacco products have not been shown to be more effective smoking cessation aids than other cessation strategies

- It has not been shown that people substitute smokeless tobacco for smoking or that they will not relapse to smoking

- Smoking prevalence has not been shown to be decreased by substitution of smokeless tobacco for smoking

Potential for harm exists

- Promoting smokeless tobacco products may encourage individuals to adopt smokeless tobacco use in addition to continuing smoking

- Use of smokeless tobacco products has been reported to increase the chances of subsequent initiation of smoking (49)

- People who may have quit tobacco use altogether will not do so (37)

- Children who might not have started smoking may start smokeless tobacco use

- Health effects from the use of smokeless tobacco products remain unclear, and the potential for long term harm cannot be ruled out

- All smokeless tobacco products are addictive (35)

The designation of smokeless tobacco products as harm reducing agents may promote a false perception of safety. A lower risk of adverse health outcomes is achieved by reducing smoking and not by substituting another form of tobacco use.

Smokeless tobacco products frequently include other ingredients such as areca nut (in South Asia) and flavouring agents. They often contain products that affect pH, such as lime (calcium hydroxide), which in turn alters nicotine absorption (50). The tobacco may be fermented, pyrolised, or otherwise processed before use. Product composition may change with storage (51, 52, 53). Products are frequently designed to provide properties that may affect nicotine absorption, flavour and taste, convenience of use that may affect health, among other properties (45, 50).

In most countries there is no specific mechanism for regulating smokeless tobacco products. Often smokeless tobacco products are not required to carry any health warnings. One country (India) has regulated some manufactured smokeless tobacco products as a food item as they are consumed orally. Smokeless tobacco contains tobacco but may not be marketed specifically as a tobacco product and may be disguised

as a consumer product such as toothpaste. There is a potential for regulating smokeless tobacco products as consumer products under categories such as food supplements, drugs, and toiletries and cosmetics.

RECOMMENDATIONS

1. Current evidence does not indicate that use of any smokeless tobacco is free of health risks. Therefore, any such health claim is presently untenable and should not be permitted.

2. There is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy. Marketing of smokeless tobacco products with harm reduction claims should not be permitted unless validated by an independent regulatory authority on review of evidence to be submitted by the manufacturer.

3. It is recognized that the currently marketed tobacco products have not been subjected to adequate regulatory review prior to introduction. New smokeless tobacco products should be subjected to review based on procedures applicable to other consumer products intended for human consumption.

4. In countries where there is no established use of smokeless tobacco products, the introduction of such products should only be permitted if the manufacturer satisfies the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).

5. In countries where some smokeless tobacco products are in established use, new smokeless tobacco product categories should only be permitted if the manufacturer satisfies the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).

6. The incorporation of non-tobacco ingredients into smokeless tobacco products may increase the a) appeal of the product by changing the taste, flavour, and ease of use, b) addictiveness, or c) potential for harm independently or by interaction with tobacco. Therefore, such ingredients also need to be regulated.

7. Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim. Each type of claim requires a substantive body of evidence and an independent regulatory body capable of examining the claims to determine whether the claims are valid.

8. Information on potential adverse health effects should be communicated to consumers. For example, health warnings and labelling should reflect the known adverse health effects of the smokeless tobacco product.

9. More research should be undertaken to evaluate nicotine and toxin exposures and health hazards and risks to individuals from use of smokeless tobacco products, as well as to identify population health effects of changing patterns of smokeless tobacco and other tobacco use.

References

(1) World Health Organization. *Tobacco or Health, A Global Status Report*. Geneva, WHO, 1997.

(2) Centers for Disease Control and Prevention, Office on Smoking and Health, Smokeless Tobacco Fact Sheets, 2002.

(3) Blot WJ, McLaughlin JK, Winn DM, Austin DF, Greenberg RS, Preston-Martin S, et al. Smoking and drinking in relation to oral and pharyngeal cancer. *Cancer Research*, 1988, 48: 3282-3287.

(4) IARC Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, International Agency for Research on Cancer, World Health Organization. *Tobacco habits other than smoking, betel-quid and areca-nut chewing, and some related nitrosamines*. Lyon, International Agency for Research on Cancer, 1985.

(5) Zahm SH, Blair A, Holmes FF, Boysen CD, Robel RJ, Fraumeni JF Jr. A case-control study of soft-tissue sarcoma. *American Journal of Epidemiology*, 1989, 130: 665-674.

(6) Idris AM, Ahmed HM, Malik MO. Toombak dipping and cancer of the oral cavity in the Sudan: a case-control study. *International Journal of Cancer*, 1995, 63(4): 477-480.

(7) Salem G, Juhl R, Schiodt T. Oral malignant and premalignant changes in 'Shammah'-users from the Gizan region, Saudi Arabia. *Acta Odontologica Scandinavica*, 1984, 42: 41-45.

(8) Zhang X, Schmitz W, Gelderblom HR, Reichart PA. Shammah-induced oral leukoplakia-like lesions. *Oral Oncology*, 2001, 37: 609-612.

(9) Zaridze DG, Blettner M, Trapeznikov NN, Kuvshinov JP, Matiakin EG, Poljakov BP, et al. Survey of a population with a high incidence of oral and oesophageal cancer. *International Journal of Cancer*, 1985, 36(2): 153-158.

(10) Winn DM. Epidemiology of cancer and other systemic effects associated with the use of smokeless tobacco. *Advances in Dental Research*, 1997, 11: 313-321.

(11) Bouquot JE, Meckstroth RL. Oral cancer in a tobacco-chewing US population--no apparent increased incidence or mortality. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics*, 1998, 86: 697-706.

(12) Mashberg A, Boffetta P, Winkelman R, Garfinkel L. Tobacco smoking, alcohol drinking, and cancer of the oral cavity and oropharynx among U.S. veterans. *Cancer*, 1993, 72: 1369-1375.

(13) Sterling TD, Rosenbaum WL, Weinkam JJ. Analysis of the relationship between smokeless tobacco and cancer based on data from the National Mortality Followback Survey. *Journal of Clinical Epidemiology*, 1992, 45: 223-231.

(14) Lewin F, Norell SE, Johansson H, Gustavsson P, Wennerberg J, Biorklund A, et al. Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck: a population-based case-referent study in Sweden. *Cancer*, 1998, 82: 1367-75.

(15) Schildt EB, Eriksson M, Hardell L, Magnuson A. Oral infections and dental factors in relation to oral cancer: a Swedish case--control study. *European Journal of Cancer Prevention*, 1998, 7: 201-206.

(16) Gupta PC, Bhonsle RB, Mehta FS, Pindborg JJ. Mortality experience in relation to tobacco chewing and smoking habits from a 10-year follow-up study in Ernakulam District, Kerala. *International Journal of Epidemiology*, 1984, 13: 184-187.

(17) Gupta PC, Mehta HC. Cohort study of all-cause mortality among tobacco users in Mumbai, India. *Bulletin of the World Health Organization*, 2000, 78: 877-883.

(18) Accortt NA, Waterbor JW, Beall C, Howard G. Chronic disease mortality in a cohort of smokeless tobacco users. *American Journal of Epidemiology*, 2002, 156: 730-737.

(19) Bolinder G, Alfredsson L, Englund A, de Faire U. Smokeless tobacco use and increased cardiovascular mortality among Swedish construction workers. *American Journal of Public Health*, 1994, 84(3): 399-404.

(20) Bolinder GM, Ahlborg BO, Lindell JH. Use of smokeless tobacco: blood pressure elevation and other health hazards found in a large-scale population survey. *Journal of Internal Medicine*, 1992, 232(4): 327-334.

(21) Eliasson M, Asplund K, Evrin PE, Lundblad D. Relationship of cigarette smoking and snuff dipping to plasma fibrinogen, fibrinolytic variables and serum insulin. *The Northern Sweden MONICA Study*, 1995, 113: 41-53.

(22) Huhtasaari F, Lundberg V, Eliasson M, Janlert U, Asplund K. Smokeless tobacco as a possible risk factor for myocardial infarction: a population-based study in middle-aged men. *Journal of the American College of Cardiology*, 1999, 34: 1784-1790.

(23) Persson PG, Carlsson S, Svanstrom L, Ostenson CG, Efendic S, Grill V. Cigarette smoking, oral moist snuff use and glucose intolerance. *Journal of Internal Medicine*, 2000, 248: 103-110.

(24) Agrawal P, Chansoriya M, Kaul KK. Effect of tobacco chewing by mothers on placental morphology. *Indian Pediatrics*, 1983, 20: 561-565.

(25) Krishna K. Tobacco chewing in pregnancy. *British Journal of Obstetrics and Gynaecology*, 1978, 85: 726-768.

(26) Krishnamurthy S, Joshi S. Gender differences and low birth weight with maternal smokeless tobacco use in pregnancy. *Journal of Tropical Pediatrics*, 1993, 39(4): 253-254.

(27) Verma RC, Chansoriya M, Kaul KK. Effect of tobacco chewing by mothers on fetal outcome. *Indian Pediatrics*, 1983, 20: 105-111.

(28) Mehta AC, Shukla S. Tobacco and pregnancy. *Journal of Obstetrics and Gynaecology of India*, 1990, 40: 156-160.

(29) Tomar SL, Winn DM, Swango PA, Giovino GA, Kleinman DV. Oral mucosal smokeless tobacco lesions among adolescents in the United States. *Journal of Dental Research*, 1997, 76: 1277-1286.

(30) Winn DM. Tobacco use and oral disease. *Journal of Dental Education*, 2001, 65: 306-312.

(31) Hoffmann D, Adams JD, Lisk D, Fisenne I, Brunnemann KD. Toxic and carcinogenic agents in dry and moist snuff. *Journal of the National Cancer Institute*, 1987, 79(6): 1281-1286.

(32) Hoffmann D, MVD. Chemical composition and carcinogenicity of smokeless tobacco. *Advances in Dental Research*, 1997, 11: 322-329.

(33) Idris AM, Ibrahim SO, Vasstrand EN, Johannessen AC, Lillehaug JR, Magnusson B, et al. The Swedish snus and the Sudanese toombak: are they different? *Oral Oncology*, 1998, 34: 558-566.

(34) Zaridze DG, Safaev RD, Belitsky GA, Brunnemann KD, Hoffmann D. Carcinogenic substances in Soviet tobacco products. *IARC Scientific Publications*, 1991, 105: 485-488.

(35) Henningfield JE, Fant RV, Tomar SL. Smokeless tobacco: an addicting drug. *Advances in Dental Research*, 1997, 11: 330-5.

(36) Hatsukami DK, Severson HH. Oral spit tobacco: addiction, prevention and treatment. *Nicotine andTobacco Research*, 1999, 1: 21-44.

(37) Tomar S. Snuff use and smoking in U.S. men. Implications for harm reduction(1). *American Journal of Preventive Medicine*, 2002, 23: 143.

(38) Henningfield JE, Rose CA, Giovino GA. Brave new world of tobacco disease prevention: promoting dual product use? *American Journal of Preventive Medicine*, 2002, 23: 226-228.

(39) Mackay J, Eriksen M. *The Tobacco Atlas*. Geneva, World Health Organization, 2002.

(40) U.S. Department of Health and Human Services. *Preventing tobacco use among young people. A report of the Surgeon General.* Washington DC, U.S. Government Printing Office, 1994.

(41) Food and Drug Administration. 21 CFR Part 801, et al. Regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents; final rule. Federal Register, 61 (168), 44396-45318, 1996.

(42) Smokeless tobacco advertising expenditures before and after the smokeless tobacco master settlement agreement. A report of the Massachusetts Department of Public Health. Boston, May 2002.

(43) Gupta PC, Ray SR. Tobacco and youth in the South East Asia Region. *Indian Journal of Cancer*, 2002, 39: 3-34.

(44) Connolly G. The marketing of nicotine addiction by one oral snuff manufacturer. *Tobacco Control*, 1995, 4:73-79.

(45) Andersson G, Axell T, Larsson A. Impact of consumption factors on soft tissue changes in Swedish moist snuff users: a histologic study. *Journal of Oral Pathology and Medicine*, 1990, 19: 453-458.

(46) The Global Youth Tobacco Survey Collaborative Group. Tobacco use among youth: a cross country comparison. *Tobacco Control*, 2002, 11: 252-270.

(47) Rodu B. An alternative approach to smoking control. *The American Journal of the Medical Sciences*, 1994, 308: 32-34.

(48) Henningfield JE, Fagerstrom KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control*, 2001, 10: 253-257.

(49) Haddock CK, Weg MV, DeBon M, Klesges RC, Talcott GW, Lando H, et al. Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males. *Preventive Medicine*, 2001, 32: 262-267.

(50) Tomar SL, Henningfield JE. Review of the evidence that pH is a determinant of nicotine dosage from oral use of smokeless tobacco. *Tobacco Control*, 1997, 6: 219-225.(51) Brunnemann KD, Prokopczyk B, Djordjevic MV, Hoffmann D. Formation and analysis of tobacco-specific N-nitrosamines. *Critical Reviews in Toxicology*, 1996, 26: 121-137.

(52) MDPH - 08/21/01 - Massachusetts Department of Public Health Issues Challenge to US Snuff Makers and Warns Consumers of High Cancer Risk Tied to Smokeless Tobacco. (http://www.state.ma.us/dph/media/2001/pr0821a.htm)

(53) Djordjevic MV, Fan J, Bush LP, Brunnemann KD, Hoffmann D.Effects of storage conditions on levels of tobacco-specific N-nitrosamines and N-nitrosamino acids in U.S. moist snuff. *Journal of Agricultural and Food Chemistry*, 1993, 41: 1790-1794.

Tab J

The Personal Economics of Smoking Cessation

ABSTRACT

The social costs and benefits of smoking cessation have been treated extensively in the literature but surprisingly personal economics have received far less attention. This article focuses on both the short-term (90-day) and the long-term costs and benefits of "quits" using a clear and simple methodology of calculation for six smoking cessation techniques. Net costs over the 90-day period range from almost $1,500 (behavior modification) to a positive net benefit of almost $400 (going "cold turkey"). Over the longer run, however, net benefits are positive for all cessation ages ranging from 40 to 60 when savings on cigarettes and life and medical insurance are considered. The article concludes that personal economics in addition to health concerns may be a strong motivation to quit smoking. Family and consumer professionals, such as teachers and family counselors, are in a unique position to utilize this information in motivating students and clients in their attempts to quit smoking. When so-called "hard-core" smokers are considered–those labeled by the Surgeon General as "chronically" addicted—the net economic and "harm reduction" benefits would appear to be clear motivations for cessation.

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INTRODUCTION

Americans are bombarded with information as well as misinformation concerning the costs of smoking to society. Court cases, jury awards, consent decrees, advertising restrictions, costs to farmers, and health warnings are daily fodder for the media. This plethora of information suggests that there are enormous costs of smoking to society. A large number of studies have attempted to calculate these social costs of smoking–costs to the whole society. These economy-wide costs, and the benefits from smoking cessation, are calculated to be extremely substantial in some models and relatively modest in others.[1] Far less information has been provided on how much it costs the individual to quit smoking and how much the benefit would be in economic terms. It is surprising because individuals who are contemplating smoke-cessation appear more likely to be influenced by information about personal costs than about social costs. An analysis of

[1] See Viscusi (1992, 1995). Viscusi argues that most of the costs due to smoking are private costs and that smokers do not (on net) use society's resources but actually may save them. This would be the case if the premature deaths of smokers, through lower Social Security and pension costs, saved more on health insurance costs and other added costs due to smoking. An excellent work that outlines a number of recent positions on smoking is the volume edited by Jeanrenaud and Soguel (1999). Rice (1999) discusses a range of macroeconomic cost estimates from smoking, including direct costs and personal health care expenditures. Between 1980 and 1993, for example, the estimates of costs range from $217 billion to $787 billion on personal health care expenses and from $14 to $72 billion in direct smoking costs.

personal costs and benefits is the purpose of this article. It is our aim in this article to provide this information to consumer and family specialists, especially to those (such as teachers) who interact with, advise, and instruct groups who have most recently begun smoking or who are contemplating doing so.

...nonsmokers pay lower health- and life-insurance premiums.

Naturally, cost to an individual from smoking cessation is the full cost of quitting, and such costs must be compared to the benefits. Costs would include the cost of the cessation method, the time spent (if any) in "treatment," and the psychological "pain" cost of kicking the habit.[2] Some of these costs are intractable, such as the pains of quitting, but other calculable economic costs will exist. Broad studies of cost effectiveness of quitting have been made (Oster et al., 1984) with specific studies dealing with the cost-effectiveness of nicotine gum as an adjunct to physicians' advice (Oster et al., 1986; Ramstrom, 1992).[3] Ramstrom (1992, citing 1986 Oster's study) found that therapies that included nicotine replacement, in this case gum, were more cost-effective for smokers who had strong nicotine dependence and less so (or not so) for those with weak dependence. In this study, out-of-pocket costs are computed for each person who quits as a result of six alternative methods: "cold turkey," behavior modification, nicotine gum, nicotine patches, prescription drug (Zyban), and smokeless tobacco. For each method, the cost of the program, the success rate for those who try each of the techniques, and cost-per-quit of each program to the individual was calculated. Finally, an estimate of the monetary benefits for smoking cessation and a comparison of the costs to the benefits over both short- and long-term periods are provided.

...over the past 10 years, cigarette prices have risen at an annual rate of about 7.2% and health-care costs have risen at an annual rate of about 5%.

Each individual, however, must calculate his or her own costs and benefits from quitting smoking. Neglecting the "pleasure obtained from smoking," which is different for each smoker and impossible to accurately calculate, there are additional costs to the various cessation techniques. Although it might safely be assumed that "light" smokers (less than a pack a day) might be able to go "cold turkey," most smokers end their habit only with help.[4] Thus, a variety of smoking cessation aids exists–from those requiring a doctor's prescription to over-the-counter aids

[2] Our analysis does not require that we taken a position on whether cigarette smoking is a "habit" or an "addiction." In a much cited article, Nobel-prize winning economist Gary Becker and Kevin M. Murphy tackled the problem of "rational addiction"–arguing that cigarettes are a "rationally addictive" good, the contemporary use of which will be inversely related to present and future (as well as current) prices (Becker and Murphy, 1988). Smoking behavior is thus subject to personal rationality. See Chaloupka (1991) for an empirical accouterment to the Becker—Murphy argument.

[3] For recent evidence, see Tara Parker-Pope, "Smokers are Quitting the Habit of Buying Aids to Stop Smoking," *Wall Street Journal* (June 9, 2000).

[4] A low success rate of about 5% from the use of "self-help" manuals is also given in the Surgeon Generals recent report Reducing Tobacco Use (2000: 102).

and smokeless tobacco. For the individual, the cost of cessation naturally will include the cost of these aids (plus, of course, the "pain cost") for as long as it takes to remain smoke-free without assistance.

The benefits for the individual might include higher lifetime income due to lower illness rates and a longer pension period due to a longer life. There are, of course, other important benefits that will vary with the individual such as quality of life. Although they are not actually measurable they are nonetheless real. Two primary gains from smoking cessation, however, are monetary. First, there is no more expense from the purchase of cigarettes, an increasingly significant benefit. Second, nonsmokers pay lower health- and life-insurance premiums. The net economic benefit, then, is equal to the total dollars saved by not having to purchase cigarettes plus the cost reduction in health and life insurance and minus the expenses associated with the particular smoke cessation technique that is utilized. In principle, the costs and benefits that occur in the future should be discounted to present value. However, over the past 10 years, cigarette prices have risen at an annual rate of about 7.2% and health-care costs have risen at an annual rate of about 5%. Assuming the trends continue, there is little difference between appropriately discounted and non-discounted estimates of the future costs and benefits of the two items. For this reason, the cost and benefits estimates that are reported here are not discounted.

COSTS AND BENEFITS FROM SMOKE CESSATION IN THE SHORT RUN

Naturally there are many advantages to smoking cessation. Some rewards, however important, are future ones. Better health 25 years hence, lower insurance premiums, and improved quality of life are motivators over the long haul. However, some, perhaps many, smokers tend to ignore events far in the future. Attempts to motivate smokers to quit, for many at least, should focus on immediate consequences, which are largely financial. Costs and benefits over a period as short as 90 days may provide an immediate incentive to many.

A. Monetary Costs from Smoking Cessation to the Individual: The First 90 Days

The explosion of health warnings concerning smoking has, quite obviously, created new demands for smoking-cessation techniques. Markets, fueled by self-interest, have risen to the occasion with technology, science, and human efforts directed to these demands. These techniques run the gamut from pharmacological treatment and highly sophisticated psychological methods to giving up cigarettes "cold turkey."

Table 1 itemizes most of the primary methods and the nature of expenses applied to them.[5] (There was no intent to analyze every possible technique.)

Many former smokers seem to argue that going "cold turkey" is the "only" way to quit smoking. That is certainly not the case based on recent and well-executed studies of smoke "quits" (Fiore et al., 2000). Indeed, there is good evidence that "quit rates" vary widely, as shown in Table 2.[6] For example, evidence shows that self-help–quitting with no assistance whatsoever–yields the lowest success rate. The statistics in Table 2, however, show that other techniques offer hope, with the use of smokeless tobacco, and the drug Zyban having the highest success rates. The success rates that are reported in Table 2 should be interpreted as applying to the "typical" smoker who is contemplating quitting. There is no doubt that factors such as smoking history, personal motivation, and recent health history will affect the probability of success for each individual. A light smoker who has had a recent health scare and attempts to quit "cold turkey" will succeed at a higher rate than the 3 to 5% rate reported in Table 2. Correspondingly, a long-term, three-pack-a-day user who responds

[5] Our survey does not include, for example, certain cessation techniques such as "smoke-enders," for which we were unable to obtain reliable data concerning success rates. Further, it is obvious that many individuals will rely on more than one or two of these techniques in order to quit smoking. We do not calculate such costs but they may be extrapolated from our figures.

[6] There are numerous studies of quit rates and a wide variety of quitting techniques, all of which are not considered in this article. See, for example, Table 4.3 in the Surgeon General's 2000 report (114) considering a number of pharmacological therapies. The success rates that are reported by Hughes et al. (1999) and Tilashalski et al. (1998) are compiled from various published studies of smoke cessation. As an independent confirmation of their reliability, we note that the numbers reported in the Surgeon General's 2000 report are quite similar.

Table 1. Nature of Expenses for Various Cessation Techniques

TECHNIQUE	TYPE(S) OF EXPENSES
1. Self-help ("Cold Turkey")	None
2. Behavioral Modification	Fees paid to therapist
3. Nicotine gum	Cost of gum
4. Nicotine patch	Cost of patches
5. Zyban	Physician fees, cost of medication
6. Smokeless tobacco	Cost of smokeless tobacco

to a nagging spouse by reluctantly attempting to quit "cold turkey" will have a lower rate of success then the reported 3%.

Naturally, success rates are associated with the costs and duration of each cessation technique. The assumptions underlying these calculations, moreover, are absolutely crucial to understanding the ultimate net costs or net benefits of quitting. In Table 3, the costs of various smoke cessation techniques during the first three months of smoke cessation are reported. Because assumptions about costs may differ from other estimates, a somewhat detailed explanation of the calculations is offered.

The first technique mentioned in Table 3 requires little explanation. It costs nothing (other than pain costs, of course) to quit "cold turkey." Further, it is our impression that behavior modification techniques that are used to help one stop smoking require from 6 to 12 sessions at about $150 per session. This would result in a three-month cost of $900 to $1,800, as shown in Table 3. Naturally, some therapies may be considerably more, but probably not less expensive.

Table 2. Success Rates for Various Smoke-Cessation Techniques

TECHNIQUE	SUCCESS RATE (%)
1. Self-help	3–5
2. Behavioral modification	15
3. Nicotine gum	13–15
4. Nicotine patches	5–11
5. Zyban	28
6. Smokeless tobacco	25

Sources: Hugh, J.R., Goldstein, M.G., Hurt, R.D., and Shiffman, S. (1990). Recent Advances in the Pharmacotherapy of Smoking. *Journal of the American Medical Association*, 281(1), 72–76, and Ken Tilashalski, Brad Rodu, and Philip Cole, (May 1998) A Pilot Study of Smokeless Tobacco in Smoking Cessation. *The American Journal of Medicine*, 104, 456–58.

The cost of the gum is assumed to be $.50 per piece (all drug prices were obtained from a nationwide pharmacy). All users are assumed to take suggested doses of 12–24 pieces/day for 6 weeks, 6–12 pieces per day for another 3 weeks, and 3–6 pieces per day for 3 more weeks. Therefore, the 90-day cost will range from about $350 for light users of gum to $700 for heavy users.

A popular procedure for quitting is the use of nicotine patches, a popular over-the-counter

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cessation technique. Cost estimates employ an approximation of average cost for two brands of patches–Habitrol and Nicoderm. For the Habitrol product, it was assumed that all users use the prescribed 21-mg patches for 1 month (cost = $148), the 14-mg patches for another month (cost = $141), and the 7-mg patch for a third month (cost = $134). The same assumptions for Habitrol were used with the cost per month being $122.50. The cost range is estimated to be between $375 and $475 over a 3-month period.

The prescription medication Zyban's cost is assumed to be $96 per month and all users are

Table 3. Three-Months Costs of Various Smoke-Cessation Techniques

TECHNIQUE	COST TO THOSE WHO QUIT
1. Self-help	0
2. Behavioral modification	$900 to $1,800
3. Nicotine gum	$350 to $700
4. Nicotine patches	$375 to $475
5. Zyban	$350
6. Smokeless	$90

assumed to pay $50 for a physician visit. Further, an assumption was made that all users buy a 3-month's supply at a cost of approximately $350. Cessation technique 6 is the use of smokeless tobacco. The Tilashalski et al. (1998) study of smokeless tobacco reports that subjects used smokeless tobacco at an average rate of 2.3 cans of tobacco per week. At a price of $3.25 per can, the cost would be about $7.50 per week or $90 for three months. The cost of one success for each of the six techniques is reported in Table 4. The number of failures per success is equal to the failure rate for each cessation techniques divided by the success rate. The success rates are reported in Table 2, and the failure rate equals 1 minus the success rate. For cessation techniques where a range of success rates are reported (for example 13–15% for nicotine gum), the midpoint and "round" numbers are used.

Table 4. Cost per Quit: Various Cessation Techniques

Cost per success = cost of one success + cost to others who fail = (cost of success) + (number of failures per success)(cost of failure)		
TECHNIQUE	SUCCESS RATE (%)	COST/SUCCESS = COST [1 + FAILURE RATE/SUCCESS RATE]
1. Self-help	3 to 5	0
2. Behavioral modification	15	$6,000 to $12,000
3. Nicotine gum	13 to 15	$2,500 to $5,000
4. Nicotine patches	5 to 11	$4,700 to $5,950
5. Zyban	28	$1,250
6. Smokeless	25	$270

B. Short-Run Gains from Smoking

During the first 90 days, the primary financial benefit due to smoke cessation is money saved from not having to purchase cigarettes. For a typical smoker who uses 1.5 packs per day at a price of about $2.75 per pack, that will amount to about $370.

In Table 5, the cost estimates from Table 3 are combined with the benefit estimate of $370 for the first 90 days to compute the net financial benefits for each of the six smoke-cessation techniques. The results show that for those who quit through the use of behavioral modification, nicotine gum, or nicotine patches, the 90-day costs exceed the 90-day benefits. For those who quit through the use of self-help, Zyban, or smokeless tobacco, the 90-day benefits exceed the 90-day costs.

LONG-RUN COSTS AND BENEFITS FROM SMOKING CESSATION

To this point in the analysis, the focus has been on the financial consequences of attempting to quit smoking during the first three-month period. But for those who remain cigarette-free beyond the initial three-month period, there are additional financial benefits and there may also be additional costs, depending on the method used by the individual to remain smoke free. In order to calculate the savings on cigarettes, it was assumed that each smoker is an average smoker who consumes 1.5 packs per day and that, in the absence of smoke cessation, the person would continue to smoke at the present rate. Furthermore, it was assumed that an average price of cigarettes was $2.75 per pack (a cost widely reported in the media recently). Therefore, quit-

Table 5. Ninety-Day Cost/Benefit Calculation: Various Techniques

TECHNIQUE	COST	BENEFIT	NET BENEFIT
1. Self-help	—	$370	$370
2. Behavioral modification	$900 to $1,800	$370	(minus) $530 to (minus) $1,430
3. Nicotine gum	$350 to $700	$370	$20 to (minus) $230
4. Nicotine patches	$375 to $475	$370	(minus) $5 to (minus) $105
5. Zyban	$350	$370	$20
6. Smokeless	$90	$370	$280

ting smoking will save each person 1.5 packs per day × \$2.75 × 365 = \$1,505.60 per year. By multiplying \$1,505.60 by life expectancies for men and women of various ages, the individual's savings on cigarettes were calculated.

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Significant monetary savings may also be acquired on both life and medical insurance from smoking cessation. Based on data obtained from the State Farm Insurance Company, the rates on a five-year term \$50,000 life insurance policy are about \$144 less per year for women who do not smoke than for women who smoke. By multiplying \$144 by life expectancy, we calculate savings on life insurance. For men, the corresponding savings on life insurance are about \$300 per year. The life insurance savings for men are therefore calculated as \$300 multiplied by life expectancy. Based on data from State Farm, both men and women who are nonsmokers pay about \$35 less per month (\$420 less per year) than do smokers for standard medical insurance coverage. Medical insurance savings were calculated by multiplying \$420 by the life expectancy for each group, recognizing that a large number of Americans do not have comprehensive health insurance. However, uninsured individuals who quit smoking will benefit from the reduced medical expenses that they will bear directly due to their decision to quit smoking. To the extent that rate differentials between smokers and nonsmokers are actuarially sound, \$420 per month is an accurate estimate of the magnitude of the direct savings.

Total savings equal the sum of the savings on cigarettes, life insurance, and medical insurance and, as Table 6 reveals, the monetary benefits from smoke cessation are significant in all categories of ex-smoker life expectancies. The range, from a savings of \$91,889 for a 40-year-old female to \$40,951 for a 60-year-old male who quits smoking, is well above America's average annual family income.

For smokers who succeed in quitting through self-help or behavioral modification, there should be no ongoing costs associated with the decision to quit. However, for those who quit by switching to a nicotine substitute (gum, patches, or smokeless tobacco), the dependence on nicotine still remains. Because the use of nicotine substitutes and Zyban as a means of smoke cessation has a relatively short history, there is considerable uncertainty about the pattern of future use by those who switch to these products. It is clear that those who do quit will not universally cease the use of gum, patches, and so forth. It is also likely that future use (both duration and dosage) will vary among former smokers. Table 7 reports our estimates of these costs for various categories of smokers. In computing these estimates, an assumption was made that users of nicotine alternatives continue their consumption of nicotine alternatives for the remainder of their life at their use level during the third month of smoke cessation.[7] The cost estimates reported in Table 7 are too high for those who continue to reduce their use of cigarette alternatives over time and too low for those who increase use of nicotine alternatives.

In motivating individuals to make a difficult change in lifestyle, it can be very useful to highlight immediate benefits that will result from the change. To this end, focus is on the costs and benefits of the various cessation techniques during the first 90 days of smoke cessation. Estimates of the costs and benefits are reported in Table 5. For smokers who quit through the use of self-help, Nicoderm, Zyban, or smokeless

[7] For smokeless users, we assume a consumption rate of 1.87 cans per week. This is the average given by Tilashalski et al. (1998), when those who stop using smokeless are included.

Table 6. Benefits of Smoke Cessation: All Techniques

AGE	LIFE EXPECTANCY AS EX-SMOKER	SAVINGS (CIGARETTES)	SAVINGS (LIFE INSURANCE)	SAVINGS (MEDICAL INSURANCE)	TOTAL SAVINGS
40 (female)	44.4	$66,848	$6,393	$18,648	$91,889
50 (female)	34.6	$52,094	$4,982	$14,532	$71,608
60 (female)	24.1	$36,285	$3,470	$10,122	$49,877
40 (male)	40.7	$61,278	$12,210	$17,094	$90,582
50 (male)	29.9	$45,017	$8,970	$12,558	$66,545
60 (male)	18.4	$27,703	$5,520	$7,728	$40,951

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tobacco, net financial benefits are realized during the first 90 days. For each of these alternatives, the cost is less than the cost of cigarettes for the average 1.5 packs of cigarettes per day per smoker. For smokers who currently consume more than 1.5 packs of cigarettes per day, the immediate net benefits are much higher. Heavy smokers who consume three packs per day can realize immediate savings of about $125 per month if they quit by using Nicoderm and about $230 per month if they quit by using smokeless tobacco.

Table 7. Long-Run Net Benefits of Various Cessation Techniques

AGE	TECHNIQUE	COST	BENEFIT	NET BENEFIT
40 (females)	Gum	$35,964	$91,889	$55,925
40	Patch	$71,395	$91,889	$20,494
40	Zyban	$51,149	$91,889	$40,740
40	Smokeless	$13,986	$91,889	$77,903
50	Gum	$28,026	$71,608	$43,582
50	Patch	$55,636	$71,608	$15,972
50	Zyban	$39,859	$71,608	$31,749
50	Smokeless	$10,899	$71,608	$60,709
60	Gum	$19,521	$49,877	$30,356
60	Patch	$38,752	$49,877	$11,125
60	Zyban	$27,763	$49,877	$22,114
60	Smokeless	$7,591	$49,877	$42,281
40 (males)	Gum	$32,967	$90,582	$57,615
40	Patch	$65,445	$90,582	$25,137
40	Zyban	$46,886	$90,582	$43,696
40	Smokeless	$12,820	$90,582	$77,762
50	Gum	$24,219	$66,545	$42,326
50	Patch	$48,079	$66,545	$18,466
50	Zyban	$34,444	$66,545	$32,107
50	Smokeless	$9,418	$66,545	$57,127
60	Gum	$14,904	$40,951	$26,047
60	Patch	$29,587	$40,951	$11,364
60	Zyban	$21,196	$40,951	$19,755
60	Smokeless	$5,796	$40,951	$35,15

CONCLUSIONS

The central conclusion is that beyond any health benefits, peace of mind, or greater quality of life, *it pays to quit smoking*! This is true whether benefits are considered in the short run or in the long run. Manifestly, an enormous effort has been undertaken to reduce smoking in the United States. The U.S. Surgeon General's extensive report *Reducing Tobacco Use* (2000) is symptomatic of this effort among public health officials. The report, which presents its own estimates of quit rates (2000: Table 4.3: 114) from a multiplicity of studies (Fiore et al., 2000), suggests that the war on smoking has not been won, especially with hard-core cases. The Surgeon General's report, in fact, maintains that smoking is a "chronic" addiction to nicotine and that most of those who attempt to quit relapse (2000: 134). Further, the report argues that nicotine replacement (in the form of gum) appears to be quite effective in helping smokers to quit and, although the long-term ingestion of nicotine may create some problems, replacement is preferable to smoking (2000: 115–116). The popular press (Barker, 2000) has taken up the issue of "nicotine gum addiction" noting that "except in toxic doses, nicotine is benign" and that "the tar and carbon monoxide are the deadly parts of tobacco smoke" (2000: 10D). Most importantly, perhaps, as the Surgeon General's and other surveys conclude, the success rates for smoking cessation without alternatives is not encouraging.

Smoking costs are a greater financial burden to poor families than wealthier families.

These considerations suggest that other tactics for smoking cessation should be considered. As noted in this study, smokeless tobacco shows a high quit rate (bested only by Zyban in Table 2) and a high net benefit vis-a-vis other techniques both in the short and in longer runs. For heavily addicted smokers, moreover, it is not clear that further progress will be made with more standard techniques. For these and other smokers, smokeless tobacco should clearly be considered as a viable alternative. The failure to present smokeless tobacco and long-term use of nicotine replacement therapies as alternatives to smoking comes from a fear of recommending any therapy that has any harmful health consequences. However, there is no logic for arguing against a therapy that results in a net reduction in harm and economic costs.

Recent data offer interesting information on cancer deaths related to the present study (Rodu and Phillip, 2001). If lung cancer deaths are removed from the post-1950 data, overall cancer deaths have been steadily declining between 1950 and 1998. In fact, cancer death rates fell by 25% and, if all smoking-related deaths are included, by 33%. The so-called cancer epidemic has one cause–cigarette smoking. Furthermore, the profile and prognosis of chronic smokers–possibly as many as 12 to 15 million Americans above 40 years of age–are relevant to our study of personal economics. These "hard-core" addicts will either satisfy their cravings by continuing to smoke or will find some substitute for smoking. The evidence is that smoking costs are a greater financial burden to poor families than wealthier families.[8] Family and consumer scientists should be aware of this fact so that they can use it to motivate low-income smokers, particularly new, young smokers to quit. The results of the present study would appear to be quite relevant for use in classes and educational programs geared to health and family finances.

A sane society must address the plight of lower socio-economic groups and acknowledge the pos-

[8] A 1990 report of the Congressional Budget Office (CBO, 1990) substantiates the inverse relation between income and tobacco use. According to the report, "spending on tobacco products as a percentage of post-tax income was highest in the lowest income quintile and fell almost proportionately with increased income" (quoted on p. 351 of the 2000 Surgeon General's report). The inverse relationship between excise tax burden on cigarettes and income level has long been known (Phares, 1980).

sible net gain in terms of longer life and health that stems from the dramatic reduction in harm possible from the use of nicotine substitutes to cigarettes. It appears socially irresponsible for government health officials not to offer healthier alternatives to the poor and the addicted. "Nirvana thinking," when it comes to lung cancer prevention and the *total* elimination of addictions, must be replaced by "possibility thinking"–the use of techniques which eliminate smoking but not nicotine use and promise the least harm to addicted individuals and some substantial money savings to boot.

REFERENCES

Ault, R. W., Ekelund, Jr., R. B., Jackson, J. D., Saba, R. S., & Saurman, D. S. (1991). Smoking and absenteeism. *Applied Economics, 23* (1991), 743–754.

Barker, O. (2000, November 28). Ex-smokers get stuck on gum. *USA Today,* 10D.

Becker, G. S., & Murphy, K. M. (1988). A theory of tational addiction. *Journal of Political Economy, 96,* 675–700.

Chaloupka, F. J. (1991). Rational addictive behavior and cigarette smoking. *Journal of Political Economy, 99,* 722–742.

Congressional Budget Office. (1990). *Federal Taxation of Tobacco, Alcoholic Beverages, and Motor Fuels.* Washington, D.C.: U.S. Government Printing Office.

Fiore, M. C., Bailey, W. C., Cohen, S. J., Dorfman, S. F., Goldstein, M. G., Gritz, E. R., Heyman, T. B., Jaen, C. R., Kottke, T. E., Lando, H. A., Mecklenburg, R. E., Mullen, P. D., Nett, L. M., Robinson, L., Stitzer, M. L., Tommasello, A. C., Villejo, L., & Wewers, M. E. (2000). *Treating Tobacco Use and Dependence. Clinical Practice Guidelines.* Rockville, MD: U.S. Department of Health and Human Services, Public Health Service.

Hughes, J. R., Goldstein, M. G., Hurt, R. D., & Shiffman, S. (1999). Recent advances in the pharmacotherapy of smoking. *Journal of the American Medical Association, 281* (1), 72–76.

Jeanrenaud, C., & Soguel, N. (Eds.). (1999). *Valuing the Cost of Smoking.* Boston, Kluwer Academic Publishers.

Maurer, H. (2000, April 10). Spotlight on Sweden: Trying to sell Europe on snuff. *Business Week.*

McClure, J., Wetter, D., de Moor C., Cofta-Gunn, L., Cinciripini, P., & Gritz, E. (2000). *A Comparison of Dual Users, Smokers, and Smokeless Users.* Center for Health Studies, Group Health Cooperative & the University of Texas, M.D. Anderson Cancer Center. Study presented at Society for Behavioral Medicine.

Melkersson, M. (2000). *Smoking Habits and Quitting Costs in the Presence of a Close Substitute.* Manuscript, University of Stockholm, pp. 1–27.

Oster, G., Colditz, G. A., & Kelly, N. L. (1984) *The Economic Costs of Smoking and Benefits of Quitting.* Lexington: D. C. Heath and Company.

Oster, G., Huse, D. M., Delea, T. E., & Colditz, G. A. (1986). Cost-effectiveness of nicotine gum as an adjunct to physician's advice against cigarette smoking. *Journal of the American Medical Association, 256,* 1315–1318.

Parker-Pope, T. (2000, June 9). Smokers are quitting the habit of buying aids to stop smoking. *Wall Street Journal.*

Phares, D. (1980). *Who Pays State and Local Taxes?* Cambridge, MA: Oelgeschlager, Gunn, and Hain, Publishers, Inc.

Ramstrom, L. M. (1992). *Cost-Effectiveness of Smoking Cessation Procedures.* Proceedings of the Third Emash Seminar of the European Medical Association Smoking or Health, Bari, Italy, pp. 15–24.

Rice, D. P. (1999). Measurement of the economic costs of smoking in the United States: an historical review. In C. Jeanrenaud and N. Soguel (Eds.), pp. 11–30.

Rodu, B. (1996). Letter. *Epidemiology, 7,* 111–112.

Rodu, B., & Phillip C. (2001). The fifty-year decline of cancer in America. *Journal of Clinical Oncology, 19,* 239–241.

Tilashalski, K., Rodu, B., & Cole, P. (1998). A pilot study of smokeless tobacco in smoking cessation. *The American Journal of Medicine, 104,* 456–458.

U.S. Department of Health and Human Services. (2000). *Reducing Tobacco Use: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

Viscusi, W. K. (1992). *Smoking: Making the Risky Decision.* New York: Oxford University Press.

Viscusi, W. K. (1995). Cigarette taxation and the social consequences of smoking In J. Poterba (Ed.), *Tax Policy and the Economy,* National Bureau of Economic Research, Cambridge: MIT Press.

Tab K

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Impact of smokeless tobacco use on smoking in northern Sweden

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Background and objectives. For many years Swedish men have had the world's lowest rates of smoking and smoking-related mortality. Despite these facts, a thorough analysis of tobacco use patterns in Sweden has not been performed. The purpose of this study was to examine the prevalence and interaction of cigarette smoking and use of Swedish moist snuff (snus) in the population of northern Sweden.

Design. The study cohort of 2998 men and 3092 women aged 25–64 was derived from the northern Sweden MONICA study, consisting of population-based surveys in 1986, 1990, 1994 and 1999. Detailed information on tobacco use was used to develop prevalence data, and the prevalence ratio was used to compare rates amongst various subgroups.

Results. Amongst men ever-tobacco use was stable in all survey years at about 65%, but the prevalence of smoking declined from 23% in 1986 to 14% in 1999, whilst snus use increased from 22% to 30%. In women the prevalence of smoking was more stable in the first three surveys (~27%) but was 22% in 1999, when snus use was 6%. In all years men showed higher prevalence of ex-smoking than women. A dominant factor was a history of snus (PR = 6.18, CI = 4.96–7.70), which was more prevalent at younger ages.

Conclusions. The recent transition from smoking to snus use amongst men, and incipiently amongst women, in northern Sweden is remarkable and relevant to the global discussion on strategies to reduce smoking.

Keywords: prevalence rates, smokeless tobacco, smoking, snus.

Introduction

For the past 100 years cigarette smoking has been the dominant form of tobacco consumption in almost all developed countries. One notable exception is Sweden, where smoking rates amongst men have been considerably lower than those of comparable countries for decades. As a result, Swedish men had the lowest rates of smoking-related cancers of the lung, larynx, mouth and bladder in Europe over the 35-year period from 1955 to 1989 [1]. A 1992 study revealed that Swedish men have the lowest percentage of deaths related to smoking of all developed countries [2]. In contrast, smoking prevalence amongst women in Sweden is closer to that of other European countries, and this is reflected in comparable data for smoking-related illnesses.

Whilst the prevalence of smoking amongst Swedish men has been historically low, the prevalence of oral smokeless tobacco use has been high. During the past century, Sweden had amongst the world's highest per-capita consumption of smokeless tobacco [3], predominantly in the form of snus, finely cut nonfermented moist snuff which is placed inside the upper lip.

Although there is general information about smoking and snus use in Sweden, a thorough investigation of tobacco use patterns within a specific population segment has not been performed previously. The purpose of this study was to document

tobacco use patterns in the two northern-most counties of Sweden, the population of which has a high prevalence of snus use [4].

Methods

This study used a dataset developed for the Northern Sweden component of the World Health Organization Multinational Monitoring of Trends and Determinants in Cardiovascular Diseases (MONICA) study. Details of sampling and selection have been published elsewhere [5, 6]. Briefly, the dataset contains information collected from four separate population-based surveys conducted in 1986, 1990, 1994, and 1999. Subjects were randomly selected from population registers, stratified for age (25–64 years in the first two surveys, 25–74 in the latter) and gender, in the two most northern Swedish counties (Norrbotten and Västerbotten; target population 320 000 in 1999). Survey participants completed questionnaires that were focused on cardiovascular disease risk factors.

In addition to questions regarding cigarette smoking on the standard MONICA questionnaire, the Northern Swedish version included detailed questions regarding current and historical snus use. We used the responses from tobacco-related questions to construct three mutually exclusive categories of snus use: past, current, or never use; and three comparable categories of smoking. We further classified subjects' tobacco use by cross-tabulating the three snus use categories with the three smoking categories (e.g. ex-smokers who were current snus users). We used survey data on tobacco consumption to calculate mean daily cigarette and snus consumption amongst subjects in different categories of current tobacco use.

We classified current smokers as those smoking at least one cigarette daily; subjects not smoking daily were nonsmokers. We categorized as current snus users those subjects who used any amount each day. We classified as ex-smokers only those subjects who reported quitting more than 1 month prior to completing their survey [7]. With regard to the association of snus use with smoking cessation, ex-smokers were classified as either those with a history of snus use (current or ex-snus users) or those reporting never-use of snus. Ever-use categories of smoking, snus and all tobacco included both current and ex-users of these products. Tobacco use is reported as gender-specific prevalence, and comparisons of prevalence rates between two groups of subjects were measured by the prevalence ratio with 95% confidence interval.

Where appropriate, statistical analysis was performed to assess prevalence trends according to various characteristics. Mantel–Haenszel chi-square test and testing interaction through a logistic regression model were used for this purpose. Age, education, marital status, and location of residence were studied as possible demographic or lifestyle characteristics influencing tobacco use status. Subjects were classified with regard to the highest level of education achieved within the Swedish education system: primary (9 years), secondary (12–14 years) and university (15+ years). Subjects were classified as single (which included never-married, divorced, separated and widowed) or married/cohabitant (given equal status under Swedish law). Subjects' location of residence was classified with respect to population size: communities with a population of 1000 or less (rural), those with a population of 1001–15 000 (small village), and those with over 15 000 residents (large village or city).

This study was approved by institutional review boards at Umeå University and the University of Alabama at Birmingham.

Results

The MONICA database from which this study is derived consists of 3030 men and 3137 women aged 25–64 years. Of these, 32 men (1.1%) and 45 women (1.4%) were missing information related to tobacco use and were excluded from the analysis. The final study population consisted of 2998 men (mean age = 45.5 years) and 3092 women (mean age = 45.0 years). Of the 6090 subjects, 1583 participated in the 1986 survey, 1561 in 1990, 1531 in 1994, and 1415 in 1999. Men accounted for 51.0% of the cohort in 1986, 49.1% in 1990, 48.7% in 1994, and 47.8% in 1999.

Figure 1 provides information on the prevalence of mutually exclusive categories of current tobacco use amongst the entire population, by gender and survey year. Overall prevalence of current tobacco use amongst men was stable at about 40%, but there were substantial differences amongst tobacco subtypes. The prevalence of exclusive smoking (no

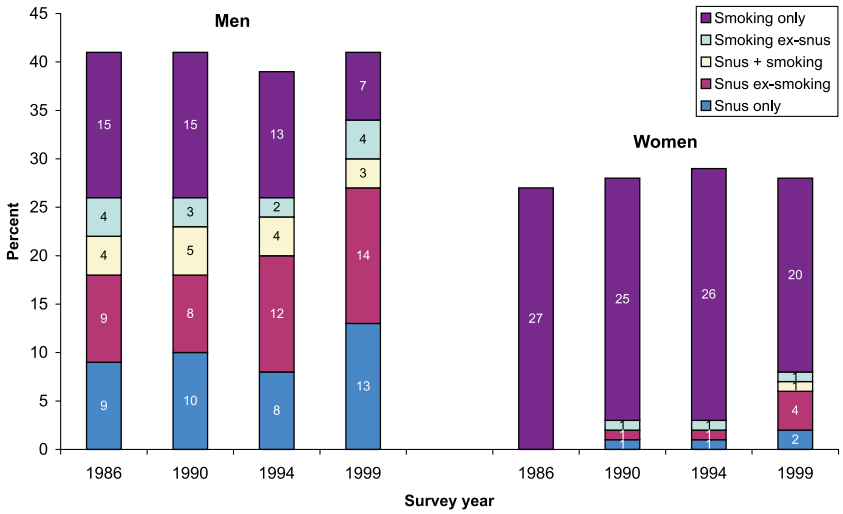

Fig. 1 Prevalence of current tobacco use (mutually exclusive categories) amongst the general population, men and women aged 25–64, by survey year.

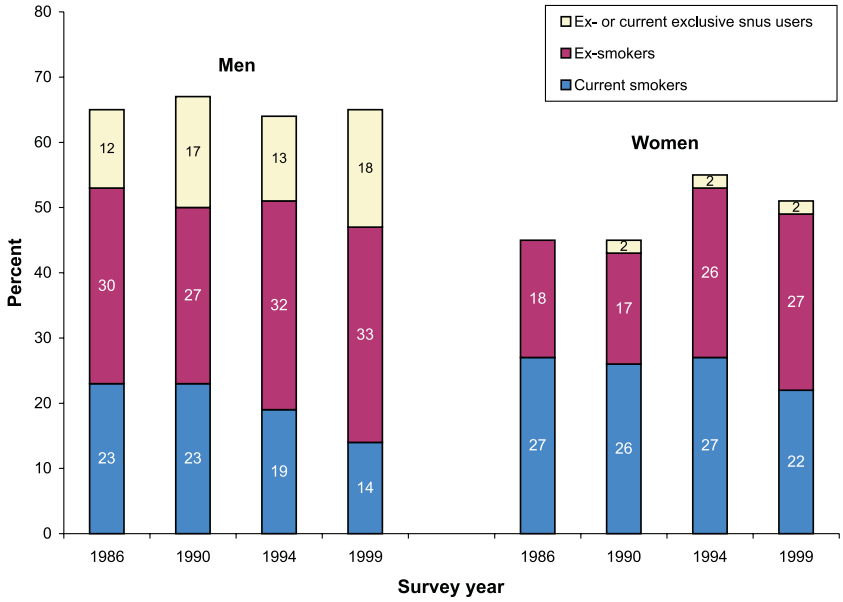

Fig. 2 Prevalence of ever tobacco use amongst the general population, men and women aged 25–64, by survey year.

prior or concurrent snus use) amongst men was 15% in 1986 but only 7% in 1999 whilst the prevalence of exclusive snus use (no prior or concurrent smoking) was 9% and 13%, respectively. The prevalence of current snus use/ex-smoking was higher than that of exclusive snus use in 1994 (12% vs. 8%) and in 1999 (14% vs. 13%). Combined use (snus + smoking) was stable (3–5%), as was ex-snus use/current smoking (2–4%). Amongst women the dominant form of current tobacco use was exclusive smoking (27% in 1986, 20% in 1999), although the prevalence of snus use was 6% in 1999. In that year 4% of women were current snus users who were ex-smokers whilst 2% reported of exclusive snus use.

Figure 2 shows the prevalence of exclusive snus use (past or current), ex-smoking, and current-smoking amongst the entire population by gender for each of the survey years. Ever-tobacco use (the entire column for each year) was relatively stable in both men (~65%) and women (45–55%). In men exclusive use of snus accounted for about one-quarter of ever-tobacco use, whilst in women smoking was the dominant form of tobacco consumption. The prevalence of ever-smoking (ex-smoking + current

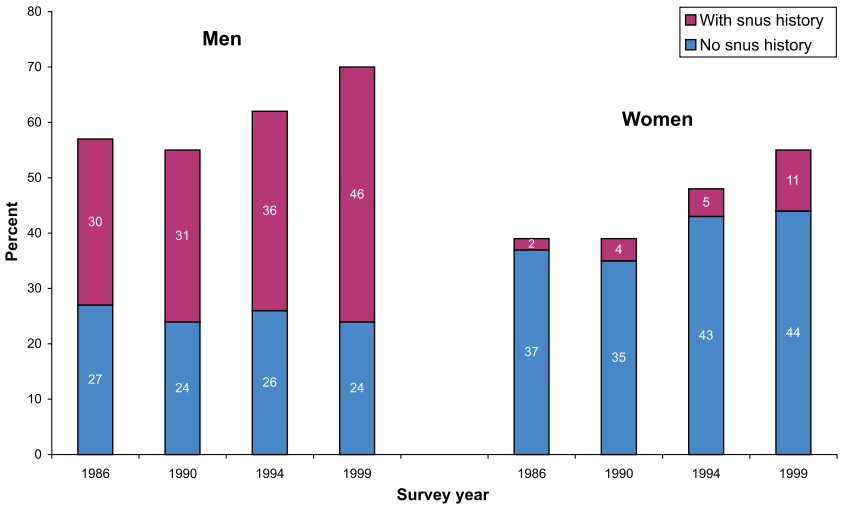

Fig. 3 Prevalence of ex-smoking amongst ever smokers, men and women aged 25–64, according to a history of snus use, by survey year.

smoking) amongst men was about 50%, but the prevalence of current smoking was 23% in 1986 and 1990, 19% in 1994 and only 14% in 1999.

Figure 3 shows the prevalence of ex-smoking (amongst ever smokers) subclassified according to a history of snus use, by gender. The overall prevalence of ex-smoking was much higher amongst men than amongst women. However, if a history of snus use is excluded, women had a higher prevalence of ex-smoking in all years. In men the prevalence of ex-smoking without a history of snus use was 27% in 1986 and lower in later survey years, whilst ex-smoking with a snus history was 30% in 1986 and was higher in each successive year. In women the prevalence of ex-smoking with a history of snus use was only 2% in 1986 but was 11% in 1999.

Amongst men there was a distinct trend of higher prevalence of ex-smoking with increasing age ($P < 0.001$). Men showed consistently higher prevalence of ex-smoking than women with respect to all ages, education levels, categories of marital status and survey years. In 1986 the male/female prevalence ratio of ex-smoking was 1.44 (95% CI 1.23–1.68) and in 1999 it was 1.27 (1.13–1.43). Although the PR was smaller in the more recent survey years, the trend was not significant. A history of snus use was a strong factor in the higher prevalence of ex-smoking in men compared with women (PR = 6.18, CI = 4.96–7.70).

Table 1 compares the demographic characteristics of male ex-smokers with and without a history of snus use. Ex-smokers with a history of snus use were more likely to be younger ($P < 0.001$). They were slightly more likely to have completed primary or secondary school versus university ($P = 0.038$) and to be single, although the latter did not reach statistical significance. In addition, there was a strong trend of increased ex-smoking with a snus history in more recent survey years ($P = 0.006$). There was no difference in location of residence between ex-smokers with and without a history of snus ($P = 0.225$).

There were statistically significant differences in mean daily tobacco consumption between men who were combined users (snus + cigarettes) and those who were exclusive users (snus or cigarettes only). Regarding exclusive snus use, average daily consumption was 0.41 packages (SD ± 0.25) amongst ex-smokers and 0.44 packages (±0.27) amongst never smokers. In comparison, combined users consumed 0.25 packages (±0.20) of snus daily, about 40% less. With regard to smoking, ex-snus users averaged 15.1 cigarettes daily (±7.52) and never users of snus smoked 16.0 cigarettes (±7.98). In comparison, combined users smoked an average of 10.8 cigarettes daily (±6.16), about 30% fewer.

Discussion

The major finding in this study is that the prevalence of smoking amongst men in northern Sweden was very low, falling from 23% in 1986 to 14% in 1999. These rates are several percentage points lower than those reported in national surveys

Table 1 Prevalence (amongst ex-smokers) of men with ($n = 527$) and without a history of snus use ($n = 381$), by age, education, marital status, survey year and location of residence

	No. with snus history (%)	No. without snus history (%)	All	Prevalence ratio (with/ without snus) (95% CI)
Age				
25–34	83 (75)	28 (25)	111	2.96 (2.11–4.16)
35–44	153 (71)	63 (29)	216	2.43 (1.94–3.04)
45–54	161 (58)	119 (43)	280	1.35 (1.14–1.60)
55–64	130 (43)	171 (57)	301	0.76 (0.64–0.89)
Trend[a]				$P < 0.001$
Education[b]				
Primary	203 (56)	158 (44)	361	1.28 (1.11–1.49)
Secondary	258 (63)	154 (37)	412	1.68 (1.45–1.94)
University	60 (50)	61 (50)	121	0.98 (0.76–1.27)
Primary + Secondary versus University				$P = 0.038$
Marital status[c]				
Single	83 (64)	46 (36)	129	1.80 (1.38–2.35)
Married	443 (57)	334 (43)	777	1.33 (1.20–1.47)
Year				
1986	128 (53)	114 (47)	242	1.12 (0.94–1.34)
1990	118 (56)	93 (44)	211	1.27 (1.05–1.54)
1994	136 (58)	98 (42)	234	1.39 (1.15–1.67)
1999	145 (66)	76 (34)	221	1.91 (1.55–2.34)
Trend[d]				$P = 0.006$
Location[e]				
<1000	131 (56)	104 (44)	235	1.26 (1.05–1.51)
1,001–15 000	142 (58)	104 (42)	246	1.37 (1.14–1.64)
>15 000	252 (59)	172 (41)	424	1.47 (1.27–1.68)
Trend				$P = 0.225$

[a]Trend of decreasing prevalence of ex-smoking with history of snus use as age increases. [b]Excludes six men in the first column and eight in the second for whom there were incomplete data. [c]Excludes one man in each column for which there were incomplete data. [d]Trend of increasing prevalence of ex-smoking with snus use in more recent surveys. [e]Population of location of residence. Excludes two men in the first column and one in the second for whom there were incomplete data.

[8–10], which is even more remarkable as Swedish men enjoy the lowest smoking prevalence in Europe [11]. Unfortunately, low smoking rates are limited to men, as the women in our study had prevalence rates very similar to those of other European countries [11]. In fact, women in this cohort had higher smoking prevalence than men in all survey years, an inversion of the pattern in virtually every other society in the world.

Whilst smoking prevalence amongst men in this study was low, the prevalence of snus use was very high and was the dominant factor in the higher prevalence of ex-smoking amongst men compared with women (prevalence ratio 6.18, 95% CI 4.96–7.70). A comparison of demographic factors between male ex-smokers with and without a snus history revealed some interesting findings. First, there was a trend of ex-smoking with snus use at younger ages ($P < 0.001$), when smoking cessation affords greater benefits to health. This was in distinct contrast to overall prevalence of ex-smoking amongst men, which was more common at older ages. Second, there were only small and insignificant differences in education, marital status or location of residence amongst ex-smokers with and without a snus history. In the United States, a country with a tradition of smokeless tobacco use and in which comparable usage data is available, prevalence is strongly correlated with lower educational status and residence in rural areas [12].

The unique trend in tobacco use in northern Sweden emerges more fully when additional comparisons are made with American statistics [13–15]. For example, in 1990 the quit ratio (prevalence of ex-smokers divided by prevalence of ever smokers × 100 [16]) amongst men in our study was 55%, compared with 53% of American men. However, in 1999 the quit ratio amongst men in

northern Sweden was 70%, whilst the figure for American men was only 52%. The trend amongst women was similar. In 1990 the quit ratio amongst women in our study was 39%, compared with 47% of American women. In 1999 the Swedish figure was 55%, whilst the American ratio was 46%.

In addition to increasing cessation rates, it is possible that snus use influenced smoking prevalence amongst men by reducing smoking initiation. First, in 1990 rates of ever tobacco use amongst men in our study were similar to those of American men (67% and 65%, respectively). In our study 17% of men were ever (exclusive) users of snus, whilst the comparable figure for American men was 6%. But only 50% of men in this cohort were ever smokers, compared with 59% of men in the US. Thus, whilst prevalence of ever tobacco use was similar for both populations, prevalence of ever smoking amongst men in northern Sweden was substantially lower than that amongst American men. In contrast, in 1990 the prevalence of ever-smoking amongst women was 43% in northern Sweden and 42% amongst American women, with very little use of smokeless tobacco (2% and <1%, respectively).

With the high prevalence of snus use amongst men, there is the possibility that a transition from snus use to smoking could also occur. We could not examine usage patterns amongst persons younger than 25 years of age, but our results do not indicate that snus use played a prominent role in smoking initiation in this adult population. For example, in this study the 1999 male cohort had the highest prevalence of current snus use (30%) and the lowest prevalence of ever-smoking (47%). The prevalence of smoking/ex-snus use was low in all survey years (2–4%), and combined users were infrequent (3–5%). So, the evidence suggests that amongst adult men in northern Sweden the dominant transition is from smoking to snus, not vice versa.

The major strengths of this study are the relative homogeneity of the population and the standardized data collection in all MONICA surveys [17]. In addition, multiple questions on tobacco use permitted accurate definitions of current and former smokers. A general limitation of prevalence data is that tobacco use is self reported [7]. However, in the 1990 survey tobacco use status, validated by nicotine and cotinine levels, was found to be highly reliable in this cohort [18].

Recent epidemiologic studies have shown that Swedish snus is not associated with oral cancer [19, 20] or other smoking-related cancers. Furthermore, snus does not appear to be a strong risk factor for cardiovascular diseases [4, 21]. Thus, the balance of tobacco use in northern Sweden amongst men – and perhaps incipiently amongst women – may confer substantial health advantages compared with smoking-dominated societies.

Acknowledgements and conflict of interest

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References

1 LaVecchia C, Lucchini F, Negri E, Boyle P, Maisonneuve P, Levi F. Trends of cancer mortality in Europe, 1955–1989: II and IV. *Eur J Cancer* 1992; **28**: 514–599, **28A**: 1210–1281.
2 Peto R, Lopez AD, Boreham J, Thun M, Heath C Jr. Mortality from tobacco in developed countries: indirect estimation from national vital statistics. *Lancet* 1992; **339**: 1268–78.
3 Nordgren P, Ramstrom L. Moist snuff in Sweden: tradition and evolution. *Br J Addict* 1990; **85**: 1107–12.
4 Huhtasaari F, Asplund K, Lundberg V, Wester PO. Tobacco and myocardial infarction: is snuff less dangerous than cigarettes? *Br Med J* 1992; **305**: 1252–6.
5 Asplund K, Huhtasaari F, Lundberg V, Stegmayr B, Wester PO. Trends in cardiovascular risk factors in the northern Sweden MONICA study: who are the winners? *Cardiovasc Risk Factors* 1993; **3**: 215.
6 Persson M, Carlberg B, Mjorndal T, Asplund K, Bohlin J, Lindholm L. 1999 WHO/ISH guidelines applied to a 1999 MONICA sample from northern Sweden. *J Hypertens* 2002; **20**: 29–35.
7 *The Health Benefits of Smoking Cessation*. U.S. Department of Health and Human Services. Public Health Service, Centers

for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication no. (CDC) 90-8416. Rockville, MD: US Department of Health and Human Services, Public Health Service, 1990.
8 Ramstrom L. *Quit-Smoking Patterns in Swedish Males and Females: The Role of Snuff Dipping and Nicotine Dependence*. Society for Research on Nicotine and Tobacco, Annual Meeting, 1995, San Diego, CA, USA.
9 Ramstrom L. *Nicotine Dependence Among Swedish Smokers and Ex-smokers*. Society for Research on Nicotine and Tobacco, Annual Meeting, 1998, New Orleans, LA, USA.
10 *Public Health Report (Sweden)*, Epidemiology Central, National Board of Health and Welfare, Stockholm, 2001.
11 Ramstrom LM. Prevalence and other dimensions of smoking in the world. In: Bolliger CT, Fagerström KO, eds. The Tobacco Epidemic. Prog Respir Res, 1997; **28**: 64–77.
12 Centers for Disease Control and Prevention. Use of smokeless tobacco among adults – United States, 1991. *MMWR* 1993; **42**: 263–6.
13 Centers for Disease Control and Prevention. Surveillance for selected tobacco-use behaviors – United States, 1900–1994. *MMWR* 1994; **43**: SS03.
14 Centers for Disease Control and Prevention. Cigarette smoking among adults – United States, 1998. *MMWR* 2000; **49**: 881–4.
15 Centers for Disease Control and Prevention. Cigarette Smoking Among Adults – United States, 1999. *MMWR* 2001; **50**: 869–72.
16 Centers for Disease Control and Prevention. *Reducing the Health Consequences of Smoking: 25 Years of Progress – A Report of the Surgeon General*. DHHS publication no. (CDC) 89-8411. Rockville, MD: US Department of Health and Human Services, Public Health Service, 1989.
17 Molarius A, Parsons RW, Dobson A *et al.* Trends in cigarette smoking in 36 populations from the early 1980s to the mid-1990s: findings from the WHO MONICA project. *Am J Public Health* 2001; **91**: 206–12.
18 Eliasson M, Asplund K, Evrin P, Lundblad D. Relationship of cigarette smoking and snuff dipping to plasma fibrinogen, fibrinolytic variables and serum insulin. The Northern Sweden MONICA study. *Atherosclerosis* 1995; **113**: 41–53.
19 Lewin F, Norell SE, Johansson J *et al.* Smoking tobacco, oral snuff and alcohol in the etiology of squamous cell carcinoma of the head and neck: a population-based case-referent study in Sweden. *Cancer* 1998; **82**: 1367–75.
20 Schildt E, Eriksson M, Hardell L, Magnuson A. Oral snuff, smoking habits and alcohol consumption in relation to oral cancer in a Swedish case–control study. *Int J Ca* 1998; **77**: 341–6.
21 Huhtasaari F, Lundberg V, Eliasson M, Janlert U, Asplund K. Smokeless tobacco a possible risk factor for myocardial infarction. A population-based study in middle-aged men. *JACC* 1999; **63**: 195–200.

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Tab L

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Programs and policies to discourage the use of tobacco products

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The past 50 years has witnessed a dramatic change in attitudes toward and use of tobacco by Americans that has resulted in recent declines in the incidence of lung cancer. Most public health scholars believe that this change has been accelerated by public policy interventions to reduce tobacco use. The research literature suggests that the most potent demand reducing influences on tobacco use have been efforts to increase the financial cost of using tobacco products primarily through taxation, smoke-free policies, comprehensive advertising bans, and paid counter-advertising campaigns. New therapies for treating nicotine dependence and measures to liberalize access to medicinal forms of nicotine have the potential to revolutionize the way societies address the problem of tobacco use in the future. Unfortunately, the economic reality of the tobacco business has hindered public health efforts to curb the use of tobacco products. While government regulation of tobacco products is a worthy goal, capitalism, and not government regulation, most likely holds the greatest potential to rapidly alter the worldwide epidemic of tobacco caused disease. It is up to the public health community to harness the powers of capitalism to speed the development of less dangerous alternatives to the conventional cigarette.
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Keywords: tobacco control; smoking cessation; prevention; nicotine dependence

Introduction

If the world had a vaccine that could prevent one-third of all cancer deaths would we use it? The answer would appear obvious, yet the reality is that nearly half a century after establishing the link between smoking and cancer, nearly one quarter of the adult population in the United States continue to smoke cigarettes, and worldwide tobacco use is increasing (Connolly, 1992; Gajalakskmi *et al*., 2000). How can this be, and what can be done to remedy this situation?

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History of tobacco control

Programs and policies to discourage the use of tobacco products have a long history in the US and in other countries. The first recorded prohibition against tobacco use resulted from a clash between Peruvian native and Christian religious customs which led to a 1586 Papal decree declaring it a sin for any priest to use tobacco before celebrating or administering communion (Slade, 1993). In the early 1600s King James I of England attempted to discourage the use of tobacco by taxing it, the czar of Russia exiled tobacco users to Siberia, and in China, those caught selling tobacco were executed (Kluger, 1996). Despite these prohibitions, the use of tobacco continued to spread, especially in the US that garnered economic benefit from growing and exporting tobacco leafs around the globe (Kluger, 1996). By the late nineteenth century, tobacco use was widespread, but most people used only small amounts and mainly in the form of pipes, cigars, chewing tobacco or a pinch of snuff. Cigarettes had to be hand rolled and thus were rarely used. This situation began to change in the 1880s following the invention of the automated cigarette-making machine that dramatically reduced the cost of cigarette production (Kluger, 1996). However, it was not until the first World War, when men were introduced to cigarettes in their K-rations that cigarettes replaced cigars and chewing tobacco as the predominant form of tobacco (Kluger, 1996).

At the turn of the century the anti-smoking movement in the United States was motivated mainly by moral and religious beliefs, although medical objections against cigarettes were beginning to be raised. Both Thomas Edison and Henry Ford voiced concerns about the detrimental health effects of cigarette smoking (Kluger, 1996). In the first quarter of the twentieth century groups such as the Non-smokers Protective League, The Women's Christian Temperance Union, and religious leaders joined forces to prohibit the sale of tobacco and alcohol (Kluger, 1996). However, the negative backlash against the federal prohibition on alcohol coupled with the more pragmatic approach of allowing governments to tax tobacco as a way of controlling its use resulted in the rescinding of most state and local prohibitions against tobacco.

By the 1930s efforts to limit smoking were fading away, allowing tobacco manufacturers to compete

vigorously against one another by spending tens of millions annually in advertising to promote their brands (Kluger, 1996). Cigarette advertisers were successful in associating smoking with images of health, athletic performance, wealth, and social standing which helped fuel a nearly three decade long increase in the prevalence of smoking (Pollay, 2000).

Medical and scientific data implicating smoking as a cause of cancer first began to surface in Germany in the 1920s and 1930s (Proctor, 1999). Ironically, the Nazis actually used this medical evidence to mount an aggressive campaign to discourage smoking in Germany in the 1930s and early 1940s. Smoking was banned in many workplaces, cigarette taxes were raised, advertising restrictions were introduced, stop smoking programs were implemented, and an aggressive public education campaign was waged against smoking (Proctor, 1999). However, the German campaign against smoking and much of the medical evidence implicating smoking as a cause of cancer was largely ignored as a result of the Second World War. It was not until the early 1950s and 1960s when scientists from the United Kingdom and the United States began to publish their research linking smoking and cancer that the modern era of tobacco control was born.

With the widespread publicity of the findings in the 1964 Surgeon General's Report on Smoking and Health, tobacco use was added, virtually overnight, to the political agenda (US DHHS, 1989, 2000; Rabin and Sugarman, 1993). Declining cigarette consumption in the US since the 1960s corresponds to increased public awareness of the dangers of tobacco use, changing social norms about tobacco, and increased governmental actions to regulate the use, sale, and advertising of tobacco products (Warner, 1986). Today, nearly half of all living adults who ever smoked have stopped smoking. In the US, the incidence of smoking-caused cancers began to decline in the late 1980s resulting in an overall decrease in cancer mortality (Wingo *et al.*, 1999). Unfortunately, in many developing countries around the world, cigarette consumption is increasing which is predicted to fuel an overall worldwide increase in cancer incidence (Liu *et al.*, 1998; Niu *et al.*, 1998; Gajalakshmi *et al.*, 2000). This study attempts to explain the various social forces, programs and policies that have combined to influence tobacco use over the past half century in the US. The goal of this exercise is to try to understand what strategies might be applied by medical and public health workers to further accelerate the decline in tobacco use in the US as well as to stem the increasing upward trend in tobacco use in the developing world.

The modern era of tobacco control

Since the mid-1960s a wide array of programs and policies have been implemented in an effort to discourage the use of tobacco (US DHHS, 2000). However, determining precisely which programs and/or policies have contributed most to population-wide fluctuations in tobacco use patterns is not easily accomplished given the multitude of factors that interact to alter these trends. Nonetheless, a substantial and growing body of scientific literature has emerged on the subject of what works in tobacco control. The British Medical Association even publishes a journal titled Tobacco Control which is devoted to publishing research papers on the impact of programs and policies to reduce tobacco use (www.tobaccocontrol.com).

Why people smoke?

In order to understand approaches used to discourage tobacco it is helpful to consider the question of why people smoke to begin with. There is little doubt today that nicotine in tobacco is the primary reason why most smokers continue to expose themselves on a daily basis to known toxins (US DHHS, 1988; Kessler, 1994). As acknowledged by one Philip Morris scientist who stated the importance of nicotine bluntly as follows, 'No one has ever become a cigarette smoker by smoking cigarettes without nicotine' (Dunn, 1972). The concept of smoking as an addiction has gained in popularity in recent years and offers a number of interesting, although until recently little used, policy options including: (1) government regulation of tobacco products; (2) tort damage claims by smokers against the tobacco companies; and (3) the provision of free or low cost smoking cessation programs funded by tobacco companies, taxes on tobacco products, or a requirement that such services be included in ordinary health insurance.

While the debate about whether smoking is a choice or an addiction is often presented in the popular media as an either/or proposition, most serious researchers in the field view smoking behavior as a blend of a combination of both cognitive and non-cognitive elements (Heath and Martin, 1993; Henningfield *et al.*, 1993; Kessler, 1994). However, until the 1980s, most tobacco control programs and policies ignored the concept of smoking behavior as an addiction. Instead, the focus of programs and policy efforts to reduce tobacco use relied mainly on an informed consumer orientation (US DHHS, 1989, 2000).

Tobacco control interventions can be grouped into one of four general categories that describe the primary intent of the intervention. These include: (1) informing and educating consumers; (2) treating nicotine dependence; (3) using economic incentives to increase or decrease the cost of using tobacco; and (4) policies that limit opportunities to use, manufacture and/or sell tobacco products. The following sections of this paper attempt to summarize the evidence regarding the efficacy of each of these approaches to controlling tobacco use.

Informing and educating consumers

As a general rule, the goal of government regulation with regards to product safety is to ensure that

consumers are informed about the inherent dangers of the product (Simonich, 1991). It is commonly assumed that smokers are adequately informed about the health risks of smoking (Wilkenfeld *et al.*, 2000; Cummings *et al.*, 2002a). In fact, one of the legal defenses used by the tobacco industry rests on the premise that smokers are adequately informed about the health risks of smoking. While population surveys do show that smokers today generally recognize some health risks from smoking, this does not necessary mean that they are adequately informed about smoking. For example, many smokers fail to appreciate that switching to a low tar and/or filtered cigarette does not make smoking less hazardous (Shiffman *et al.*, 2001). Also, smokers tend to be overly optimistic about their personal risk of illness (Ayanian and Cleary, 1999). This misperception is due in part to the belief that the person will be able to stop smoking before health problems occur (Slovic, 2001). Also, an optimistic perception of one's ability to stop smoking ignores evidence showing that the majority of smokers are dependent on nicotine, which will inhibit their ability to stop smoking easily (US DHHS, 1988). Also, while general awareness of the health risks of smoking may be high in the developed world, this is not necessarily the case in many parts of the developing world where tobacco use is accelerating.

Government efforts to warn the public about the dangers of tobacco use have included: (1) requiring information about the health risks of tobacco on advertising and packages of cigarettes and smokeless tobacco products; (2) sponsorship of antismoking campaigns through the mass media; and (3) the issuing of government reports summarizing information on the health risks of using tobacco, and disclosing the levels of certain tobacco smoke constituents. What is known about the impact of each of these efforts on cigarette smoking behavior is described below.

Warning labels

Congress has enacted a series of laws specifying that warning labels be placed on cigarette packages. The first of these laws was enacted in 1965, updated in 1969, and revised again in 1984 (US DHHS, 1989). Also, in 1986, Congress enacted warning requirements for smokeless tobacco products (US DHHS, 1989).

Eleven days after the 1964 Surgeon General's Report on Smoking and Health was released, the Federal Trade Commission (FTC) proposed rules requiring cigarette manufacturers to disclose on all cigarette packages and advertising that 'cigarette smoking is dangerous to health' and 'may cause death from cancer and other diseases' (FTC, 1964). However, before the FTC rule could take effect, Congress passed the Cigarette Labeling and Advertising Act of 1965 (US DHHS, 1989). This law preempted the FTC warning label and in its place required the following health warning be place on all cigarette packages: 'Caution: cigarette smoking may be dangerous to your health'. Unlike the proposed FTC regulation, Congress did not require the warnings on product advertisements. The 1965 act also preempted federal agencies, state and local governments from issuing its own health warnings, and prohibited the FTC from requiring health warnings on cigarette advertising until July 1, 1969.

In 1969, the FTC again proposed regulations requiring manufacturers to print a stronger health warning on cigarette packages and on cigarette advertisements (FTC, 1969). In response to the FTC proposed regulations, Congress passed the Public Health Cigarette Smoking Act of 1969 which amended the 1965 labeling act to require a slightly strengthened health warning: 'Warning: The Surgeon General Has Determined that Cigarette Smoking is Dangerous to Your Health' (US DHHS, 1989). Again, the Congressionally mandated warning was milder than that recommended by the FTC and omitted reference to death, and other specific diseases. The 1969 act also prohibited the FTC from requiring health warnings on cigarette advertisements until July 1, 1971. The 1969 act also preempted states and local governments from regulating cigarette advertising based on smoking and health concerns. In March 1972, FTC rules went into effect requiring manufacturers to display the same health warning mandated on cigarette packages on all cigarette advertising.

In 1981, the FTC issued a report on the effectiveness of the federally mandated cigarette warning label (FTC, 1981a). The report concluded that the warning label was 'worn out', and had little impact on the public's level of knowledge about smoking (FTC, 1981a). In 1984, Congress enacted the Comprehensive Smoking Education Act, which required four rotating health warnings on all cigarette packages and advertisements (US DHHS, 1989):

(1) SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
(2) SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
(3) SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
(4) SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Despite an FTC recommendation that the size of the warning be increased and that the shape of the health warning be changed to a circle-and-arrow format making it more noticeable, Congress retained the size and rectangular format of the previous health warnings.

In 1986, Congress passed the Comprehensive Smokeless Tobacco Health Education Act, which mandated for the first time warning labels on smokeless tobacco products and advertisements (US DHHS, 1989). Under the act, three rotating warning labels are required to be printed on smokeless tobacco packaging and advertisements using the circle-and-

arrow format originally recommended for cigarettes by the FTC. The three required health warnings include:

(1) WARNING: This product may cause mouth cancer.
(2) WARNING: This product may cause gum disease and tooth loss.
(3) WARNING: This product is not a safe alternative to cigarettes.

The 1986 law also preempted federal agencies and state and local governments from imposing additional health warnings on smokeless tobacco packages and advertisements. Despite the fact that government mandated health warning labels are an important area of government intervention on tobacco, few studies have actually evaluated the impact of warning labels on knowledge, beliefs, attitudes, or tobacco use behaviors (US DHHS, 1989; Simonich, 1991). A recent review of the literature (Mitchell, 1999) listed 37 published articles and reports on health warning messages and toxic constituent labeling for tobacco products. Some studies assessed individuals' awareness or recall of existing warning labels (Malouff *et al.*, 1992; Fischer *et al.*, 1989), believability of the messages (Cecil *et al.*, 1996; Borland and Hill, 1997), or presented them with existing, new, or proposed warning labels and asked them to comment on their possible effectiveness (Linthwaite, 1985). Such studies are limited because they ask respondents to imagine how they or others might be affected rather than measuring actual effectiveness, and there may be a considerable discrepancy between the two. Other studies (Simonich, 1991; Ho, 1992; Robinson and Killen, 1997) have correlated knowledge of warning label messages with smoking behavior, but the use of cross-sectional designs led to problems of interpretation. In the only longitudinal study conducted on the effects of warning labels across a change in the labels, Borland (1997) surveyed smokers by phone before and 6 months after new, larger and enhanced warning labels were introduced in Australia in 1995. In both cross-sectional and longitudinal samples, smokers contacted after the new enhanced warning labels had been introduced provided survey responses that were consistent with the notion that the new warning labels had some beneficial effects, including a greater likelihood of noticing the health warnings, refraining from smoking on at least one occasion, and making a quit attempt. Although these results are consistent with the notion that enhancing warning labels may have beneficial effects, any inferences based on this one-group pre-post design are vulnerable to alternative explanations.

Studies on US government mandated health warnings suggest that they are largely ineffective (Simonich, 1991). In one study that used a sophisticated eye-tracking device, 44% of adolescents asked to view cigarette advertisements did not even look at the warning label displayed on the advertisement (Fischer *et al.*, 1989). A second study evaluating warnings appearing on roadside billboards found that under typical driving conditions, observers could read the entire warning message on only 5% of cigarette advertisements (Davis and Kendrick, 1989). However, observers were able to identify the brand name and advertising message on the billboards.

In December 2000, the Canadian government introduced new graphic warning labels on cigarette packages (Mahood, 1999; see Figure 1). The new warning labels were enhanced in three ways. First, increased in size, from 25% of the package to 50%. Second, the warnings contain graphic color photographs depicting the adverse health consequences of smoking, including a cancerous lung, a burst blood vessel in the brain of a smoker who died of a stroke, and mouth cancer. Third, the new warnings on the outside of the package are accompanied by information on the inside of the package about the detrimental effects of smoking along with messages designed to encourage smokers to quit; these include specific messages designed to increase both smokers' efficacy to quit and to highlight the response efficacy of quitting. A recent survey (Cunningham, 2002) of Canadian smokers found that 90% had noticed the new graphic warnings and 44% said that the new warnings had increased their motivation to stop smoking.

Strahan *et al.* (1999) identifies the following features of warning labels as critical to the their salience: (1) if the warning label is located on the larger surfaces (i.e., front and back); (2) larger warning labels are more likely to be noticed than smaller labels; (3) warning labels located at the top of the surface as opposed to the bottom; (4) if the warning label is graphically dissimilar to the rest of the packaging. Based on these criteria, the current US warning labels would be judged to be lacking in salience. The overall low salience of the US warning labels may account for their weak effects on influencing smoking trends (Balla *et al.*, 1984; Simonich, 1991; Fischer *et al.*, 1993).

Some investigators have suggested that no matter how graphic the warning label might be consumption will not be affected unless smokers are given substitutes to use in place of cigarettes (Simonich, 1991). For example, Simonich (1991) noted that studies have found that labeling of food products substantially alters consumption so long as close substitutes exist (i.e., shifting from high fat to lower fat foods). Since cigarette warnings provide exactly the same information for every brand they have no ability to stimulate brand switching. As a group, cigarettes do not have a close substitute that can be used to provide the nicotine that most smokers crave. In the US, nicotine gum and nicotine skin patches are available only by prescription and are therefore not good substitutes for cigarettes (Warner *et al.*, 1997). This situation could change if nicotine medications were made more readily available at a competitive cost compared to purchasing cigarettes (Warner *et al.*, 1997; Novotny *et al.*, 2001). Cigarette companies are also developing nicotine delivery devices that look and taste like regular cigarettes, but do not contain the

Figure 1 Examples of Canada's new graphic cigarette package warning labels

same levels of toxic constituents as conventional cigarettes (see Figure 2a,b, Hoffmann *et al.*, 2001; Wilson, 2001). These alternative tobacco products are being designed to appeal to the health concerns of smokers, and may represent closer substitutes for conventional cigarettes. At present, it is not clear whether these alternative tobacco products should be required to carry the same health warning found on regular cigarettes (Stratton *et al.*, 2001).

Informational campaigns

Although concerns about increasing cancer rates associated with cigarette smoking began to appear in the medical literature in the 1930s, it was not until the 1950s and 1960s that the research on smoking and cancer began to receive media attention. Despite the emerging scientific consensus that smoking was a cause of lung cancer, the tobacco industry continued to

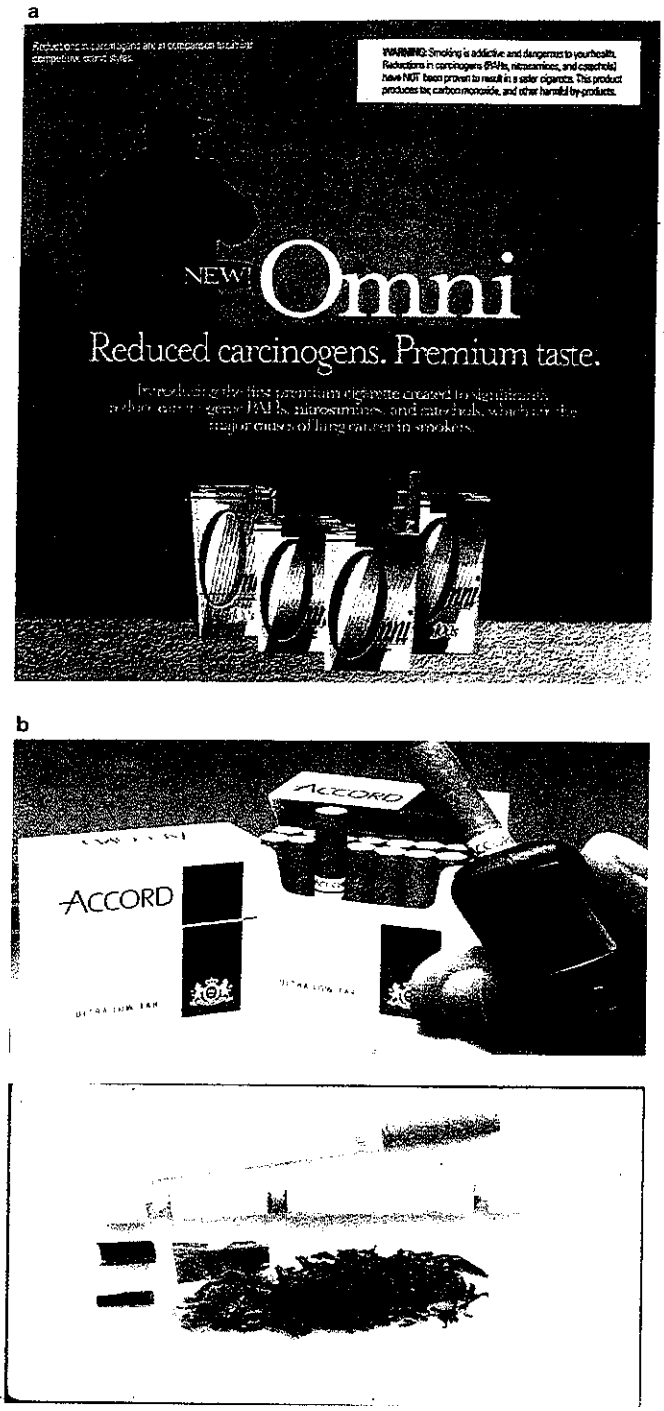

Figure 2 (a) Advertisement for new Omni cigarette brand promising reduced carcinogens. (b) Top panel: Philip Morris' new Accord 'electric heating' cigarette sold in Richmond, Virginia; bottom panel: RJ Reynolds Tobacco Companies new Eclipse cigarette that primarily heats rather than burns tobacco

reassure the public that cigarettes were not injurious to health (Pollay, 1997; Cummings, 2002). The controversy about smoking as a cause of ill health helped fuel media attention on the subject of smoking and health, which in turn contributed to increasing levels of public awareness of the health risks of smoking (Warner, 1989). Pierce and Gilpin (2001) have shown that the level of news media coverage of smoking and health in the US from 1950 to the early 1980s mirrored population trends in awareness about smoking as a cause of lung cancer and rates of smoking cessation.

The first large scale national counter-advertising campaign to educate the public about the health risks of tobacco use occurred between 1967 and 1970 when the Federal Communications Commission (FCC) required licensees who broadcast cigarette commercials to provide free media time for antismoking public service announcements (PSA) under the Fairness Doctrine (US DHHS, 1989). The Fairness Doctrine, which was repealed by the FCC in 1988, obligated licensed broadcasters to 'encourage and implement the broadcast of all sides of controversial public issues over their facilities, over and beyond their obligation to make available on demand opportunities for the expression of opposing views' (FCC, 1987).

In January 1967, an attorney by the name of John Banzhaf, petitioned the FCC to apply the Fairness Doctrine to cigarette advertising (US DHHS, 1989). In June of 1967, the FCC accepted Banzhaf's petition and ruled that licensed broadcasters were required to air roughly one antismoking message for every three cigarette brand commercials. In July 1967, antismoking PSAs developed by voluntary health agencies and the government began to air. Unlike most public service advertising campaigns, many of the antismoking ads were aired during prime time. The time donated for the antismoking messages amounted to approximately 276 million dollars per year (in 1993 dollars). The Fairness Doctrine campaign ended in January 1971, as a result of a federal law that banned cigarette advertising on television and radio. After 1970, the number of antismoking PSAs declined markedly as antismoking messages were forced to compete for donated airtime.

Between 1967 and 1970 cigarette consumption in the US dropped at a much faster rate than during the period immediately before or after the time when the Fairness Doctrine antismoking campaign was operational (US DHHS, 1989). While it is impossible to rule out the effects of other influences that may have contributed to the decline in cigarette consumption between 1967 and 1970, several studies have concluded that the antismoking messages mandated by the Fairness Doctrine were responsible for much of the reduction in smoking during this period (O'Keefe, 1971; Hamilton, 1972; Warner, 1989; Simonich, 1991). Support for this conclusion is found in a study published by O'Keefe (1971) that found high levels of recall for the antismoking PSAs aired as part of the campaign among both adults and youth. Analysis of trends in national survey data also suggest that the Fairness Doctrine PSAs contributed to increases in public knowledge of the health hazards of smoking (US DHHS, 1989).

The 1998 Master Settlement Agreement (MSA) between the tobacco industry and state governments provided resources to create a new foundation – the American Legacy Foundation – that had as one of its

mandates sponsorship of a national counter-advertising campaign (Daynard *et al.*, 2001; Healton, 2001). The American Legacy Foundation was created in 1999 and has spent approximately $100 million annually on a nationwide broadcast counter-advertising campaign (known as the 'truth campaign') targeting teens and young adults. The campaign has been successful in creating a high level of awareness of its messages among the intended target audience although it is still too early to determine what effect the campaign will ultimately have on smoking behavior (Healton, 2001).

The experience with the Fairness Doctrine antismoking messages has prompted some state governments to implement paid anti-tobacco advertising campaigns to counteract the impact of cigarette advertising. The main problem with a counter-advertising approach is funding it. Several states including California, Massachusetts, and Oregon have used ballot initiatives to increase cigarette taxes with the proceeds from the tax earmarked to finance informational campaigns against tobacco. Figure 3 shows two examples of billboard advertisements run as part of California's paid anti-tobacco advertising campaign. Other states have also used funds from the MSA to finance tobacco education campaigns. Evidence in support of the effectiveness of paid counter-advertising campaigns is found in the sharp declines in cigarette consumption observed in states that have invested heavily (in contrast to those that have not) in paid counter-advertising campaigns (see Figure 4; Harris *et al.*, 1997; Pierce *et al.*, 1998; Siegel and Biener, 2000; Fichtenberg and Glantz, 2000; US DHHS, 2000).

Issuing government reports

Since 1964, government agencies have issued hundreds of reports summarizing the scientific evidence about the health risk of tobacco use (US DHHS, 1989). Many of these reports are required under legislative mandate. Because these reports frequently receive extensive media coverage and are widely disseminated, they have helped educate the public about the health risks of tobacco.

The Federal Cigarette Labeling Act of 1965 and the Public Health Cigarette Smoking Act of 1969 require that the Secretary of Health and Human Services produce an annual report for Congress updating information on the health consequences of smoking. These reports are referred to as Surgeon General's Reports. Including the 1964 Report of the Surgeon General (which was not mandated by Congress) there have been 27 US Surgeon General's Reports on smoking.

The impact of these reports on smoking behavior is difficult to assess, although several studies suggest that the first Surgeon General's Report in 1964, contributed to a drop in cigarette consumption (Hamilton, 1972; Warner, 1989; Simonich, 1991). Recent reports have helped influence policy development on such issues as passive smoking (1986 report, US DHHS, 1986), nicotine addiction (1988 report, US DHHS, 1988), and youth tobacco use (1994 report, US DHHS, 1994).

Federal law also requires the FTC to produce an annual report for Congress on cigarettes sales and advertising (US DHHS, 1989). These reports generally include data on per capita cigarette sales, market share for filtered and unfiltered cigarettes, the market share for cigarettes of varying tar and nicotine yields, and cigarette advertising and promotional expenditures. Over the years, the FTC has proposed rules which would require cigarette manufacturers to list yields of tar, nicotine, and other hazardous components on their packages and in their advertising. In 1967, the FTC opened its own laboratory to analyse the tar and nicotine content of cigarette smoke. In 1981, the FTC published a list showing the tar, nicotine, and carbon monoxide yields of domestic cigarette brands based on its own laboratory tests (FTC, 1981b). However, the FTC has also acknowledged that its testing procedures are flawed and probably underestimate the amount of tar, nicotine and carbon monoxide that smokers receive from smoking (NCI, 1996). In 1987, the FTC closed its laboratory, and has relied on nicotine, tar, and carbon monoxide ratings provided by the cigarette industry under a voluntary reporting agreement (US DHHS, 1989). Today, cigarette companies are not required to disclose information about the tar and nicotine content of cigarettes. However, the disclosure of tar and nicotine levels is frequently seen on packaging and on advertising. Such disclosure is done voluntarily, and usually appears on cigarette brands with less than 8 mg or less of tar, but rarely for higher tar brands. Some researchers have speculated that the FTC effort to inform people about tar and nicotine yields of cigarettes may have inadvertently increased cigarette demand by suggesting that less dangerous cigarette brands exist (Warner and Slade, 1992; NCI, 1996; Pollay and Dewhirst, 2002).

The Comprehensive Smoking Education Act of 1984 and the Comprehensive Smokeless Tobacco Health Education Act of 1986 require manufacturers of tobacco products to annually provide a list of additives used in manufacturing to the Secretary of Health and Human Services (US DHHS, 1989). However, the government is required to treat the lists as 'trade secrets'. Under these laws Congress can be informed about research activities on health risks of these additives and may call attention to ingredients that pose a health risk to smokers. Otherwise, the lists of additives must be treated confidentially and not divulged to the public. These laws also did not give the government authority to regulate the use of additives in tobacco products, even if a health hazard is identified.

Many government reports are issued without a specific legislative mandate. For example, in 1992 the US Environmental Protection Agency (EPA) issued an important scientific report on the health risks of ETS (EPA, 1992). This report received extensive media coverage and has helped reinforce public concern about the dangers of ETS and has served as a springboard for both public and private regulatory initiatives to protect nonsmokers from tobacco smoke (Kennedy and Bero, 1999).

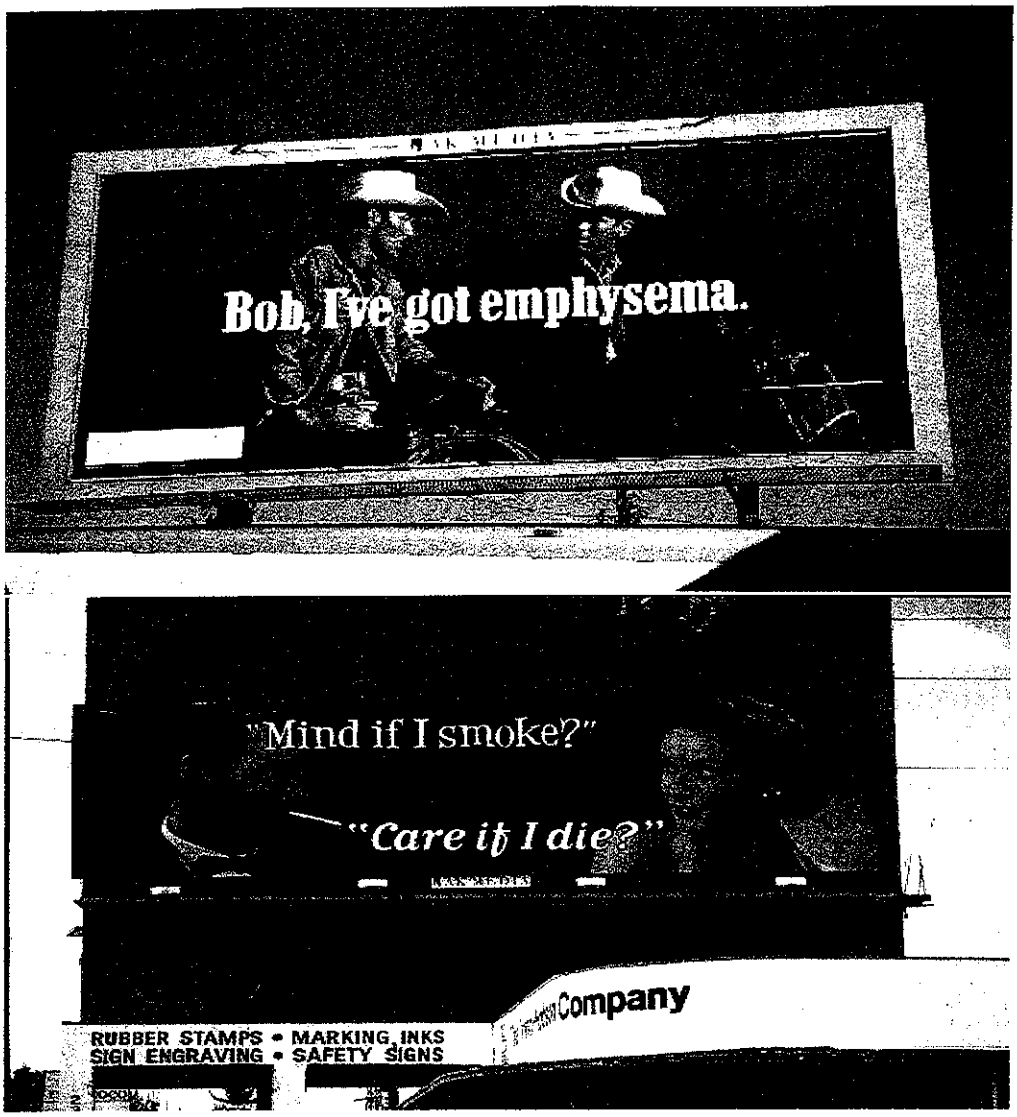

Figure 3 Examples of anti-tobacco billboard advertisements sponsored by the California Department of Health

The publication and dissemination of scientific information on the health consequences of tobacco use represents the least coercive of government interventions to combat tobacco (Pierce and Gilpin, 2001). The impact of this effort on tobacco use behavior is impossible to measure precisely. However, information dissemination is essential to the formulation of all other policy initiatives. Without appropriate information, it is difficult to form the popular consensus necessary to create and enforce more restrictive policies.

Treatments for smoking cessation

Historically, the vast majority (>90%) of former smokers have reported that they stopped smoking without receiving formal assistance or help from anyone (Hughes, 1999). However, this statistic has changed in the past two decades with the introduction and wide scale availability of effective drug therapies to help smokers alleviate withdrawal symptoms commonly associated with cessation (Hughes, 1999). Prescription only nicotine gum was introduced in the US in February 1984. The nicotine patch was introduced in 1992. In 1996, the FDA granted over-the-counter (OTC) status to nicotine gum and patch. Shiffman *et al.* (1997) tracked sales of pharmacological aids to smoking cessation and found that nicotine gum and patch sales increased 250% in the year following approval of OTC status. Today, approximately one third of smokers who report making a quit attempt indicate that they have used some form of nicotine (patch, gum, inhaler, nasal spray) or non-nicotine therapeutic aid (bupropion) (Hughes, 1999). Randomized clinical studies have demonstrated the efficacy of these stop smoking medicines for smoking cessation (Fiore *et al.*, 2000). However, data are still lacking as to the impact of expanded access to and utilization of these stop smoking medications on population smoking rates (Novotny *et al.*, 2001).

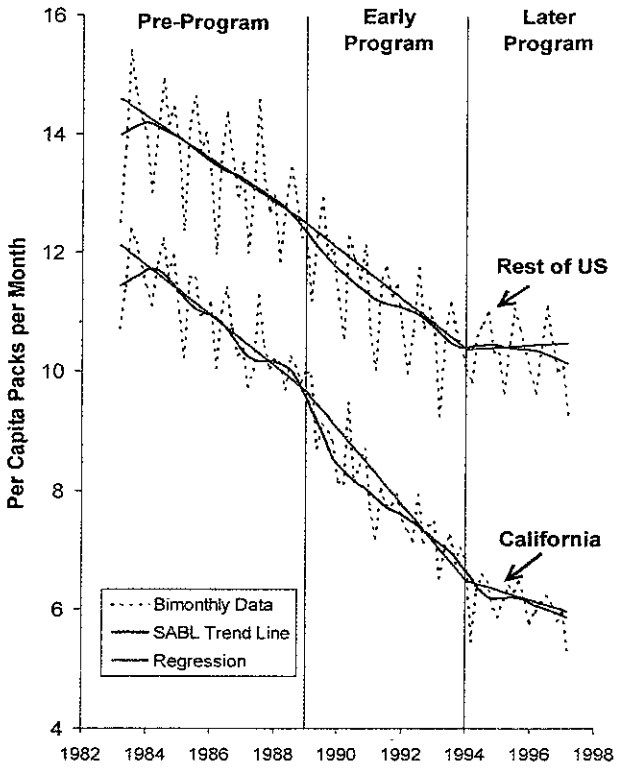

Figure 4 Trends in per capita cigarette consumption in California and the rest of the United States before and after the California public health campaign on tobacco

New therapeutics approaches for treating nicotine dependence are under development (Swain *et al.*, 1996; Hieda *et al.*, 1999; Westrum *et al.*, 2001). One company has begun clinical trials of a vaccine for the treatment of nicotine addiction (Thompson, 2002). The treatment is intended to block nicotine delivery to the brain, thereby removing the main reinforcement for smoking. The conjugated vaccine works by stimulating the immune system to produce antibodies that find and attach to nicotine molecules. The resulting compounds are too large to pass through the blood-brain barrier so that most of the nicotine is unable to reach the brain. Animal studies (Hieda *et al.*, 1999) have clearly demonstrated that the vaccine can work, however, it remains unclear if human smokers will respond to the vaccine by increasing cigarette consumption to compensate for the lack of nicotine. However, should this treatment modality work it would have profound implications for addressing the problem of nicotine dependence.

Economic incentives

It is well recognized in economic theory, as well as in everyday life, that purchasing decisions are influenced by the affordability of a product (Watson, 1972). The affordability of a good is influenced both by the price of the good as well as the income of the consumer. The price of tobacco products is determined by the manufacturer's price, wholesale and retail markups and tobacco taxes.

Price of tobacco products

One of the most straightforward ways to influence the price of tobacco products is through taxation. Studies indicate that taxes on tobacco products, usually in the form of an excise tax, are passed directly onto the consumer (US DHHS, 2000). In the US, tobacco taxes are levied at the federal, state, and local levels. During the first part of the century taxes of tobacco products were typically very low, were primarily used to generate revenue, and were raised infrequently. In 1951, the Federal tax was set at 8 cents per pack – the level at which it would remain for more than 30 years (Orzechowski and Walker, 2000). With the release of the first scientific studies on the health risks from smoking in the 1950s, and the subsequent 1964 Surgeon General's report, the landscape began to change. Many states began increasing cigarette excise taxes in an apparent effort to reduce smoking and its consequences. Economists and others began producing studies documenting the impact of cigarette taxes and prices on smoking, particularly among youth and young adults. These findings led to growing pressure from public health groups for further increases in state taxes and increased federal cigarette taxes. Eventually, the federal cigarette tax was doubled to 16 cents per pack on January 1, 1983. In the 1990s federal cigarette taxes were progressively raised to its current rate of 39 cents per pack. Since 1980, most states have increased taxes on tobacco products, with some increases of 200% or more (Chaloupka *et al.*, 2002).

Economists use estimates of the price elasticity of demand to quantify the impact of a change in price on consumption. Formally, the price elasticity of demand is defined as the percentage change in consumption resulting from a 1% increase in price. While a relatively wide range of estimates has been produced for the price elasticity of demand for cigarettes, most of the estimates from the US and other high-income countries tend to fall in the relatively narrow range from -0.25 to -0.50 (Chaloupka *et al.*, 2001). Thus, a cigarette price rise by 10%, overall translates into a reduction in cigarette smoking by between 2.5 and 5%. Several recent studies imply that half or more of the effect of price on overall cigarette smoking results from reductions in the number of smokers. Moreover, a number of recent studies conclude that youth smoking is relatively more sensitive to price than adult smoking, with some estimates implying that teen smoking is up to three times more sensitive to price than adult smoking (US DHHS, 2000).

Indirect economic incentives

While tobacco taxes represents a fairly direct means of influencing consumption, other policies can influence the price of tobacco products indirectly. For example,

the federal policy of tobacco price supports and the allotment system, which were designed to aid tobacco farmers, has helped keep the price of domestically produced tobacco artificially elevated. Also, product liability suits brought against tobacco manufacturers have had an effect on increasing the price of tobacco products (Daynard, 1994). Although product liability suits are not policies *per se*, legislation pertaining to them could influence the impact of legal actions against tobacco manufacturers. For example, some states have enacted legislation which exempt tobacco manufacturers from product liability actions.

Insurance premiums

In 1964, a person's smoking status was not a consideration in the premiums paid for insurance. Today, premium differentials based on whether a person is a smoker or not are nearly universal for life insurance, and increasingly common for health insurance. Smoker-nonsmoker premium differentials were first introduced by the life insurance industry in the mid-1960s when actuarial studies demonstrated the higher mortality of smokers compared to nonsmokers (US DHHS, 1989; Schauffler, 1993). Because life insurance is usually sold on an individual basis it is possible to adjust prices according to the applicant's mortality risk status. Health insurance, on the other hand, is typically purchased on a group basis, usually as an employment benefit. As a result health insurance policies are seldom tailored to individual health risks. Differences in health insurance premiums paid by smokers and nonsmokers are much less common, although this situation is changing (US DHHS, 1989; Parkinson *et al.*, 1992; Schauffler *et al.*, 2001).

Currently, publicly funded health insurance such a Medicaid includes coverage for nicotine replacement therapy in about 30 states, although eligibility requirements vary widely between states. An increasing number of private health insurance carriers now provide coverage for stop smoking treatments, although this benefit is by no means universal. Congress or state governments could mandate coverage of smoking cessation treatments by insurance companies, but this has not occurred to date (Novotny *et al.*, 2001).

Among adult smokers, premium differentials may have both an economic and educational effect that discourages smoking (US DHHS, 1989; Curry *et al.*, 1998). In addition to increasing the cost of smoking, higher premiums charged to smokers help to reinforce knowledge of the harm caused by smoking. Health insurers who cover the cost of smoking cessation programs and aids, reduce the cost of quitting for the smoker, and provide an economic incentive to cessation providers to offer more services.

Restriction on tobacco

Public policies intended to inform consumers about the health hazards of tobacco or that make tobacco products more costly, discourage tobacco use indirectly. A third category of policies affect tobacco use more directly by limiting locations where tobacco can be used, and by placing restrictions on the sale and advertising of tobacco products.

Restriction on where tobacco products are used

In 1964, there were no laws regulating smoking in public locations such as schools, public transportation, government buildings, elevators, and restaurants. However, as scientific studies regarding the health consequences of passive smoke exposure began to emerge, policies limiting where people could smoke also increased. Today, nearly all states and thousands of localities have enacted laws restricting smoking in public places and workplaces (NCI, 1993). Most businesses, and several fast food restaurant chains, have instituted no smoking policies. Federal law prohibits smoking on buses, trains, and on domestic airline flights (US DHHS, 1989). In 1994, Congress outlawed smoking in most of the nation's public schools and in federally funded programs that serve children including Head Start centers, day-care centers, and community health centers. The US military prohibits smoking in common work areas. Smoking has even been restricted in many outdoor sports arenas. As Brandt (1990) points out '... cigarette smoking has become the most rigorously defined of all public behaviors'.

Policies restricting where people can smoke have made smoking less socially acceptable and have contributed to reductions in smoking behavior, although the precise impact on smoking behavior is difficult to quantify (US DHHS, 2000). Econometrics studies by Simonich (1991); Wasserman *et al.* (1991), Emont *et al.* (1993) and Evans *et al.* (1999) have each found that the strength of a state's smoking rules were important predictors of reduced aggregate cigarette consumption, even after controlling for other types of government policies (i.e., higher taxes). Thus, while rules limiting the locations where people can smoke are intended to protect the health of nonsmokers, these rules have helped redefined smoking behavior in our society, making it less acceptable, more inconvenient and less pleasurable, thereby encouraging cessation and discouraging uptake of smoking.

Restrictions on tobacco sales

With over 40 million adult cigarette smokers, a total prohibition on tobacco sales is not practical. However, in the US, there is a tradition of limiting minors' access to tobacco products (US DHHS, 1994; IOM, 1994). The argument for limiting tobacco sales to minors is based on the idea that children and adolescents may not be mature enough to adequately appreciate the long-term consequences of their use of tobacco (IOM, 1994). Abundant evidence illustrates that many youths who begin to use tobacco do not fully comprehend the nature of addiction and as a result, believe that they

will able to avoid the harmful consequences of smoking by stopping smoking after a few years (IOM, 1994; Slovic, 2001).

Laws intended to curtail tobacco sales to minors date back to the turn of the century (US DHHS, 1994). In 1964, all but two states had laws prohibiting the sale or gift of tobacco to children. After 1964, several states repealed their tobacco access laws because they were not being enforced. However, in recent years governments at all levels have begun to address the problem of youth access to tobacco. Today, all states have enacted laws that prohibit the sale of tobacco products to persons under the age of 18 years. In 1993, Congress passed legislation that linked state program funding for mental health services to control of youth access to tobacco (US DHHS, 1994). As a result, several states and hundreds of localities have taken meaningful steps to enforce youth access laws.

The impact of enforcing youth access laws on deterring tobacco use by minors remains unclear, although the emerging evidence suggests that the impact is likely to be small (Cummings *et al.*, 2002c). The only community based experimental study that has been done for the explicit purpose of measuring the impact of enforcing retailer compliance with a tobacco youth access law on youth smoking was conducted by Rigotti *et al.* (1997) in Massachusetts. This study involved three matched pairs of communities with one community within each pair randomly assigned to get active enforcement of the youth access law while the other communities received no active enforcement of the law. This study demonstrated that active enforcement of the law increased retailer compliance, but had little impact on indicators of adolescent smoking behavior. However, the real public health benefit of a reinvigorated effort to limit youth access to tobacco may not lie directly on its effect on youth smoking behavior, but rather on the declarative effects of reinforcing the social norm that disapproves of tobacco use.

Restrictions on tobacco product marketing

In the US the Federal Trade Commission (FTC) has the authority under the Federal Trade Commission Act to regulate the advertising of consumer products to prevent 'unfair or deceptive acts or practices in commerce' (FTC, 1964). Over the years, the FTC has used its regulatory authority to challenge the advertising practices of cigarette manufacturers. For example, in 1950, the FTC prohibited the RJ Reynolds company from claiming in its advertising that Camel cigarettes aided digestion, did not impair the wind or physical condition of athletes, would never harm or irritate the throat or leave an aftertaste, were soothing, restful, and comforting to the nerves, and contained less nicotine than any of the four largest selling brands (Wagner, 1971). In 1983, the FTC blocked the advertising of Brown and Williamson's Barclay cigarettes for incorrectly stating the tar yield, and in 1986, the FTC successfully challenged an RJ Reynold's advertisement that misrepresented the results of a study on heart disease and smoking (US DHHS, 1989).

In 1964, the FTC proposed rules for regulating the imagery and copy of cigarette ads to prohibit unsubstantiated health claims (FTC, 1964). However, the FTC rules were never adopted due to passage of the 1965 Federal Cigarette Labeling and Advertising Act. Public pressure to regulate tobacco advertising was widespread and strong in the mid-1960s, especially because of concerns regarding youth smoking. In 1963, the average teenager viewed 100 cigarette commercials a month (Pollay, 1994a). In response to mounting pressure to limit cigarette advertising, in 1964, the tobacco industry adopted a voluntary code of conduct (Pollay, 1994b). The tobacco industry's self-regulatory code, which is still in use today, covered four areas: (1) advertising appealing to the young; (2) advertising containing health representations; (3) the provision of free tobacco samples; and (4) the distribution of promotional items to the young (Pollay, 1994b). For example, a specific stipulation of the voluntary code is that models used in ads should not appear to be younger than 25 years of age. Over the years, public health groups have argued that the voluntary code is inadequate and largely ignored by the tobacco industry (Blum and Myers, 1993).

In 1969, the FTC recommended in a report to Congress that a ban on cigarette advertising on television and radio be enacted (FTC, 1969). In 1969, Congress passed the Public Health Cigarette Smoking Act that prohibited cigarette advertising in the broadcast media effective beginning in 1971 (US DHHS, 1989). Congress extended the ban on broadcast advertising to little cigars in 1973, and to smokeless tobacco products in 1986 (US DHHS, 1989). The federal law banning cigarette advertising on television and radio also included a clause preempting states and localities from regulating or prohibiting cigarette advertising or promotions for health reasons. The purpose of the preemption was to avoid chaos created by different, potentially conflicting regulations. However, the effect of the federal preemption is that few states and localities have attempted to regulate advertising of tobacco products (US DHHS, 1989). In recent years, a number of cities and states have acted to restrict transit advertising, the free distribution of tobacco product samples, and point-of-sale advertising. In Massachusetts, a state law prohibiting point-of-sale advertising was recently revoked on the basis of violating the federal preemption on cigarette advertising.

In 1998, as part of the MSA cigarette manufacturers agreed to discontinue billboard advertising, advertising in magazines with a high percentage of underage readers, and place limits on their sponsorship of sporting and cultural events (Daynard *et al.*, 2001). The actual impact of the MSA agreement on smoking behavior has not been formally evaluated, although the impact on youth smoking habits appears to be minimal since adolescent smokers continue to report smoking the most heavily advertised cigarette brands – Marlboro, Newport, and Camel (Kopstein, 2001).

The impact of voluntary and government restrictions on tobacco advertising and promotion has been the subject of many research studies. In a recent review of the evidence on the effectiveness of advertising bans, Saffer (2002) concluded that cigarette consumption is reduced when a comprehensive advertising ban is implemented. Saffer (2000) noted that in countries that have enacted partial advertising bans the industry has typically found ways to get around the restrictions by increasing advertising expenditures in alternative venues. For example, following the 1971 US broadcast ad ban cigarette marketing expenditures increased and were redirected into the print, billboards, and promotions. Evidence suggests that the same thing has occurred following the MSA agreement in 1998, with advertising revenue shifted from billboards and magazines to point-of-sale and retail marketing incentives (King and Siegel, 2001; Wakefield *et al.*, 2002).

Advertising may influence tobacco use in a number of ways. For example, advertising could encourage current smokers to smoke more, reduce the resolve of current smokers to stop or to consider stopping, encourage ex-smokers to take up smoking again, and seduce nonsmokers, especially children, to use tobacco (Warner, 1986). Critics of the cigarette industry have argued that a large share of cigarette advertising is intended to encourage induce young people to smoke (Blum and Myers, 1993). The portrayal of extreme sports popular with young people in cigarette advertising, sponsorship of sporting events such as auto-racing, and the use of promotional items with appeal to young people all support the view that a share of cigarette product marketing is intended to induce young people to smoke (see Figure 5a–c). Recent analyses of internal tobacco industry documents confirm this intent and suggest that cigarette manufacturers explicitly design and formulate cigarette brands to appeal to beginning smokers (Cummings *et al.*, 2002b; Wayne and Connolly, 2002). Internal industry documents also reveals that advertisements of filtered and low tar cigarettes were intended to reassure smokers concerned about the health risks of smoking, and to give the 'health concerned smoker' an alternative to quitting (Pollay and Dewhirst, 2002). The inherent deceptiveness of marketing low tar cigarettes has caused some countries to consider enacting legislation to ban the use of marketing labels such as 'light' and 'mild' (Bates *et al.*, 1999).

Product regulation

In the US, nearly all consumer products are subject to a variety of federal regulatory statutes designed to insure that the products are safe and that consumers are informed about possible risks. Tobacco products, however, are an exception (IOM, 1994; Kessler, 1996). With the exception of warning labels, Congress has explicitly excluded tobacco products from regulatory control both for political and practical reasons. During the mid-1990s the Food and Drug Administration (FDA) attempted to exert regulatory control over tobacco products under the Food, Drug, and Cosmetic Act (FDCA) that gives the FDA authority to regulate drugs 'intended to affect the structure or any function of the body of man'. However, the Supreme Court ruled that Congress, and not the FDA, is the only Federal group that has the authority to regulate tobacco products. New York State recently enacted the first state law intended to regulate the design of cigarettes (Brown and Williamson, 2000). This law requires cigarette manufacturers to design cigarettes so they more readily self extinguish, thus lowering the risk of a fire resulting from a smoldering cigarette.

Without some type of regulatory oversight there remains little incentive for manufacturers to design and formulate less hazardous cigarettes. The incentives that have worked to cause the industry to change in the past have related to consumer demand and liability risk. Increased consumer awareness of the health risks of smoking during the 1950s and 1960s was the main reason cigarette manufacturers introduced filtered and low tar cigarettes (Pollay and Dewhirst, 2002). However, industry documents reveal that their scientists recognized that these product design features would not reduce the risks of smoking and most likely contributed to a smoker maintaining their smoking behavior under the false belief that their disease risk would be reduced by switching to a filtered low tar cigarette (Leavell, 1999; Pollay and Dewhirst, 2002). The recent wave of litigation against the tobacco industry has resulted in the tobacco industry introducing a number of new novel cigarette-like products (Wilson, 2001). However, it remains to be seen whether any of these new products can reduce cancer risk (Stratton *et al.*, 2001). At least for the foreseeable future, it is likely that tobacco products will remain lawful and thus devising efforts to promote the development and marketing of less harmful alternatives to conventional cigarettes would seem like sound public health policy (Sweanor, 2000; Hoffmann *et al.*, 2001; Wilson, 2001; Stratton *et al.*, 2001; Cummings, 2002).

As it stands today, there is really no real incentive for the cigarette industry to change the status quo. Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk (Sweanor, 2000; Kozlowski *et al.*, 2001). Amazingly, many smokers don't perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes (Cummings, 2002). Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as pretty minor compared to the difference in disease risk between smoked and smokeless products. Until smokers are given enough information to allow them to chose products because of lower health risks, then the status quo will likely remain (Wilkenfeld *et al.*, 2000; Cummings, 2002c). Unfortunately, the MSA created economic disincen-

Figure 5 (a) 1998 Newport cigarette advertisement featuring rock climbing. (b) Top panel: Marlboro cigarettes featuring Indy car racing; bottom panel: Winston cigarette advertisement featuring NASCAR Winston Cup racers. (c) Top panel: Young boy with a Marlboro 'Indy car – Team Penske' bag; bottom panel: Plastic Joe Camel cooler mug given away with purchase of three packs of Camel cigarettes

tives for new companies to introduce less toxic alternatives to tobacco products (Daynard *et al.*, 2001).

Conclusions

The past 50 years has witnessed a dramatic change in attitudes toward and use of tobacco by Americans (US DHHS, 1989; US DHHS, 2000). Most public health scholars believe that this change has been accelerated by public policy interventions to reduce tobacco use (Warner, 1989; Simonich, 1991; US DHHS, 2000; Jha *et al.*, 2000). The research literature suggests that the most potent demand reducing influences on tobacco use have been increasing the financial cost of using tobacco products primarily through taxation, smoke-free policies, comprehensive advertising bans, and paid counter-advertising (US DHHS, 2000; Jha *et al.*, 2000). Other policies such as the requirement of warning labels on tobacco products, restrictions on tobacco sales to minors, and increasing access to stop smoking services appear to have had less direct impact on cigarette consumption, although the potential impact of these policies may not have been fully realized to date. For example, it is probably too soon to determine the population wide impact on smoking rates and ultimately on disease incidence of access to nicotine medications. Emerging knowledge regarding possible genetic modifiers of treatment response and the development of new therapeutic modalities such as the nicotine vaccine hold the promise of dramatically altering the way society addresses the problem of nicotine dependence in the future.

Up to now, government policies have actually hindered the development and marketing of less harmful alternatives to conventional cigarettes (Warner *et al.*, 1997; Jha *et al.*, 2000). If all nicotine products were regulated on the basis of their risk of causing health problems, nicotine medications would be the least regulated while cigarettes would be the most heavily regulated. Ironically, just the opposite has occurred with nicotine medications carefully regulated by governments while cigarettes have escaped regulatory control (Warner *et al.*, 1997; Sweanor, 2000; Stratton *et al.*, 2001). Developing a rational basis for regulating nicotine delivery products on the basis of harm would appear to hold great promise for achieving a rapid reduction in the health toll caused by cigarettes (Kozlowski *et al.*, 2001).

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References

Ayanian JZ and Cleary PD. (1999). *JAMA*, **281**, 1019–1021.
Bates C, McNeill A, Jarvis M and Gray N. (1999). *Tobacco Control*, **8**, 225–235.
Blum A and Myers M. (1993). *Tobacco use: An American Crisis*. Houston TP (ed). Chicago: American Medical Association, pp. 63–71.
Borland R. (1997). *Addiction*, **92**, 1427–1435.
Borland R and Hill D. (1997). *Tobacco Control*, **6**, 317–325.
Brandt A. (1990). *Daedalus*, **119**, 155–176.
Brown & Williamson Tobacco Company. (2000). New York Senate Bill on 'Fire-Safe' Cigarettes – An Unwise Proposal. *Press release*.
Cecil H, Evans RI and Stanley MA. (1996). *J. Applied Soc. Psych.*, **26**, 502–519.
Chaloupka FJ, Hu TW, Warner KE, Jacobs R and Yueki A. (2001). *Tobacco control in developing countries*. Jha P and Chaloupka F (eds). New York, New York: Oxford University Press, Inc., pp. 237–272.
Chaloupka FJ, Cummings KM, Morely CP and Horan JK. (2002). *Tobacco Control*, **11**, (Suppl. 1): i62–i72.
Connolly GN. (1992). *J. Natl. Cancer Inst.*, **12**, 29–35.
Cummings KM. (2002). *Addiction* (in press).
Cummings KM, Morley C and Hyland A. (2002a). *Tobacco Control*, **11**, (Suppl. 1) i110–i117.
Cummings KM, Morley C, Horan J, Steger C and Leavell NR. (2002b). *Tobacco Control*, **11**, (Suppl. 1): i5–i17.
Cummings KM, Hyland A, Perla J and Giovino GA. (2002c). *Nicotine & Tob. Res* (in press).
Cunningham R. (2002). *Evaluation of new warning labels on cigarette packages*. Canadian Cancer Society. www.ontario.cancer.ca.
Curry SJ, Grothaus LC, McAfee T and Pabiniak C. (1998). *N. Engl. J. Med.*, **339**, 673–679.
Davis RM and Kendrick JS. (1989). *JAMA*, **261**, 90–94.
Daynard RA. (1994). *Tobacco Control*, **3**, 59–64.
RA, Parmet W, Kelder G and Davidson P. (2001). *Am. J. Pub. Health*, **91**, 1967–1971.
Dunn Jr WL. (1972). *Motives and incentives in cigarettes*. Richmond, Virginia: Philip Morris Research Center.
Economic Consulting Firm of Orzechowski and Walker. (2000). *The Tax Burden on Tobacco: Historical Compilation*. Volume 35.
Emont SL, Choi WS and Novotny TE. (1993). *Tobacco Control*, **2**, 13–17.
Evans WN, Farrelly MC and Montgomery E. (1999). *Am. Econ. Rev.*, **89**, 728–747.
Federal Communications Commission. (1987). *Federal Communications Commission Record*, **2**, 5272.
Federal Trade Commission. (1964). *Federal Register*, **29**, 530–532.
Federal Trade Commission. (1969). *Federal Registry*, **34**, 7917–7918.
Federal Trade Commission. (1981a). *Federal trade commission staff report on the cigarette advertising investigation*. Federal Trade Commission.
Federal Trade Commission. (1981b). *Report of tar, nicotine and carbon monoxide of the smoke of 187 varieties of cigarettes*. Federal Trade Commission.
Fischer PM, Richards JW, Berman EF and Krugman DM. (1989). *JAMA*, **261**, 84–89.
Fischer PM, Krugman DM, Fletcher JE, Fox RJ and Ras TH. (1993). *Tobacco Control*, **2**, 279–285.
Fichtenberg CM and Glantz S. (2000). *N. Engl. J. Med.*, **343**, 1772–1777.

Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG and Gritz ER. (2000). *Treating tobacco use and dependence: clinical practice guideline*. Rockville, Maryland: US Department of Health and Human Service.

Gajalakshmi GK, Jha P, Ranson K and Nguyen S. (2000). *Tobacco control in developing countries*. Jha P and Chaloupka F (eds). New York, New York: Oxford University Press, Inc., pp. 11–39.

Hamilton JL. (1972). *Rev. Econ. Statistics*, **54**, 401–411.

Harris JE, Connolly GN and Davis B. (1997). *MMWR*, **45**, 960–970.

Heath AC and Martin NG. (1993). *Addictive Behaviors*, **18**, 19–34.

Healton C. (2001). *Am. J. Pub. Health.*, **91**, 554–558.

Henningfield JE, Cohen C and Pickworth WD. (1993). *Nicotine addiction. Principles and management*. Orleans CT and Slade J (eds). New York: Oxford University Press, pp. 24–45.

Hieda Y, Keyler DE, VanDeVoort JT, Niedbala RS, Raphael DE, Ross CA and Pentel PR. (1999). *Psychopharmacology*, **143**, 150–157.

Ho R. (1992). *Australian Psychologist*, **27**, 109–113.

Hoffmann D, Hoffmann I and El-Bayoumy K. (2001). *Chem. Res. Toxicol.*, **14**, 768–790.

Hughes JR. (1999). *Tobacco Control*, **8**, 323–326.

Institute of Medicine. (1994). *Growing up tobacco free*. Washington, DC: National Academy Press.

Jha P, Paccaud F and Nguyen S. (2000). *Tobacco control in developing countries*. Jha P and Chaloupka F (eds). New York, New York: Oxford University Press, Inc. pp. 449–473.

Kennedy GE and Bero L. (1999). *Tobacco Control*, **8**, 254–260.

Kessler DA. (1994). *Tobacco Control*, **3**, 148–158.

Kessler DA Witt AM, Barnett PS, Zeller MR, Natanblut SL, Wilkenfeld JP, Lorraine CC, Thompson LJ and Schultz WB. (1996). *N. Engl. J. Med.*, **335**, 988–994.

Kluger R. (1996). *Ashes to ashes: America's hundred-year cigarette war, the public health, and the unabashed triumph of Philip Morris*. New York, NY: Alfred A. Knopf.

Kozlowski LT, Strasser AA, Giovino GA, Erickson PA and Terza JV. (2001). *Tobacco Control*, **10**, 201–203.

King C and Siegel M. (2001). *N. Engl. J. Med.*, **345**, 504–511.

Kopstein A. (2001). *Tobacco Use in America: Findings from the 1999 National Household Survey on Drug Abuse*. Analytic Series: A-15, DHHS Publication No. SMA 02-3622. Rockville, Maryland: Substance Abuse and Mental Health Services Administration, Office of Applied Studies.

Leavell NR. (1999). *Tobacco Control*, **8**, 433–439.

Linthwaite P. (1985). *Health Educ. J.*, **44**, 218–219.

Liu BQ, Peto R, Chen ZM, Boreham J, Wu YP, Li JY, Campbell TC and Chen JS. (1998). *BMJ*, **317**, 1411–1422.

Mahood G. (1999). *Tobacco Control*, **8**, 356–361.

Malouff J, Schutte N, Frohardt M, Deming W and Mantelli D *et al.* (1992). *J. Psych.*, **126**, 371–383.

Mitchell B. (1999). *Review of documents on tobacco package warning and toxic constituent labeling*. Report to the Center for Behavioral Research and Program Evaluation, National Cancer Institute of Canada.

National Cancer Institute. (1993). *Major local tobacco control ordinances in the United States*. NIH Publication No. 93-3532. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.

National Cancer Institute. (1996). *The FTC cigarette test method for determining, tar, nicotine, and carbon monoxide yields of U.S. cigarettes*. Report of the NCI Expert Committee. Smoking and Tobacco Control, Monograph 7: NIH Publication No. 96-4028. Washington, D.C.: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.

Niu SR, Yang GH, Chen ZM, Wang JL, Wang GH, He XZ, Schoepff H, Boreham J, Pan HC and Peto R. (1998). *BMJ*, **317**, 1423–1424.

Novotny TE, Cohen JC, Yurekli A, Sweanor D and de Beyer J. (2001). *Tobacco control in developing countries*. Jha P and Chaloupka F (eds). New York: Oxford University Press, Inc., pp. 287–307.

O'Keefe MT. (1971). *Public Opinion Quarterly*, **35**, 242–248.

Parkinson MD, Schauffler HH, Kottke TE, Curry SJ, Sulberg LI, Arnold CB, Butz RH, Taylor R, Halloway JB and Meltzer C. (1992). *Tobacco Control*, **1**, (Suppl): S52–S56.

Pierce JP, Gilpin EA, Emery SL, White MM, Rosbrook B and Barry CC. (1998). *JAMA*, **80**, 893–899.

Pierce JP and Gilpin EA. (2001). *Tobacco Control*, **10**, 145–153.

Pollay RW. (1997). *Public Relations Review*, **16**, 27–42.

Pollay RW. (1994a). *Tobacco Control*, **3**, 130–133.

Pollay RW. (1994b). *Tobacco Control*, **3**, 134–144.

Pollay RW. (2000). *Tobacco Control*, **9**, 136–147.

Pollay RW and Dewhirst T. (2002). *Tobacco Control*, **11**, (Suppl. 1): i18–i31.

Proctor RN. (1999). *The Nazi War on Cancer*. Princeton, New Jersey. Princeton University Press, pp. 173–247.

Rabin RL and Sugarman SD. (eds). (1993). *Smoking Policy: Law, Politics & Culture*. New York: Oxford University Press, Inc.

Rigotti NA, DiFranza JR and Chang Y. (1997). *N. Engl. J. Med.*, **337**, 1044–1051.

Robinson TN and Killen JD. (1997). *Arch. Ped. Adol. Med.*, **151**, 267–272.

Saffer H. (2000). *Tobacco control in developing countries*. Jha P and Chaloupka F (eds). New York, New York: Oxford University Press, Inc., pp. 215–236.

Schauffler HH. (1993). *Smoking policy: law, politics, & culture*. Rabin RL and Sugarman SD (eds). New York: Oxford University Press, Inc., pp. 184–207.

Schauffler HH, McMenamin S, Olson K, Boyce-Smith G, Ridout JA and Kumil J. (2001). *Tobacco Control*, **10**, 175–180.

Shiffman S, Gitchell J, Pinney JM, Burton SL, Kemper KE and Lara EA. (1997). *Tobacco Control*, **6**, 306–310.

Shiffman S, Pillitteri JI, Burton SL, Rohay JM and Gitchell JG. (2001). *Tobacco Control*, **10**, (Suppl): i17–i23.

Siegel M and Biener L. (2000). *Am. J. Pub. Health.*, **90**, 380–386.

Simonich WL. (1991). *Government anti-smoking policies*. New York: Peter Lang Publishing.

Slade J. (1993). *Nicotine Addiction. Principles and Management*. Orleans CT and Slade J (eds). New York: Oxford University Press.

Slovic P. (2001). *Smoking: risk, perception & policy*. Thousand Oaks, California: Sage Publications, Inc.

Strahan EJ, Fabrigar LR, Fong GT, Zanna MP and Cameron AJR. (1999). *Enhancing the effectiveness of message labels on tobacco packaging*. Report to the Centre for Behavioural Research and Program Evaluation, National Cancer Institute of Canada.

Stratton K, Shetty P, Wallace R and Bondurant S. (2001). *Clearing the smoke: assessing the science base for tobacco harm reduction*. Washington, DC: National Academy Press.

Swain PA, Schad VC, Greeenstein JL, Exley MA, Fox BS, Powers SP and Gefter ML. (1996). *United States Patent 5,876,727*. ImmuLogic Pharmaceutical Corporation, pp 1–60.

Sweanor D. (2000). *Addiction*, **95**, (Suppl): S25–S28.

Thompson S. (2002). *Stop Magazine*, **9**, 26–27.

US. Department of Health and Human Services. (1986). *The health consequences of involuntary smoking. A report of The Surgeon General, 1986*. DHHS Publication No. (CDC) 87-8398. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health.

US. Department of Health and Human Services. (1988). *The health consequences of smoking: nicotine addiction. A report of the surgeon general, 1988*. DHHS Publication No. (CDC) 88-8406. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health.

US. Department of Health and Human Services. (1989). *Reducing the health consequences of smoking: 25 years of progress. A report of the surgeon general*. DHHS Publication No. (CDC) 89-8411. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

US. Department of Health and Human Services. (1994). *Preventing tobacco use among young people: a report of the surgeon general*. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

US. Department of Health and Human Services. (2000). *Reducing tobacco use: a report of the surgeon general*. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

US. Environmental Protection Agency. (1992). *Respiratory health effects of passive smoking: lung cancer and other disorders*. EPA 600/6-90/006F. Office of Research and Development, Office of Health and Environmental Assessment.

Wagner S. (1971). *The Federal Trade Commission*. New York: Praeger Publishers.

Wakefield MA, Terry YM, Chaloupka FJ, Barker DC, Slater SJ, Clarke PI and Giovino GA. (2002). *Am. J. Pub. Health*. (in press).

Warner KE. (1986). *Selling smoking: cigarette advertising and public health*. Washington D.C. American Public Health Association.

Warner K. (1989). *Am. J. Pub. Health*, **79**, 144–151.

Warner KE and Slade J. (1992). *Am. J. Pub. Health*, **82**, 17–18.

Warner KE, Slade J and Sweanor DT. (1997). *JAMA*, **278**, 1087–1092.

Wasserman J, Manning WE, Newhouse JP and Winkler JD. (1991). *J. Health Econ.*, **10**, 43–64.

Watson DS. (1972). *Price theory and its uses*. Boston: Houghton Mifflin Company.

Wayne GF and Connolly GN. (2002). How cigarette design can effect youth initiation into smoking. Camel cigarettes, 1983–93. *Tobacco Control*, **11**, (Suppl. 1): i32–i39.

Westrum EC, Tomlin KF, Perkins CS and Rose JE. (2001). *Nicotine & Tob. Res.*, **3**, 391–396.

Wilkenfeld J, Henningfield J and Slade J. (2000). *J. Natl. Cancer Inst.*, **92**, 90–92.

Wilson C. (2001). *New Scientist*, **10**, 28–31.

Wingo PA, Ries LAG, Giovino GA, Miller DS, Rosenberg HM, Shopland DR, Thun MJ and Edwards BK. (1999). *J. Natl. Cancer Inst.*, **91**, 675–690.

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Commentary

Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options

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Public health policy needs to be assessed for effects on human rights as well as public health. Although promoting harm reduction products to cigarette smokers might lead to greater total public health harm, if the products become too popular, human rights issues also need to be considered. Avoiding, or objecting to, the fair presentation of information on effective harm reduction products to smokers to allow them to make an informed choice to reduce health risk can represent a violation of a human right – the right to information. The necessary conditions are not met for protecting public health by restricting information on certain risk reduction products. As examples, based on current evidence, smokers have a right to information on snus (Swedish moist snuff) and medicinal nicotine as harm reduction options that would reduce substantially the risk of death to individuals. Smokers also have a right to truthful information about lower-tar cigarettes that have been erroneously promoted as risk reducing.

Introduction

Two recent, major publications have helped shape consideration of pharmaceutical or tobacco products for reducing harm to cigarette smokers who are unwilling to cease nicotine use completely. The first book resulted from an international workshop funded by the Robert Wood Johnson Foundation, the American Society of Addiction Medicine, and the Addiction Research Foundation (Ferrence, Slade, Room, & Pope, 2000), and the second book was the result of an expert committee convened by the prestigious Institute of Medicine of the National Academy of Sciences and partially funded by the U.S. Food and Drug Administration (Stratton, Shetty, Wallace, & Bondurant, 2001). In nicotine-related public health policy, there has been a desire to avoid promotion of harm reduction products that, while reducing toxicity to individual users, might increase public health harm because of increased numbers of users.

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Ferrence et al. (2000) noted one of the important questions: 'Would there be a net benefit to society if novel products reduced risk but increased use?' Later in the book, Henningfield and Fant (2000) indicated that, in evaluating a harm reduction product, it is important to include 'the potential immediate and long-term health effects at the population level' (p. 240). A later chapter urged that a key question in evaluating harm reduction products is whether the product 'ends up reducing harm for the population as a whole' (Reuter, 2000, p. 337). The Institute of Medicine report (Stratton et al., 2001) assessed the science base for tobacco harm reduction. Before endorsing any product, the committee wanted to see evidence on increase in harm 'to the population from encouraging initiation or continuation of smoking'. The Executive Summary had as its final conclusion, 'Conclusion 6. *The public health impact of PREPs [Potential Reduced Exposure Products] is unknown. They are potentially beneficial, but the net impact on public health could, in fact, be negative*' (p. 6).

The principle of protecting the health of the public has been offered, then, as one guiding principle in the development of harm reduction products; but these major works (Ferrence et al., 2000; Stratton et al., 2001) offer no consideration of another established principle: the

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human right of individuals to receive information relevant to their health and their health choices. The right to information derives from the principle of respect for autonomy. (The principle of autonomy is also the source of the requirement for informed consent for individuals who take part in research.) If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health (Freedman, 1999). In a tradition deriving from the Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948), the American Public Health Association concluded, 'Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances, in accordance with internationally recognized standards' (Bird, 2001). Assessments need to be made if a public health goal justifies restrictions on human rights (Gostin & Mann, 1999).

The present commentary asserts that (a) snus (Swedish moist snuff) and medicinal nicotine, based on present evidence, make dramatic reductions in health risks to individual smokers; (b) there is an established right to information that affects health; and (c) the potential public health harm is not clear and convincing enough to justify suspension of advice about reduced risks to individuals from these products. Other possible issues involved with reluctance to promote known harm reduction products will be discussed briefly. These include (a) concern that addicts are impaired in making free choices, (b) belief that no harm reduction products of any kind are warranted, (c) refusal to advise at all in the absence of strong governmental regulation, and (d) preference to let the industry solely promote its own products.

Two significant harm reduction products for individuals who smoke cigarettes

This commentary is not the place for a detailed review of harm reduction products; for that, see the Institute of Medicine report (Stratton et al., 2001). The Institute of Medicine report avoided recommendations about harm reduction products, declared every product as a 'potential' harm reduction product, and proposed an elaborate, extensive scheme for assessment (based on toxicology, epidemiology, as well as proper governmental regulation). Though such assessment is desirable, the feasibility or practicability of the Institute of Medicine report is far from clear. It is sufficient in this commentary to establish that a product lowers risks substantially to individuals. While further research is needed, the toxicology and epidemiology of smokeless products and medicinal nicotine are well enough understood at present to be confident that these products are substantially less dangerous than cigarettes. For purposes of this argument, it is unnecessary to establish a precise estimate of risk and unnecessary to show that the product is absolutely 'safe.' This commentary focuses on two types of products to illustrate, snus and medicinal nicotine.

Snus reduces tobacco harm dramatically in comparison to cigarettes (Ramström, 2000; Henningfield & Fagerström, 2001). Rodu and Cole (1994, 1999) have presented evidence for substantial harm reduction from smokeless tobacco in general. Since about half of cigarette deaths arise from lung cancer and respiratory disease (English et al. 1995; Peto, Lopez, Boreham, Thun, & Heath, 1994) and since smokeless products are not otherwise more dangerous than cigarettes, smokeless tobacco products can be estimated to reduce mortality by at least half, because they do not cause lung cancer or respiratory disease. Snus is lower than other moist snuffs in known toxins (N-nitrosamines and polynuclear aromatic hydrocarbons) (see Ramström, 2000). There has been concern about smokeless tobacco and oral cancer. Noting the high rate of snus use in Sweden and citing five studies, the Institute of Medicine report stated, '[T]he use of snus in Sweden has generally not been associated with oral cavity cancer' (p. 428). The Institute of Medicine report also indicated, 'In a large population-based study looking at risk factors for squamous cancer of the head and neck, Lewin et al. (1998) found no increased risk with the use of Swedish snuff' (p. 301). There also are no secondhand smoke or fire risks from snus. The findings are mixed on whether snus contributes to cardiovascular disease (Ramström, 2000; Henningfield & Fagerström, 2001; Rodu & Cole, 1999). Snus is not safe, but, on the basis of toxicological principles (no smoke toxins from smoke exposure to the lungs) and current epidemiological knowledge, snus is significantly less dangerous to individual users than cigarettes.

Medicinal nicotine products (nicotine replacement therapies) such as gum, patch, nasal spray, and inhaler also are likely to be much less dangerous than cigarettes (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). They deliver no smoke or tobacco toxins (except nicotine) to the user. Medicinal nicotine products have been judged to be so low in risk that some of the varieties are available as non-prescription pharmaceuticals in many countries around the world, including Australia, Austria, Brazil, Canada, Denmark, France, Spain, Sweden, Taiwan, and the United States (Corrao, Guindon, Sharma, & Shokoohi, 2000). On current epidemiological evidence, these products appear to reduce risk in comparison with cigarettes by close to 100% (Kozlowski, Strasser, Giovino et al., 2001). They have been demonstrated to carry little to no excess cardiovascular risk (Kimmel et al., 2001; Benowitz, & Gourlay, 1997), even in heart patients (Rennard, Daughton, & Windle, 1998), and no risks of oral cancer, lung cancer, or respiratory disease (Greenland et al., 1998). As much as five years use of medicinal nicotine in the Lung Health Study (Murray & Daniels, 1998) was unrelated to cardiovascular disease or other serious health effects. While greater, longer-term use of medicinal nicotine might reveal some increased to risk to health, it is not plausible to expect that such risks would ever come close to the dangers of cigarettes.

The Institute of Medicine report itself shows guarded support for this position: 'The committee also concludes that for persons addicted to nicotine, a nicotine-containing drug product is preferable to a cigarette or other tobacco-containing product as a chronic source of nicotine' (p. 227). The very next sentence in the report goes on, not to encourage such use, but rather to encourage that the Food and Drug Administration look into the matter: 'The FDA should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy, again, if supported by valid clinical data' (p. 227).

Snus and medicinal nicotine are not safe or completely without risk. Both snus and medicinal nicotine may cause reproductive health problems and should be avoided during pregnancy, but these problems should still likely be less than for cigarettes (Benowitz, 1998; Stratton et al., 2001). Medicinal nicotine probably is somewhat less dangerous than snus, because medicinal nicotine lacks some of the tobacco toxins still present in snus, and because medicinal nicotine gives clearer evidence of low cardiovascular risk. However, for the present argument, it is not important to compare snus with medicinal nicotine, but it is critical to establish each as significantly less dangerous than cigarettes.

There are supposed harm reduction products that have been proved to not reduce harm to individuals. The lower-tar cigarette appears to not reduce toxic smoke delivered to smokers (Jarvis et al., 2001; Kozlowski & O'Connor, 2000; Kozlowski & O'Connor, 2001; National Cancer Institute, 1996; Benowitz et al. 1983) or mortality (Burns, Major, Shanks, & Thun, 2001). Newer cigarette-like products (Eclipse and Accord) at best make smaller changes in the product (smaller than snus or medicinal nicotine in comparison to cigarettes), and likely make concomitantly small changes, if any, in risk. Careful testing such as prescribed by the Institute of Medicine report would be needed to establish the magnitude, if any, of risk reduction from the products.

The human right to health-relevant information rises out of the principle of autonomy

Several ethical traditions (legal, medical, and public health) lead to a view that there is a human right to fair information relevant to health care. All traditions depend upon the principle of individual autonomy. Beauchamp and Childress (1994) argue that both Emmanuel Kant and John Stuart Mill helped establish the philosophical basis for valuing an individual's self worth and the individual's rights to determine goals. The Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948) acknowledge a basic human right of autonomy. Legal traditions have also helped shape expectations about patient autonomy and patient rights to be informed of and consent to medical treatment (Wear, 1998). McCullough and Wear (1985) described a 'new ethos of patient autonomy' that has arisen in the face of benevolent but paternalistic ('doctor knows best') practices. Increasing governmental regulations on formal informed consent procedures and research have influenced the modern context in which patients deal with health care (Wear, 1998).

Public health ethics overlap with biomedical ethics but also have some distinctive emphases (Mann, 1999). Working in the public health field of family planning information, which can involve both one-on-one clinical encounters as well as diverse social sources of information, Freedman (1999) argued that censorship of information about reproductive and sexual health violates individual human rights. Freedman wrote: 'Women need and want reproductive health services because they want – and have – a fundamental human right to live lives that are free from unnecessary physical and mental suffering, and that permit the exercise of fundamental freedoms' (p. 147). Similarly, censoring information on genuine risk reductions to individual smokers restricts the ability of smokers to exercise their fundamental freedoms to make choices that can have dramatic effects on individual health risks.

In public health, benefit to the many can override the rights of the individual. Public health interests should prevail when there is low cost to the individual and high benefit to society (Annas, 1999). For an individual smoker who will not give up nicotine use, the benefits of snus or medicinal nicotine could be profound to the individual (and possibly to society), while the costs to society are far from clear and convincing.

Clear and convincing evidence needed to favor public health over individual health

In law there are three standards of evidence, in order of increasing stringency: (1) the *preponderance* of the evidence, where a conclusion is 'more likely than not' to be true; (2) *clear and convincing* evidence, producing firm belief or conviction; and (3) evidence *beyond a reasonable doubt*. Clear and convincing evidence has been required in court cases involving issues like quarantine, where an individual's rights are suspended to protect the public from the risk of spreading a serious disease (Annas, 1999).

Two principles have been emphasized in determining whether public health interests should override individual health interests: proportionality and probability. The limitation of rights 'must be proportional to the public health interest and its objective.' (International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights 1999, p. 48); and 'The risks to the public must be probable, not merely speculative or remote.' (Gostin & Mann, 1999, p. 67).

The language of the prospects for adverse public health effects is decidedly tentative with little indication of adverse public health effects being either probable or proportional. The Institute of Medicine report (Stratton et al., 2001) notes: 'Both Pauly & colleagues (1995) and Hughes (1998) *raise the possibility* that the introduction

of PREPs and their promotion as less harmful ways to smoke *could* lead to increased initiation.' (Stratton et al., 2001, p. 73); and 'The major concern for public health is that tobacco users who might have otherwise quit will use PREPs instead, or others may initiate smoking, feeling that PREPs are safe. That will lead to less harm reduction for a population (as well as less risk reduction for that individual) than would occur without the PREP, and *possibly* to an adverse effect on the population' (Stratton et al., 2001, pp. 8–4; italics added.)

When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001). The risk to individuals from medicinal nicotine seems to be so low that it is not possible for use to increase enough to cause a net public health loss: If risks from these often over-the-counter products are less than 0.1% (1 per 1000), then use would have to increase over 1000 times to cause an equal public health problem (Kozlowski, Strasser, Giovino, et al., 2001). For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.

Other issues that might prevent public health advice

Are addicts in a position to freely choose?

To hold that adult nicotine addicts are too impaired by their addiction to give informed choice is not in keeping with prevailing legal traditions on competency. Nearly every individual is assumed to be competent to choose, unless proved otherwise (Wear, 1998).

Are any harm reduction products warranted?

At least one distinguished public health scientist has raised doubts about whether harm reduction products are needed at all (Pierce, 2000, p. 227). He stated that prevention and cessation programs should possibly be the sole focus of controlling smoking-caused disease. This position can be seen as an extreme form of neglecting the right of smokers to make informed choices. If complete abstinence is *not* the only way for an individual smoker to significantly reduce health risks from nicotine addiction, then the rights of smokers to be informed of this is still in opposition to an exclusive emphasis on prevention and cessation.

Should we provide advice in the absence of proper governmental regulation?

The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.

Shouldn't manufacturers do their own promotion?

I have also heard colleagues say that manufacturers of these products don't need our help to promote their products. But that should not be justification for avoiding any positive comment or support for information that might reduce for individual smokers the harm from smoking. Note that the public health community has not similarly left all advice or encouragement about products–vaccines or seat belts or condoms (another harm reduction product) – to the manufacturers.

Public health approaches to informing smokers of harm reduction options

I am not primarily calling on the medical profession to talk with their noncompliant smoking patients about harm reduction. A broad-based model for public health interventions can be found in work on reproductive health. In the area of reproductive health and the right to information, it is argued that *comprehensive programming is needed to inform individuals* (Cohen, 1994). Such programs should include mass media advertising, message placements in TV programs, and systematic training of health professionals to discuss the needed information (Freedman, 1995).

Public health policies should be assessed for their affect on human rights

The late Jonathan Mann was a leader in calling for formal assessments of the impact of public health policies on human rights (Gostin & Mann, 1999; Mann et al., 1999). Figure 1 is derived from some of his work (Mann et al., 1999). The best policies are those that protect human rights as well as promote public health. Mann noted that it was a violation of human rights on the

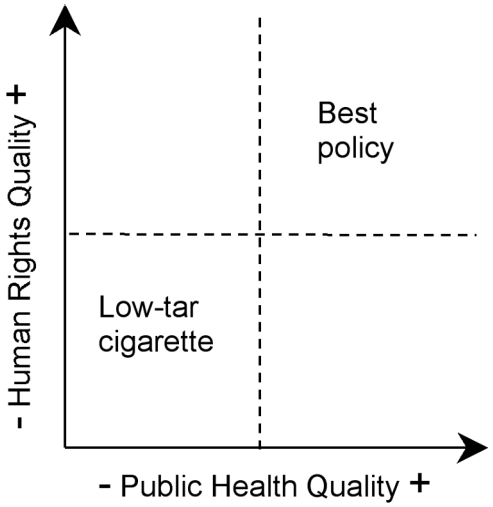

Figure 1. Schematic showing the interactive relationship between public health policy and human rights. The best policies are those that are consistent with human rights. Low-tar cigarettes are both poor public health policy and in violation of human rights to information.

part of governments to not provide honest information about the dangers of cigarettes (Mann et al., 1999). Low-tar cigarettes are designed to reassure smokers and keep them smoking (Kozlowski & Sweeney, 1997) but do not reduce health risks to smokers (Burns et al., 2001). This is both a violation of the human right to know and a counterproductive public health measure.

Cigarettes kill about half of those who smoke them (English et al., 1995; Peto et al., 1994; U.S. Department of Health and Human Services., 1989). It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information.

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References

Annas, G. J. (1999). The impact of health policies on human rights: AIDS and TB control. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights*. New York: Routledge Publishing.

Beauchamp, T. L., Childress, J. F. (1994). *Principles of Biomedical Ethics* (4th ed.). New York: Oxford University Press.

Benowitz, N. L. (Ed.). (1998). *Nicotine safety and toxicity*. New York: Oxford Press.

Benowitz, N. L., & Gourlay, S. G. (1997). Cardiovascular toxicity of nicotine: implications for nicotine replacement therapy. *Journal of the American College of Cardiology*, *29*, 1422–1431.

Benowitz, N. L., Hall, S. M., Herning, R. I., Jacob, P. III, Jones, R.. T., & Osman, A.-L. (1983). Smokers of low-yield cigarettes do not consume less nicotine. *New England Journal of Medicine*, *309*, 134–142.

Bird, M. E. (2001, May). Human rights and health. *The Nation's Health*, 3.

Burns, D., Major, J., Shanks, T., & Thun, M.. (2001). Smoking lower yield cigarettes and disease risk. *Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. Smoking and Tobacco Control Monograph No. 13*. (NIH Publication No. 02–5074). Retrieved July 10, 2002, from http://cancercontrol.cancer.gov/tcrb/monographs/13/

Cohen, S. I. (1994). *Developing information, education, and communications (IEC) strategies for population programmes. Technical Paper No.1*. New York: United National Population Fund (UNPFA).

Corrao, M. A., Guindon, G. E., Sharma, N., & Shokoohi, D. F. (Eds.). (2000). Tobacco Control Country Profiles. Atlanta, GA: American Cancer Society.

English, D. R., Holman, C. D. J., Milne, E., Winter, M. G., Hulse, G. K., Codde, J. P., Bower, C. I., Corti, B., de Klerk, N., Knuiman, M. W., Kurinczuk, J. J., Lewin, G. F., & Ryan, G. A. (1995). *The quantification of drug caused morbidity and mortality in Australia, 1995 Edition*. Canberra: Commonwealth Department of Human Services and Health.

Ferrence, R., Slade, J., Room, R., & Pope, M. (Eds.). (2000). *Nicotine and Public Health*. Washington, DC: American Public Health Association.

Freedman, L. P. (1995). Censorship and manipulation of family planning information: an issue of human rights and women's health. In S. Coliver (Ed.) *The right to know: Human rights and access to reproductive health information*. Philadelphia: University of Pennsylvania Press.

Freedman, L. P. (1999). Reflections on emerging frameworks of health and human rights. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights*. New York: Routledge Publishing.

Gostin, L., & Mann, J. (1999). *Toward the development of a human rights impact assessment for the formulation and evaluation of public health policies*. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights*. New York: Routledge Publishing.

Greenland, S., Satterfield, M. H., & Lanes, S. F. (1998). A meta-analysis to assess the incidence of adverse effects associated with the transdermal nicotine patch. *Drug Safety*, *18*, 297–308.

Henningfield, J. E., & Fagerström, K. O. (2001). Swedish Match Company, Swedish snus and public health: A harm reduction experiment in progress? *Tobacco Control*, *10*, 253–257.

Henningfield, J. E., & Fant, R. V. (2000). Nicotine delivery systems: Implications for Abuse Potential, Medications Development, and Public Health. In R. Ferrence, J. Slade, R. Room, & M. Pope (Eds.), *Nicotine and Public Health* (pp. 229–247). Washington, DC: American Public Health Association.

Hughes, J. R. (1998). Dependence on and abuse of nicotine replacement medications: an update. In N. L. Benowitz (Ed.), *Nicotine safety and toxicity* (pp. 147–157). New York: Oxford Press.

International Federation of Red Cross and Red Crescent Societies & François-Xavier Bagnoud Center for Health and Human Rights. 1999. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights*. New York: Routledge Publishing.

Jarvis, M. J., Boreham, R., Primatesta, P., Feyerabend, C., & Bryant, A. (2001). Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: Evidence from a representative population survey. *Journal of the National Cancer Institute*, *93*, 134–138.

Kimmel, S. E., Berlin, J. A., Miles, C., Jaskowiak, J., Carson, J. L., & Strom, B. L. (2001). Risk of acute first myocardial infarction and use of nicotine patches in a general population. *Journal of the American College of Cardiology*, *37*, 1297–1302.

Kozlowski, L. T., & Sweeney, C. T. (1997). Low-yield, light, and ultra-light cigarettes: let's understand the product before we promote. In M. E. Goldberg, M. Fishbein, & S. Middlestadt (Eds.), *Social marketing: Theoretical and practical perspectives*. Mahwah, New Jersey: Erlbaum.

Kozlowski, L. T., O'Connor, R. J. (2000). Official cigarette tar tests are misleading: Use a two-stage, compensating test. *Lancet*, *355*, 2159–2161.

Kozlowski, L. T., & O'Connor, R. J. (2002). Filter ventilation is a defective design because of misleading taste, bigger puffs, blocked vents. *Tobacco Control* (Suppl. 1), i40–i50.

Kozlowski, L. T., Strasser, A. A., Giovino, G. A., Erickson, P. A., & Terza, J. V. (2001). Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tobacco Control*, *10*, 201–203.

Lewin, F., Novell, S. E., Johansson, H., Gustavsson, P., Wennerberg, J., Biorklund, A., & Rutqvist, L. E. (1998). Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck: a population-based case-referent study in Sweden. *Cancer*, *82*, 1367–1375.

Mann, J. M. (1999). Medicine and public health, ethics and human rights. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights* (pp. 439–452). New York: Routledge Publishing.

Mann, J. M., Gostin, L., Gruskin, S., Brennan, T., Lazzarini, Z., & Fineberg, H. (1999). Health and human rights. In J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights* (pp. 7–20). New York: Routledge Publishing.

McCullough L., & Wear, S. (1985). Respect for automony and medical paternalism reconsidered. *Theoretical Medicine*, *6*, 295–308.

Murray, R. P., & Daniels, K. (1998). Long-term nicotine therapy. In N. L. Benowitz (Ed.), *Nicotine safety and toxicity* (pp. 173–182). New York: Oxford Press.

National Cancer Institute. (1996). *The FTC cigarette test method for determining tar, nicotine, and carbon monoxide yields of U.S. Cigarettes: Smoking and Tobacco Control Monograph 7*. Bethesda, MD: National Cancer Institute.

Nuremberg code: Directives for human experimentation. 1949. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2* (pp. 181–182). Washington, DC: U.S. Government Printing Office.

Pauly, J. L., Streck, R. J., & Cummings, K. M. (1995). US patents shed light on Eclipse and future cigarettes. *Tobacco Control*, *4*, 261–265.

Peto, R., Lopez, A. D., Boreham, J., Thun, M., & Heath, C. (1994). *Mortality from smoking in developed countries 1950–2000*. Oxford, England: Oxford University Press.

Pierce J. (2000). Discussant remarks. In R. Ferrence, J. Slade, R. Room, & M. Pope (Eds.), *Nicotine and public health* (p. 227). Washington, DC: American Public Health Association.

Ramström, L. M. (2000). Snuff – An alternative nicotine delivery system. In R. Ferrence, J. Slade, R. Room, & M. Pope (Eds.), *Nicotine and public health* (pp. 159–174). Washington, DC: American Public Health Association.

Rennard, S. I., Daughton, D., & Windle, J. (1998). Toxicity of nicotine replacement in patients with coronary artery disease. In N. L. Benowitz (Ed.), *Nicotine safety and toxicity* (pp. 49–53). New York: Oxford Press.

Reuter, P. (2000). Discussant remarks. In R. Ferrence, J. Slade, R. Room, & M. Pope (Eds.), *Nicotine and public health* (p. 337). Washington, DC: American Public Health Association.

Rodu, B., Cole, P. (1994). Tobacco-related mortality. *Nature*, *370*, 184.

Rodu, B., Cole, P. (1999). Nicotine maintenance for inveterate smokers. *Technology*, *6*, 17–21.

Russell, M. A. H., Jarvis, M. J., & Feyerabend, C. (1980). A new age for snuff? *Lancet*, *1*, 474–475.

Stratton, K., Shetty, P., Wallace, R., & Bondurant, S. (Eds.). (2001). *Clearing the smoke: Assessing the science base for tobacco harm reduction*. Washington, DC: National Academy Press.

U. S. Department of Health and Human Services. (1989). *Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General*. (DHHS Publication No. CDC 89–8411. Washington: U.S. Government Printing Office. Retrieved July 10, 2002, from http://www.cdc.gov/tobacco/sgr_1988.htm

Universal Declaration of Human Rights. (1948). Cited in J. Mann, S. Gruskin, M. Grodin, & G. Annas (Eds.), *Health and Human Rights*. New York: Routledge Publishing.

Wear, S. (1998). *Informed consent: Patient autonomy and clinician beneficence within health care* (2nd ed.). Washington, DC: Georgetown University Press.