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IN ASSOCIATION WITH BRYAN CAVE,
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LONDON, ENGLAND

July 26, 2002

Delivery by Hand

The Honorable Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: U.S. Smokeless Tobacco Company's Request for Advisory Opinion

Dear Secretary Clark:

I am writing on behalf of U.S. Smokeless Tobacco Company ("USSTC") to respond to comments opposing USSTC's request for an advisory opinion. In particular, I wish to respond to comments contained in a May 31, 2002, letter to the Commission from Howard K. Koh, Commissioner, Executive Office of Health and Health Services, of the Massachusetts Department of Public Health (the "MDPH letter"), and those contained in a June 4, 2002, letter to the Commission from Senator Richard J. Durbin and Congressman Henry A. Waxman (the "Durbin/Waxman letter"), opposing USSTC's request for an advisory opinion.

Like most of the other comments submitted to the Commission in response to USSTC's request for an advisory opinion, neither the MDPH letter nor the Durbin/Waxman letter challenge the truthfulness of the contents of USSTC's exemplar statement it proposes to disseminate in advertising.[1] Instead, the letters dispute USSTC's right to make such statements, even if true and substantiated.

Both letters claim that USSTC seeks to target youth with its proposed advertising statements. The Durbin/Waxman letter also objects to the Federal Trade Commission providing an advisory opinion in response to USSTC's request on the grounds that smokeless tobacco is a "gateway to smoking;" that the FTC lacks the requisite authority to issue such an advisory opinion; and that "leading health agencies and expert panels" would not support USSTC's

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1 In its Request for Advisory Opinion, USSTC proposed the following exemplar statement:

The Surgeon General in 1986 concluded that smokeless tobacco "is not a safe substitute for smoking cigarettes." While not asserting that smokeless tobacco is "safe," many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products.

request. Many of the positions taken in the two letters are unsupportable or are contradicted by other research. To the extent that they raise real public policy issues, they are the subject of substantial, continuing debate.

USSTC Does Not Seek to Target Youth in its Advertising

The most significant issue raised by the MDPH letter is the claim that USSTC is seeking to target youth in the use of the advertising statements USSTC proposed to the FTC. The MDPH letter argues that the statements in advertising about which USSTC requests an advisory opinion from the FTC are for the purpose of enabling USSTC to "expand their efforts to market to youth arguing that the product is safer than cigarette smoking." MDPH letter at 1. This argument is repeated in the Durbin/Waxman letter, citing to the Massachusetts Tobacco Control Program ("MTCP"), which, according to Senator Durbin and Congressman Waxman, "has . . . determined that UST is aggressively advertising its smokeless tobacco products in youth-oriented magazines including *Sports Illustrated*, *Hot Rod*, and *Rolling Stone*." Durbin/Waxman letter at 4 (citing Massachusetts Department of Public Health, Smokeless Tobacco Advertising Expenditures Before and After the Smokeless Tobacco Master Settlement Agreement (May 2, 2002) (hereinafter MTCP report)).

Nothing could be further from the truth. USSTC has made clear its commitment to advertise and sell its smokeless tobacco products only to adults. As stated in its request for an advisory opinion, USSTC is the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement ("STMSA") with the Attorneys General of a number of states and territories. (It should be noted that, while USSTC is the only smokeless tobacco company to undertake this legally binding commitment, the Commonwealth of Massachusetts did not choose to enter into the STMSA. Of course, USSTC's compliance voluntarily extends to Massachusetts.) As a result, USSTC is supporting programs to reduce youth usage of tobacco, and has agreed to limitations on its advertising and marketing efforts that might be attractive, in the view of the Attorneys General, to underage potential consumers of smokeless tobacco, even though USSTC's competitors have agreed to no such restrictions.

The MTCP's allegation that USSTC is "targeting" youth, contrary to the provisions of the STMSA, is without merit.[2] Nonetheless, in order to leave no doubt that its marketing program is oriented to adults and adults only, USSTC announced on June 7, 2002, that it would suspend

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[2] The STMSA does not define the term "target." The MTCP report attached to the MDPH letter defines targeting purely in terms of the readership of various publications, concluding that advertising in publications with 15% youth readership constitutes "targeting." MTCP report at 2. This simplistic approach is contrary to the FTC's more realistic definition of "targeting" in connection with both the Children's Online Privacy Protection Act ("COPPA") and the Trade Regulation Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 (the "900-Number Rule"). COPPA's implementing regulations provide a multifactor analysis to determine when a website is "targeted to children," including an examination of the website's "subject matter, visual or audio content, age of models, language or other characteristics of the website or online service, as well as whether advertising promoting or appearing on the website or online service is directed to children." 16 C.F.R. § 312.2 (2002). Under the 900-Number Rule, to deem an advertisement as "directed to children under 12," the Rule requires either that 50% of the audience be under age 12, or that the same kind of multifactor analysis used in COPPA be applied. 16 C.F.R. § 308.3 (e) (2002).

advertising in *Sports Illustrated*, *Hot Rod*, *Motor Trend* and *Sporting News*, pending review, even though the vast majority of the readers of those publications are adults.[3]

In fact, as discussed in USSTC's request for an advisory opinion, youth usage of smokeless tobacco has declined substantially over the last decade. USSTC's clear intent – as evidenced by the nature of the statements it proposes to make and as suggested in its proffered "exemplar" – is to communicate to adult smokers the fact that many researchers are of the opinion that smokeless tobacco products are a significant harm reduction alternative to cigarettes.

Smokeless Tobacco is not a "Gateway to Smoking"

The Durbin/Waxman letter asserts "gateway" arguments, in claiming that "[a] growing body of evidence suggests that smokeless tobacco acts as a 'gateway drug' to cigarette use." Durbin/Waxman letter at 2. To support this assertion, the Durbin/Waxman letter relies on three studies.

The first of these studies was published last year by Dr. C. Keith Haddock, et al. That paper makes assertions the paper's own data does not support. As summarized in the Durbin/Waxman letter, "Dr. C. Keith Haddock and colleagues reported in *Preventive Medicine* last year that in a population of 7,865 male Air Force recruits, smokeless tobacco users were 233% more likely to be smoking at the end of a year than non-users. The study concluded that use of smokeless products 'appears to be an important predictor of smoking initiation among young adult males.'"[4] In fact, however, the Haddock paper contains little, if any, support for the hypothesis either that smokeless tobacco use is a "predictor" of smoking initiation in the general population, or that smokeless tobacco is a "gateway" that leads to cigarette smoking.

The authors recognize that their findings are "inconsistent" with other studies, even though they do not understand why:

> The large number of nonsmokers who initiate smoking following [basic military training] is disturbing from a preventive medicine perspective. The high initiation rates among both [smokeless tobacco] users and nonusers is inconsistent with epidemiological studies based on the civilian population where most smoking initiation occurs prior to age 18 years. . . . The vast majority of initiation of cigarette smoking was within 6 months post-[basic military training]. Haddock, et al. at 266.

The authors also concede that their study population of USAF recruits is "unique" and that their findings may not be applicable to the general population:

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[3] USSTC had previously stopped advertising in a five other magazines, including *Rolling Stone* and *Spin*.

[4] Durbin/Waxman letter at 2. A copy of the Haddock, et al. (2001) paper is attached to this response at "A."

> [B]ecause the participants are limited to military recruits the generalizability of the findings may be limited. Factors such as the personal characteristics of those who join the military, the unique nature of [basic military training], the 6-week tobacco ban, and the requirements of military service suggest that this population is unique. *Id.*

Moreover, the researchers' conclusions are subject to serious challenge because they apply inconsistent definitions of who is a "smoker" at entry into the study compared to who is classified as having begun smoking after basic training. Simply put, the study was much more inclusive (in the definition of who was a "smoker") at the end of the study period than at the beginning, which severely skewed the results. Any conclusions from this study that use of smokeless tobacco products preceded cigarette smoking must fail because it is impossible to know how many recruits actually initiated smoking during the one year follow-up period, if a consistent definition of who was a "smoker" were applied.

Specifically, in the study, a recruit was considered to be a "smoker" upon entry into the study if he had smoked at least one cigarette per day before entering the service. *Id.* at 264. In comparison, a recruit who took only one puff of a cigarette in a seven day period after basic training was considered to be a "smoker." *See id.* Thus, for example, a recruit who resumed -- after the forced abstinence of basic training -- his former tobacco-use habits of occasional but not daily smoking of cigarettes would be considered to have "initiated" smoking at the end of basic training. Incorrectly, the study would point to that recruit's case as an example establishing the "gateway" principle even though he merely resumed his former routine of occasional, non-daily use of cigarettes.[5]

It is not possible to determine how many pre-service non-daily smokers were classified as having "initiated" smoking after basic training, but the large percentages who "initiated" smoking shortly after basic training suggests the number could be substantial. *Id.* at 265, tbl. 2. Of the approximately 1,100 recruits who reportedly initiated cigarette smoking during the one year follow-up, approximately 16 percent started smoking within one week after completing basic training, approximately 42 percent started within one month and approximately 90 percent within six months. *Id.*

The authors concede that they cannot explain why there was a higher rate of reported smoking initiation among those who had used smokeless tobacco, although they identify a number of family, social and personality factors that might be involved:

- The reasons why [smokeless tobacco] use preceded cigarette smoking in this sample are unclear. However, lower family disapproval for [smokeless tobacco] use than for cigarette smoking may be a contributing factor. *Id.* at 265.

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[5] The researchers' definition of "smoking" during the follow-up period (*i.e.*, just one puff of a cigarette in a seven day period) brings into further question the significance of the study's reported findings. Not surprisingly, approximately 70 per cent of those who reportedly initiated cigarette smoking during the follow-up period "smoked" ten or fewer cigarettes per day, the lowest consumption category described in the paper. *Id.* at 265, tbl. 2.

- Social influences may be another consideration in why [smokeless tobacco] use may precede cigarette smoking. *Id.* at 266.

- [W]e were unable to identify mechanisms linking [smokeless tobacco] use to adult-onset smoking. Future research should examine the mechanisms involved in smoking initiation among [smokeless tobacco] users, such as cognitive (i.e., greater acceptance of tobacco use) . . . . *Id.* at 266-67.

Accordingly, the Haddock et al., paper states conclusions that are not consistent with its own data, are not readily explainable, and, in any case, may have no bearing to the general population.

The Durbin/Waxman letter also makes reference to a 1989 paper by Peterson, et al., to support the "gateway" argument. That paper was based on a 1986 questionnaire survey of Washington State tenth grade students. It does not support the "gateway" argument, however, because it showed that a majority of students who had used both cigarettes and smokeless tobacco had used cigarettes first:

> Among boys who used both, 25% tried [smokeless tobacco] first and 60% tried cigarettes first. Fifteen percent first tried both at the same age. In contrast, the vast majority of females tried cigarettes first (76%) rather than [smokeless tobacco] first (12.5%). Peterson, et al (1999) at 67.[6]

Finally, the letter refers to a study by Dr. Scott Tomar which is said to be "slated for publication," but which is currently available only as a one paragraph abstract from a scientific conference. According to the Durbin/Waxman letter, the Tomar study concludes that there is a "strong association between use of smokeless tobacco and eventual smoking." Durbin/Waxman letter at 2. Because Dr. Tomar's study has yet to be published and is not available to us, it is not possible to comment on the validity of his analysis.[7]

Thus, the studies that are available to USSTC and are relied upon in the Durbin/Waxman letter do not support the proposition that the use of smokeless tobacco is a "gateway" to cigarette smoking.

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6 A copy of the Peterson, et al. paper (1989) is attached to this response at "B."

7 The letter also states that Dr. Tomar concludes that the use of smokeless tobacco "may have little effect on quitting smoking." *Id.* at 2. That conclusion, however, appears to be contradicted by other analyses. A report of a Swedish survey sponsored by the Swedish Cancer Foundation and Pharmacia appeared in a recent Swedish newspaper article (original and English translation attached at "C"). The survey involved 2002 individuals, half of whom were smokers and half of whom had quit smoking. Of those who quit, 33% had used snuff during the smoking cessation period, compared to 17% who had used nicotine replacement therapy ("NRT"). Of those who had quit smoking and had used snuff, 84% reported snuff was a "great help," compared with 76% of those who used NRT.

Like the Tomar study, the Swedish study is not available to us. We have informed the Commission staff of the study's existence, however, and suggested that the FTC may be able to obtain it from the Swedish Cancer Foundation.

The "Gateway" Concept Has Been Rejected in Other Analyses

In contrast to the suggestion in the Durbin/Waxman letter, a recent scientific conference and resulting publication concluded that there is no scientific support for the notion that the use of one substance can be a causal "gateway" to another substance. In order to examine the validity of the so-called "gateway hypothesis" as it relates to substance use, a multi-disciplinary group of scientists and other researchers was convened for a four day conference in 1998. The 34 participants represented the disciplines of sociology, psychology, epidemiology, statistics, animal behavior, molecular biology and prevention. The result of the conference was a book, published earlier this year, entitled "Stages and Pathways of Drug Involvement: Examining the Gateway Hypothesis," edited by Dr. Denise B. Kandel, Professor of Public Health and Psychiatry, Columbia University, and Chief, Department of the Epidemiology of Substance Abuse, New York State Psychiatric Institute (Cambridge University Press, 2002).

Dr. Kandel summarized the rationale for the conference and book as follows:

> The notion that use of certain drugs is a precursor to the use of other drugs was first proposed in the 1970s. The notion derived from the empirical observation that young people progressed from the use of legal drugs, such as tobacco or alcohol, to the use of illicit drugs, such as marijuana, cocaine, and heroin. In the 1980s, the term *Gateway drug* was introduced and it was emphasized that certain drugs serve as gateways for other substances. Because of the theoretical and public policy implications of the Gateway Hypothesis for understanding the progression of adolescent drug use and for formulating prevention and intervention programs, a conference was organized to examine the hypothesis critically. That conference, Stages and Pathways of Drug Involvement: Examining the Gateway Hypothesis, was held in Los Angeles on June 27-30, 1998. This book derives from the conference. (*Id.* at xv.)

With respect to the "causal" element of the "gateway hypothesis," Dr. Kandel and one of her colleagues summarized the findings of the conference and the research reported in the book as follows:

> The third proposition encompassed by the Gateway Hypothesis is that *the use of a drug earlier in the sequence, such as alcohol or tobacco, causes the use of a drug later in the sequence, for instance, marijuana.* [Emphasis in original.] This is the Gateway Hypothesis proposition that is most widely invoked in public discourse and in policy debates. Even among interventionists, it is often part of the rationale for a focus on programs to prevent initiation of drugs early in the sequence. *The research reported in this volume and that reviewed in the various chapters provide no support for the proposition about causality. There is no compelling evidence that the use of a drug earlier in the sequence, in and of itself, causes the use of a drug later in the sequence or, for that matter, that it causes the use of any other drug or, indeed, any other behavior.* [Emphasis supplied.] (*See* p. 366.)

Important Information Relevant to Adult Smokers' Health Should Not Be Withheld

Included under the "gateway" heading of the Durbin/Waxman letter, is the argument that adult smokers should not be informed that a considerable number of researchers believe that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. This argument appears to be based on the view that providing this vital information may have unintended consequences: first, that "some smokers who would have quit altogether may instead take up 'safer' smokeless products;" and, second, that "health claims for smokeless tobacco products may increase their attractiveness to nonsmokers." Durbin/Waxman letter at 1. These issues are addressed in USSTC's request to the Commission (*see* Section V of Attachment A entitled "Individual Risk Versus Population Risk" at pages 9-11).

In addition, recent scientific and public health analysis relevant to these issues has become available since USSTC filed its request for an advisory opinion. In particular, Prof. Lynn T. Kozlowski of the Department of Biobehavioral Health at Pennsylvania State University has prepared an analysis entitled "Harm Reduction, Public Health and Human Rights: Smokers Have a Right to be Informed of Significant Harm Reduction Options." The commentary (in press), a copy of which is attached at "D," is to be published in the journal *Nicotine and Tobacco Research.*[8] In that commentary, Prof. Kozlowski makes the following points:

- The present commentary asserts that (a) snus [a form of moist snuff used in Sweden] 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. *Id.* at 4.

- 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* than cigarettes to individual users. *Id.* at 6.

- 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). . . . 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. *Id.* at 10.

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[8] The commentary was part of Prof. Kozlowski's presentation at a conference held on May 16, 2002 in London entitled "Harm Reduction, Smoking and Smokeless Tobacco Seminar." The commentary, and a substantial amount of additional material presented at the conference, is available on line at [http://www.ash.org.uk/html/regulation/hrseminar].

Although Prof. Kozlowski's comments refer specifically to Swedish snus, he does not distinguish between Swedish snus and U.S. moist snuff products when it comes to tobacco harm reduction policy. In a July 11, 2002, article in the *Hartford Courant* relating to USSTC's request to the Commission for an advisory opinion, Prof. Kozlowski's views were reported as follows:

> Kozlowski – who said he has never taken tobacco company funding – said that smokeless tobacco does not cause lung cancer or respiratory illness. These account for about 60 percent of the deaths from smoking. And although smokeless products increase the risk for oral cancer, he said, there is evidence that cigarette use poses a much higher risk of oral cancer.
>
> "It is bad for you," Kozlowski said of snuff and other spit tobacco products. "It's not a safe alternative, but it is a much, much safer alternative to cigarettes." For hard-core smokers who haven't been able to quit using medicinal nicotine, such as patches and gum, smokeless tobacco might help, he said. Garrett Condon, *State Rips Plan to Label Snuff 'Safer' Tobacco*, Hartford Courant, July 11, 2002, at B9. (A copy of this article is attached at "E".)

The FTC Can and Should Issue an Advisory Opinion Pursuant to Applicable Federal Statutes

The Durbin/Waxman letter next asserts that the Food and Drug Administration and the Department of Health and Human Services ("DHHS") are more appropriate agencies than the FTC to deal with USSTC's request.[9] To the contrary, the Commission has clear statutory authority over this smokeless tobacco advertising issue under the Comprehensive Smokeless Tobacco Health Education Act of 1986. As Chairman Muris made clear before the Commerce, Trade and Consumer Protection Subcommittee of the House Energy and Commerce Committee on November 7, 2001, the Commission has the "authority now" to address reduced risk claims by tobacco manufacturers. *Challenges Facing The Federal Trade Commission, Before the House Subcomm. On Commerce, Trade, and Consumer Protection of the Comm. On Energy and Commerce*, 107th Cong. 24 (2001) (Statement by Timothy Muris, Chairman, FTC). Furthermore, the Commission can consult and, as a matter of policy, has consulted with appropriate DHHS agencies in formulating its response in numerous other situations involving technical, scientific claims in advertising.[10]

The Durbin/Waxman letter also argues that the information which USSTC seeks to communicate to adult smokers would undermine the warning mandated on smokeless tobacco

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9 The letter argues that "if smokeless tobacco manufacturers wish to advertise their addictive product as a healthier alternative to smoking, they must submit their claims to FDA." Davis/Waxman letter at 4. The letter further argues that the Comprehensive Smokeless Tobacco Health Education Act of 1986 was intended to vest in DHHS authority over issues such as those raised by USSTC's request, and that "[t]his authority should not be usurped by FTC through an order allowing manufacturers to make comparative health claims." *Id.*

10 The FTC has repeatedly addressed advertising issues relating to complex, scientific and medical claims with much success. For example, the Commission has taken action in claims involving HIV tests, dietary supplements, and over-the-counter drugs.

products and advertisements by the 1986 Act that "[t]his product is not a safe alternative to cigarettes." Durbin/Waxman letter at 3. The letter argues that "FTC should not permit a marketing claim that directly contradicts this message." *Id.* This misstates USSTC's submission. First, the submission notes that USSTC has and will continue to include on all of its smokeless tobacco product packaging and advertising the appropriate federally-mandated health warnings, including the warning that "this product is not a safe alternative to cigarettes." Second, the exemplar statement proposed by USSTC contains the following language: "The Surgeon General in 1986 concluded that smokeless tobacco 'is not a safe substitute for smoking cigarettes.'" Third, USSTC's exemplar statement specifically states: "*While not asserting that smokeless tobacco is 'safe,'* many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes." (Emphasis supplied.)

USSTC's Proposed Statements Reflecting the Views of a Growing Number of Researchers are No Less Truthful and Substantiated Because Some Others in the Public Health Community Have Different Views

USSTC's exemplar statement reflects the views of a number of public health professionals and commentators who have expressed the opinion that the time has come to inform adult smokers about the developing support for smokeless tobacco as one component of a harm reduction strategy for dealing with the health effects of smoking. In response, the Durbin/Waxman letter argues that "leading health agencies and expert panels would not support UST's request to FTC." Durbin/Waxman letter at 4.

That the issues USSTC raises in its request for an advisory opinion are novel and of significant public interest, makes USSTC's request for an advisory opinion appropriate.[11] A number of individuals have filed comments with the Commission expressing a wide range of views both in support of and in opposition to USSTC's request for an advisory opinion. In addition, a number of groups, including The Cato Institute, the American Council on Science and Health, and Northwestern University, have held forums recently on this topic.[12]

The Durbin/Waxman letter also argues that MTCP "tested UST's brands of smokeless tobacco against Swedish varieties and found that UST's brands had far higher levels of nitrosamines, which are linked to cancer." Durbin/Waxman letter at 4. This issue, which USSTC has discussed with MTCP, is addressed in USSTC's February 5, 2002, submission (*see* Section VI of Attachment A entitled "The Swedish Experience" at pages 11-15).

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11 *See* 16 C.F.R. § 1.1 (a) (2002).

12 USSTC has suggested that a workshop sponsored by the FTC would be a useful means of obtaining the multiplicity of views and guidance of other government agencies, non-governmental institutions, and individuals with relevant expertise on this important issue. This would be a preferable way to explore the broader public policy views of such agencies as the National Cancer Institute, which the Durbin/Waxman letter identifies as potentially opposing USSTC's request to the FTC, than relying on short excerpts from such organizations' web-sites which may not recognize the evolving nature of this public policy debate.

Lastly, the Durbin/Waxman letter asserts that the Institute of Medicine report issued last year "recommended that comparative claims only be allowed after further research is completed and only when there is authority to assure that the marketing of smokeless tobacco as less dangerous than cigarettes does not do more harm than good." Durbin/Waxman letter at 4. It would be poor public policy, however, to withhold from adult smokers truthful, substantiated and valuable information that could have a significant health benefit for each such smoker and public health overall, merely in order to further other policy goals. As Prof. Kozlowski has stated in a commentary to be published in the journal *Nicotine and Tobacco Research*:

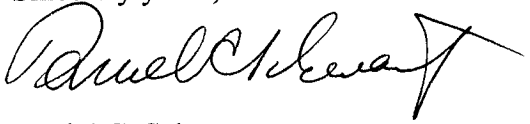
> The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related 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 IOM report.) Clearly the best of all possible research has not yet been done on snus or medical 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*. Kozlowski at 11-12 (emphasis supplied).

Conclusion

As demonstrated above, many of the comments set forth in the MDPH and the Durbin/Waxman letters are without merit. In any case, they do not dispute the basic truthfulness and substantiation of the statements USSTC proposes to make. They do raise broader public policy issues regarding the appropriateness of communicating tobacco harm reduction information as part of smokeless tobacco advertising, which should be addressed in a workshop or other forum which would afford all of the participants in this public health debate an opportunity to present their views in a constructive and productive manner, and would facilitate public discussion of this important issue.

USSTC requests that these comments be placed on the public record relating to this matter.

Sincerely yours,



Daniel C. Schwartz

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

J. Howard Beales, III, Director, Bureau of Consumer Protection
Lydia B. Parnes, Deputy Director, Bureau of Consumer Protection
C. Lee Peeler, Deputy Director, Bureau of Consumer Protection
Heather A. Hippsley, Acting Associate Director, Division of Advertising Practices
Gerard Butters, Assistant Director, Bureau of Economics

ATTACHMENT A

Preventive Medicine 32, 262–267 (2001)
doi:10.1006/pmed.2000.0802, available online at http://www.idealibrary.com on IDEAL®

Evidence That Smokeless Tobacco Use Is a Gateway for Smoking Initiation in Young Adult Males[1]

C. Keith Haddock, Ph.D.,*,[2] Mark Vander Weg, Ph.D.,† Margaret DeBon, Ph.D.,† Robert C. Klesges, Ph.D.,† G. Wayne Talcott, Ph.D.,‡ Harry Lando, Ph.D.,§ and Alan Peterson, Ph.D.‖

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Background. **This study was designed to test the hypothesis that smokeless tobacco (SLT) serves as a gateway drug for smoking among young adult males.**

Methods. **A cohort (n = 7,865) of U.S. Air Force recruits who claimed to have never smoked cigarettes was followed prospectively for 1 year. The participants were male, 32.9% were ethnic minorities, and their average age was 19.84 years (SD = 2.29). Among recruits entering basic military training, 403 (5.1%) reported current SLT use and 198 (2.5%) reported a past history of SLT use.**

Results. **At the 1-year follow-up current SLT users were 233% more likely to have initiated smoking than nonusers (odds ratio = 2.33, 95% CI = 1.84–2.94). Similarly, recruits who reported past SLT use were 227% more likely to begin smoking than participants who had never used SLT (odds ratio = 2.27, 95% CI = 1.64–3.15). SLT use remained a potent predictor of smoking initiation in a multivariate logistic model that included demographic factors and other risk factors for initiation.**

Conclusions. **SLT use appears to be an important predictor of smoking initiation among young adult males. This study suggests that smoking prevention and cessation programs should also include strategies related to SLT use.**

Key Words: **smokeless tobacco; smoking initiation; gateway drug; young adults; military recruits.**

INTRODUCTION

Consumption of snuff and chewing tobacco, commonly referred to as "smokeless tobacco" (SLT), is associated with a number of serious medical diseases, including gingival recession, leukoplakia, nicotine addiction, increased cardiovascular mortality, and cancers of the oral cavity, larynx, and pharynx [*1*]. Unfortunately, SLT is often viewed as a safe alternative to cigarette smoking and its use among U.S. residents is increasing. For instance, between 1991 and 1997, SLT use increased 32% among high school students in the United States [*2*]. According to the 1997 Youth Risk Behavior Survey [*2*], approximately 9.3% of U.S. students in Grades 9 to 12 reported using smokeless tobacco in the 30 days prior to the survey. State prevalence rates varied from 5.1% (New York) to 22.5% (Wyoming). The greatest prevalence of SLT use occurs among white males and those from rural areas [*3*].

Not only is smokeless use associated with serious health effects, its use is linked with a high prevalence of other health risks. For instance, in a cross-sectional study of military recruits, we compared participants who reported never using tobacco (never users), those who only smoked cigarettes (smokers), individuals who used only SLT, and participants who used both smokeless tobacco and cigarettes (polyusers) on a variety of health-related factors [*4*]. We found that, as with smokers, SLT users reported a high prevalence of risky health behaviors, such as safety risk taking (e.g., driving fast) and alcohol use. SLT users actually reported a *higher* likelihood of binge drinking (i.e., eight or more alcoholic beverages per day) and less frequent use of seat belts than smokers. Furthermore, on several measures of health risk (e.g., risk taking, seat belt use, alcohol use, binge drinking, intake of high-fat foods), polyusers scored significantly higher than the other

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groups and the magnitude of these differences was typically striking.

In addition to the evidence that SLT use is a potent health risk factor and tends to co-occur with other harmful practices, several researchers have proposed that SLT use serves as a "gateway drug" for cigarette smoking [*3,5*]. For instance, Heishman *et al.* [*6*] hypothesized that the dramatic increase in smokeless use among adolescents has contributed to the increasing rates of smoking that occurred in the 1990s. Given that the negative health effects of cigarette smoking are even more dramatic than those associated with SLT use, examining the potential gateway effect of SLT use is an important area of research.

A small number of studies have reported the influence of SLT use on cigarette smoking using cross-sectional or retrospective designs. There are at least two lines of evidence that support the notion that SLT use is a gateway to cigarette smoking. First, if SLT users frequently transition to smoking, one would expect a significant relationship in the use of the two forms of tobacco. Indeed, a host of studies have found that SLT use and cigarette use co-occur in both adolescents and adults [*7–10*]. For instance, among white males (those with the highest rates of SLT use), Hatsukami and colleagues [*8*] found that in a nationally representative sample of adolescents in the United States, the prevalence of smoking was 60.2% among SLT users and 24.9% among nonusers.

Second, if SLT use leads to cigarette smoking, one would expect a significant proportion of polyusers (those using both cigarettes and SLT) to report using SLT prior to smoking in retrospective studies. Unfortunately, the evidence is mixed for SLT use preceding smoking in polyusers. In favor of the gateway hypothesis, Hunter and colleagues [*11*] found that early use of SLT was more common than early use of cigarettes in youth who participated in the Bogalusa Heart Study. Similarly, Glover *et al.* [*12*] noted that the prevalence of switching from SLT to smoking was more prevalent than the converse in a representative sample of college students in the United States. In a study by Peterson and colleagues [*10*] it was found that use of SLT or cigarettes predicted initiation of the alternative method. That is, SLT use predicted cigarette smoking initiation and cigarette smoking predicted onset of SLT use among adolescents. In contrast, Hatsukami and colleagues [*8*] found no evidence that SLT use tended to precede smoking onset in a group of 402 SLT users seeking assistance with quitting. Similarly, Gingiss and Gottlieb [*13*] found no evidence that SLT served as a gateway for smoking in a small sample (n = 284) of college athletes.

The current study provides the first prospective examination of this phenomenon in a population that is equally vulnerable to the influence of SLT use—young adults. Given that SLT use may be a more acceptable form of nicotine administration within the social milieu of some children and the fact that SLT promotes nicotine addiction, it is possible that many childhood SLT users will progress to cigarette smoking as young adults when social constraints regarding smoking decrease. This study examined the incidence of smoking initiation among a large cohort of young military recruits who varied on SLT use but reported never smoking cigarettes.

METHODS

Description of the Parent Study

The Wilford Hall/University of Memphis and Minnesota Smoking Cessation Program is a collaborative endeavor between the two above-cited universities and the U.S. Air Force (USAF), funded by a grant from the National Institutes of Health (NHLBI). In this investigation, the entire population of Air Force Basic Military Training (BMT) recruits was randomized to either a smoking cessation program or control condition during a 6-week BMT-imposed tobacco ban. Every individual who entered the active duty service in USAF from August 1995 to August 1996 was a participant in the study (n = 29,044). A detailed description of the treatment portion of this project is published elsewhere [*14*]. Human subject protocol approval was obtained from the University of Memphis institutional review board as well as the USAF.

Procedure and Measures

Baseline Assessment

The baseline survey was a 53-item behavioral health risk questionnaire. Administration was in a group setting in "flights" (the USAF equivalent of platoons) of approximately 50 recruits. Instructions were read and recruits completed all items using a scannable questionnaire. All questionnaires were checked for completeness prior to the flight departing. Participants were informed that their responses would be confidential except in the most extreme circumstances. In addition, questions that could result in disciplinary action were not asked. The measure collected information from four general domains. First, basic demographics were assessed. Second, a history of tobacco use (smoking and SLT) was assessed. Regular SLT use was defined as using SLT at least once per day. Third, questions thought to be associated with smoking onset/relapse were asked. Two risk factors for smoking were used in this study due to their ability to discriminate between SLT use categories [*4*]: self-rated rebelliousness and safety risk taking. Finally, other health risk factors, such as alcohol use and physical activity, were assessed. Five health risk factors were used in this

study, again due to differences in the three SLT use categories (i.e., never users, past users, current users): seat belt use, alcohol use, binge drinking, physical activity level, and fruit/vegetable intake. Given the large-scale nature of the parent study, each factor was measured with single-item, epidemiological questions based on well-established surveys.

Given the numerous quality control checks and the fact that the baseline questionnaire was given as *part* of BMT, the response rate was extremely high. To derive an estimate of the stability of the measure, a 6-week test–retest reliability was performed on items using a randomly selected subgroup of trainees (n = 7,080). Specific to tobacco, the correlations of the smoking status (r = 0.97) and SLT use (r = 0.93) items indicated that participants reported their tobacco use in a highly consistent manner.

Follow-up Assessment

Securing follow-up data at the 1-year follow-up was challenging because study participants were stationed all over the world. However, the military is particularly adroit at locating personnel. This project collaborated with the USAF Survey Branch, whose sole mission is to conduct and complete worldwide USAF-approved surveys. At the 1-year follow-up, participants were located by the World Wide Locator in the Survey Branch, and addresses and phone numbers of participants were delivered to the project monthly. A brief survey (see below) was then mailed to participants. Those not responding to the initial and a follow-up survey were contacted by phone to obtain this information. A priori, the goal was to obtain 1-year follow-up data on 95% of smokers (given that the goal of the larger study was to reduce current smoking rates) and a sample of 60% of nonsmokers (to provide an adequate sample of nonsmokers for this and other studies). Final follow-up rates in the larger study were 96 and 66% for available smokers and nonsmokers, respectively. Not included in the follow-up were those who had dropped out of BMT, those who completed BMT but dropped out of the USAF by the 1-year follow-up, those who were deceased, and those who were "unavailable" (defined as being on assignments and not reachable) or in locations (e.g., Bosnia) where only secured radio communication was available. Smoking at follow-up was defined by 7-day point prevalence (smoking, even a puff, over the past 7 days).

Participants

Active duty recruits (n = 29,044) who participated in the parent study were screened for inclusion in this study. First, male participants (n = 21,690) who reported that they had never smoked regularly (n = 14,340; defined as smoking at least one cigarette per day) prior to entry into the USAF were selected. Second, among never smokers, those who were selected for the 1-year follow-up assessment were identified (n = 7,865). These participants were divided into three groups based on baseline SLT use status: never users (n = 7,264), current users (n = 403), and past users (n = 198). Table 1 presents demographic differences between the three groups. There was a significant difference between groups on two factors, the percentage of participants from minority ethnic background (X^2 = 187.2, P <0.001) and percentage of individuals from a low-income background (X^2 = 12.6, P = 0.002). Specifically, few ethnic minorities were either users or former users and the prevalence of low income was higher among never users compared with either past users or current users. Therefore, the analysis of smoking initiation was statistically adjusted for ethnicity and income.

RESULTS

Smoking Initiation

Univariate Analysis

Univariate logistic analysis of the risk of smoking initiation from SLT use, controlling for differences in demographic factors, revealed that past users were 227% more likely (Odds Ratio (OR) = 2.27, 95% CI = 1.64–3.15) and current SLT users were 233% more likely (OR = 2.33, 95% CI = 1.84–2.94) to initiate smoking than never users. Specifically, nearly 27% (107/403) of current SLT users initiated smoking, whereas 26.3% (52/198) of former users and 12.9% (940/7264) of never users began to smoke after BMT.

TABLE 1

Demographic Characteristics by SLT Use Status

Factor	Never users (n = 7,264)	Past users (n = 198)	Current users (n = 403)
Age (mean/SD)	19.81/2.16	19.96/2.03	19.74/2.06
Ethnicity			
% Euro-American (n = 5,346)	89.2	4.6	6.2
% African-American (n = 1,117)	99.6	0.2	0.2
% Hispanic-American (n = 620)	96.0	2.0	1.9
% Asian-American (n = 297)	97.8	1.3	0.9
% Other (n = 485)	96.7	1.1	2.1
Income (% < $20,000)	23.9	15.7	18.6
Education (% some college)	38.2	39.4	38.2
Marital status (% single)	82.4	77.3	82.4

Multivariate Analysis

Next, we assessed the relative predictive ability of SLT use on smoking initiation when statistically adjusting for the predictive ability of other risk factors for smoking and demographic differences among the groups. Based on our previous study of risk factors for smoking that distinguish SLT users from nonusers [4], the following variables were included in the multivariate analysis: safety risk taking, rebelliousness, seat belt use, total alcohol use, binge drinking, physical activity level, and intake of fruits and vegetables. Figure 1 presents the results of the multivariate model. SLT use, either past or current, was the most robust predictive factor, nearly doubling the likelihood of smoking initiation.

Characteristics of SLT Users, Past Users, and Never Users Who Initiate Smoking

Table 2 presents smoking demographics for participants in the three SLT use categories who initiated smoking following BMT. None of the smoking parameters were significantly different between the three groups. Most participants initiated within 6 months of BMT. As would be expected for new smokers, most smoked less than one pack each day, although a sizable proportion (>10%) had progressed to more than 20 cigarettes per day. Many of the smokers were ambivalent about their tobacco use, as is evidenced by the significant proportion who had attempted to quit and who were seriously considering smoking cessation.

TABLE 2

Tobacco Demographics at 1-Year Follow-up among Initiators

Factor	Never users (n = 940)	Past users (n = 52)	Current users (n = 107)
Time to initiation after BMT			
% Within 1 week	12.8	17.3	18.7
% Within 1 month	25.3	28.8	24.3
% Within 6 months	48.0	44.3	47.6
% > 6 months	13.9	9.6	9.4
Number of cigarettes smoked per day in past 7 days			
% ≤ 10	70.7	67.3	70.1
% 11–20	16.4	17.3	16.8
% > 20	12.9	15.4	13.1
% Attempting to quit smoking after BMT	41.6	34.6	42.1
% Seriously considering quitting in next 30 days	49.1	44.2	49.5
% Seriously considering quitting in next 6 months	34.8	40.4	35.5

DISCUSSION

This study supported the hypothesis that SLT use is a potent predictor of smoking initiation among a group of never smokers entering the USAF. Both current and former SLT users were more than twice as likely to initiate smoking than those who had never used SLT. These findings are consistent with studies conducted with adolescents [e.g., *15*] which suggest that SLT serves as a gateway drug for cigarette smoking. It appears that not only does smoking and SLT use co-occur as demonstrated in a study by Hatsukami and colleagues [*8*], but SLT use often leads to cigarette smoking.

The reasons why SLT use preceded cigarette smoking in this sample are unclear. However, lower family disapproval for SLT use than for cigarette smoking may be a contributing factor. For example, Ary and colleagues

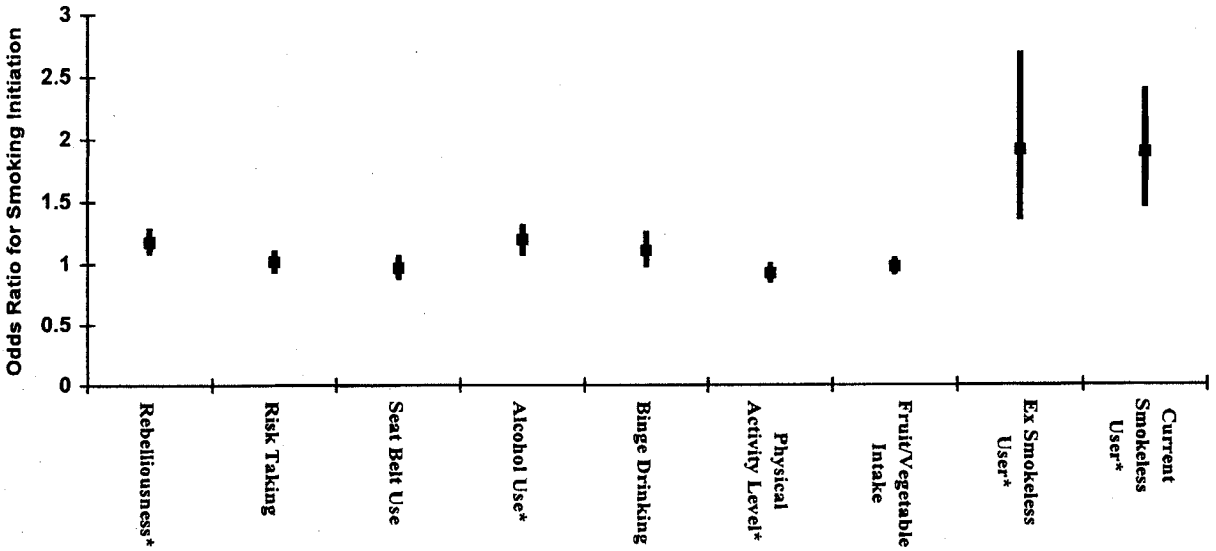

FIG. 1. Multivariate model of risk factors for smoking initiation. High/low Lines represent 95% confidence interval. Asterisks denote significant predictors, $P < 0.05$. Model adjusted for demographic differences between smokeless use categories.

[16] noted that parents of SLT users are more likely than parents of cigarette smokers to be aware of their child's use of SLT products and to tolerate such use. Similar findings have also been noted by Chassin *et al.* [17] and by Boyle and colleagues [18]. Conversely, a contributing factor may also be the ease in which use of SLT can be concealed relative to cigarette smoking both at home and at school. Further, these restrictions are lifted as independence is gained in young adulthood, inviting the option to smoke cigarettes.

Social influences may be another consideration in why SLT use may precede cigarette smoking. Several studies [e.g., *19,20*] found that the image associated with SLT use among adolescents was more positive relative to that of cigarette smoking. It may be that the perceived positive image of SLT use changes with age, prompting a switch to the more "sophisticated" look that is commonly associated with cigarette smoking.

Another potential mechanism linking SLT consumption with cigarette smoking is that SLT serves as a "starter" product for subsequent tobacco use [*21,22*]. Kessler and colleagues have documented that tobacco manufacturers knowingly market SLT products with lower levels of nicotine in an effort to eventually graduate the users to a higher nicotine product [*21*]. Therefore, SLT users in this study may have initially developed addiction to nicotine with low-yield SLT products and moved to smoking once they entered the military.

Another finding in the sample under study was that the greatest predictor of smoking initiation in a multivariate analysis was past or current SLT use at baseline. Additional predictors of smoking onset were rebelliousness, physical activity level, and alcohol use. Numerous studies have demonstrated the association between cigarette smoking and risk taking behaviors and substance use [cf, *23*]. For example, in the National Household Survey on Drug Abuse [*24*], young adults aged 18 to 25 who were current smokers were significantly more likely to be using alcohol, marijuana, and cocaine than never smokers.

Similar to previous research in this area [*25*], SLT users in this study tended to be white. Ethnic minorities were less likely to use SLT than their white counterparts. In addition, as opposed to the literature on cigarette smoking and socioeconomic status [*26*], and consistent with previous literature on socioeconomic status and SLT use [*23*], the present study indicated that the prevalence of low family income (i.e., total family income prior to BMT) was higher among never users as compared with past and current users. This suggests that limited income may be a greater barrier to SLT than cigarette use or that SLT use is more acceptable among higher-income families.

The large number of nonsmokers who initiate smoking following BMT is disturbing from a preventive medicine perspective. The high initiation rates among both SLT users and nonusers is inconsistent with epidemiological studies based on the civilian population where most smoking initiation occurs prior to age 18 years [*23*]. Thus, interventions aimed at reducing smoking initiation among military recruits are desperately needed. The vast majority of initiation of cigarette smoking was within 6 months post-BMT. This suggests that the posttraining environment (i.e., technical training) may be an opportune time to deliver supplemental prevention messages. First, given the large percentage of those interested in making a quit attempt, it is likely that the recruits would be receptive to strategies for smoking cessation. Second, among the airmen who initiated cigarette smoking, the rate of smoking in most was relatively low. Therefore, physiological dependence on nicotine is likely to be low and less of a barrier to quitting.

Along this line, this study suggests that smoking prevention and cessation programs should also include strategies related to SLT use. Most SLT initiation occurred during adolescence in this group (average age of participants who used SLT was 19.7 years) and these SLT users were at high risk for smoking initiation as young adults. Thus, addressing SLT use during smoking prevention efforts may reduce the rate of adult smoking initiation. For instance, the military might consider targeting SLT users at the beginning of BMT with tobacco prevention counseling to determine whether an intervention can promote SLT cessation and prevent smoking initiation. This suggestion does not imply that most smokers first use SLT. Many factors contribute to smoking initiation and many more smokers have not used SLT than those who have. However, SLT use does appear to be one important risk factor for smoking initiation and addressing its use is a reasonable addition to prevention programs.

Although this study offers several methodological advantages (e.g., large, nationally recruited, and diverse sample; prospective data), because the participants are limited to military recruits the generalizability of the findings may be limited. Factors such as the personal characteristics of those who join the military, the unique nature of BMT, the 6-week tobacco ban, and the requirements of military service suggest that this population is unique. Therefore, future studies should examine whether SLT use leads to adult smoking initiation in other groups. Similarly, because of the low prevalence of SLT use among women, the generalizability of the findings to females is uncertain. The results of this study were based on self-reports of smoking status; therefore, the prevalence rates reports may be underestimates of actual tobacco use. Finally, we were unable to identify mechanisms linking SLT use to adult-onset smoking. Future research should examine the mechanisms involved in smoking initiation among SLT users, such as cognitive (i.e., greater acceptance of tobacco

use), social (i.e., greater number of friends who use tobacco), and biological (i.e., nicotine dependence) factors.

CONCLUSION

This study found that in a large, diverse sample of military recruits, SLT use was associated with a significantly increased risk of adult-onset smoking initiation. The predictive ability of SLT use remained strong when other predictors of smoking initiation (e.g., alcohol use, risk taking, other health habits) were included in a multivariate model. Thus, smoking prevention and cessation programs should include strategies related to SLT use. In addition, future research should examine whether interventions with SLT users could prevent smoking initiation among military recruits.

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ATTACHMENT B

Initiation and Use of Smokeless Tobacco in Relation to Smoking[1]

Arthur V. Peterson,[2, 3] Patrick M. Marek,[2] *and* Sue L. Mann[2, 4]

ABSTRACT—**Questionnaire data obtained from 1,631 tenth grade students in 14 school districts in the State of Washington are used in this investigation of the relationship between the onset processes for smokeless tobacco use and smoking. Emphasized is the use of time-to-event data on the ages of occurrence of six events in these onset processes. Concepts and methods for the statistical analysis of time-to-event data are demonstrated. The occurrence of events in the smoking onset process are strongly related to increases in the subsequent onset rate for smokeless tobacco use. Compared with *before* initial smoking has occurred, the onset rates for weekly smokeless tobacco use *after* initial smoking has occurred are 2.03 ($P < .001$) and 6.72 ($P < .001$) times as large for males and females, respectively. Furthermore, both initial and weekly use of cigarettes contributes to the risk of subsequent weekly smokeless tobacco use. Conversely, the steps in the onset process of smokeless tobacco use are strongly related to increases in the subsequent smoking onset rate. Possible implications for intervention in prevention of smokeless tobacco use and for further research are discussed.—NCI Monogr 8:63-69, 1989.**

The use of SLT among adolescents, especially snuff among adolescent males, has skyrocketed in recent years (*1*). This development has ominous health implications, because SLT contains known carcinogens and because a growing body of epidemiologic evidence indicates that its use carries the risk of various adverse health effects including oral cancer (*2*). Scientists are expending considerable effort to establish the circumstances and factors related to SLT use and its onset process among youth and to incorporate these findings in the designs of effective prevention programs.

Determining the relationship between smoking and the use of SLT is important for their investigation of 1) smoking as a possible risk factor for the onset of SLT use and 2) the extent to which such use is associated with subsequent smoking. That both cigarettes and SLT are tobacco products and contain absorbable nicotine indicates strongly that an associated nicotine dependence may result in individuals taking up one when quitting the other to maintain a habituated nicotine level.

It is clear that the concurrent use of cigarettes and SLT are associated (*3-6*). The purpose of our investigation is to use data on the ages at which young people begin to smoke and use SLT to examine the relationship between the smoking and SLT onset processes. Some basic concepts and methods for the statistical analysis of time-to-event data are demonstrated.

The concept of a smoking onset process, i.e., a series of events that describe an increasing level and/or frequency of cigarette use, has been advanced by Flay et al. (*7*), Leventhal and Cleary (*8*), Hirschman and co-workers (*9*), and others. Our description of such a process consists of 1) specifying meaningful events of tobacco use and 2) determining transition rates between the events with data on the times (ages) at which the events occur. The investigations reported here are restricted to such events; other important aspects of the smoking onset process, such as social influences, the environment, and motivation, will be added in subsequent investigations. We used data on the ages of occurrence of six tobacco use events: initial, tenth, and first weekly use of SLT, and initial, tenth, and first weekly use of cigarettes.

METHODS

Survey procedures.—Tobacco use, including cigarette smoking and SLT, was assessed through a questionnaire administered in the classroom to entire grades of tenth-grade students in 14 rural and suburban school districts in the State of Washington in January 1986. Through an informational letter to parents and by in-class procedures, parents and students were fully informed in advance and were given an opportunity to ask questions and to decline to participate.

The tobacco survey was part of a baseline assessment of tobacco use among students in school districts participating with the Fred Hutchinson Cancer Research Center in the Hutchinson Smoking Prevention Project, a long-term, randomized controlled trial in school-based smoking prevention.

Of the total enrollment of 2,214 tenth graders, 1,918 (87%) took part in the survey. Twelve percent were absent from class; 0.2% (parents) and 0.8% (students) declined participation. Data for all questionnaire items pertinent in this investigation are available on 1,631 students. All results reported below are based on analyses of data from 1,631 students (840 males, 791 females).

ABBREVIATION: SLT = smokeless tobacco.

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Measures we used to enhance the accuracy of the responses to the questionnaire items included 1) administration of the questionnaire on an unannounced date; 2) procedures to maintain confidentiality and assurances about these to the parents and students; 3) classroom procedures designed to maintain and demonstrate confidentiality, including the use of study identification numbers and the handling of questionnaires by project data collectors only; 4) explanation and collection of saliva samples from all participating students concurrent with administration of the questionnaire; and 5) explanation of the data collection objectives and the important role of the students in achieving them.

The questionnaire included items that assessed various aspects of current, past, and future intended use of cigarettes and SLT products. The wording for questions and multiple-choice responses for cigarettes was similar to that for SLT, so that differences in patterns for smoking and SLT use could be ascertained without confounding from differences in the nature or wording of the items.

Analysis.—For binary data items (e.g., whether a certain level of past or current use of tobacco was achieved), simple proportions (prevalences) are reported. Data on time-to-smoking and time-to-SLT-use are analyzed by standard time-to-event statistical methods (survival analysis methods) that accommodate data on individuals for which the event (smoking, SLT use) has not occurred (censoring). Two time-to-event statistical methods are used:

1) Kaplan-Meier survival curves provide a descriptive display of time-to-event data (e.g., age at initial smoking) obtained on a set of individuals. When data on time-to-event are completely available for all participants, then this curve (at any age t) is simply the fraction of individuals whose observed times-to-event are greater than t (e.g., a fraction of individuals who have not smoked at age t). The Kaplan-Meier curve can also accommodate the situation characteristic of time-to-event data, when, for some individuals, the age at initial smoking is not known, but only that no smoking has occurred by a certain age (e.g., the age at which data collection occurs). Mathews and Farewell (*10*), Lawless (*11*), Miller (*12*), and Kalbfleisch and Prentice (*13*) provide further descriptions of the Kaplan-Meier survival curve, including formulas for its computation and assumptions for its use.
2) We used the Cox regression method (*10-14*) to analyze the impact of the occurrence of one tobacco use event (e.g., initial smoking) on the subsequent rate of onset of another event (e.g., weekly use of SLT). By such analyses, one can investigate directly the interrelationship between the smoking and SLT use onset processes. The Cox regression method models the onset rate $\lambda(t)$ for some specified event (e.g., weekly use of SLT) as a function of the follow-up time t (e.g., age). The model specifies that the onset rate $\lambda(t;z)$ for any individual with explanatory (regression) variables $z_1, z_2, \ldots z_p$ is just the product of a "baseline" onset rate $\lambda_0(t)$ and a function $g(z\beta)$ of the covariates, often taken to be the exponential function $g(z\beta) = \exp(z\beta)$:

$$\lambda(t;z) = \lambda_0(t) \cdot \exp(z\beta),$$

where $\lambda_0(t) > 0$ is a completely unspecified baseline onset rate, $z = (z_1, \ldots, z_p)$ is a regression vector consisting of the p explanatory variables, and $\beta' = (\beta_1, \ldots, \beta_p)$ is a vector of regression coefficients to be estimated from the data.

The Cox regression model offers a number of desirable features and improvements over more traditional methods that make it particularly helpful in investigations of onset processes, such as those of smoking and SLT use:

1) The age-specific onset rate $\lambda(t)$, a meaningful measure of smoking onset as a function of age, is modeled directly.
2) No assumption is made about the shape or magnitude of the onset rate as a function of age. It is data determined.
3) The quantities $\exp(\beta_1), \ldots,$ for which estimates are readily obtained by the usual partial likelihood analysis, have the useful interpretation of *relative onset* rates, e.g., the estimated smoking onset rate for prior SLT users relative to that for prior nonusers.
4) As in other regression models, the effect of other variables can be conveniently controlled by their inclusion as covariates in the regression model.
5) Unlike binary data methods, the model and analysis can accommodate censored data.
6) The model can be generalized in numerous ways for adaptation to a wide range of applications.

Used in this paper is a generalization that allows an explanatory variable to depend on follow-up time t. In our application below, we let $z_1 = z_1(t)$ depend on the follow-up time (age) and define it to be the indicator function for the occurrence of a specified prior event (e.g., the occurrence of initial smoking), taking the value 0 before the event occurs and 1 afterward. The quantity $\exp(\beta_1)$ is interpreted as the relative onset rate (e.g., of weekly SLT use after the prior event of initial smoking compared with before). See the references above for a complete description of this model, its generalizations and assumptions, and method of analysis.

RESULTS

Prevalence of Smoking and Smokeless Tobacco Use

Table 1 presents, first for cigarettes and then for SLT, the fraction of boys and girls who have ever used, currently use, and have attained certain events of the onset process.

The percentage of males who have ever smoked cigarettes is about the same as have ever used SLT. More boys have dipped more than five pieces of SLT than have smoked more than five cigarettes (40.6% vs. 32.5%). Almost 70% of the females have ever smoked cigarettes and about 31% have ever used SLT; almost 6% of the girls have used more than five pieces of SLT.

More boys are currently using SLT than cigarettes: 17.7% versus 14.4% (weekly use). Although 19.4% of the girls

TABLE 1.—Current use, lifetime use, and attainment of onset events: cigarettes and SLT

Use/onset/transition	Boys, %		Girls, %	
	Cigarettes	SLT	Cigarettes	SLT
Lifetime use				
Ever	69.8	71.1	68.6	31.2
>Five times	32.5	40.6	39.1	5.9
Current use				
≥Once/mo	19.7	25.3	26.1	2.8
≥Once/wk	14.4	17.7	19.4	1.4
Onset of use				
First	69.8	71.1	68.6	31.2
Tenth	30.8	40.5	37.7	5.8
First weekly	22.4	31.1	31.2	4.4
Transition probabilities				
Between no use and first	69.8	71.1	68.6	31.2
Between first and tenth use	44.1	57.0	55.0	18.6
Between tenth and weekly use	70.3	73.6	79.9	69.8

smoke cigarettes at least weekly, only 1.4% of them use SLT at least weekly.

Consistent with the results just presented, more boys attained the tenth use for SLT than for cigarettes (40.5% vs. 30.8%), and more boys attained weekly use of SLT than cigarettes (31.1% vs. 22.4%). Also, far fewer girls attained both tenth and weekly use of SLT than for cigarettes. It is noteworthy that 4.4% of the girls did use SLT weekly at one time in their lives.

Because tobacco use onset is a process of increasing use, presentation of the results in transition probabilities (lower portion of table 1) from one event to another is helpful. These results reinforce the ideas that 1) the higher prevalence for male use of SLT compared with smoking is attributed mostly to the higher first-to-tenth use transition probability (57.0% vs. 44.1%), and 2) the drastically lower prevalence for female use of SLT compared with smoking is attributed to both a lower prevalence of initial use and a lower first-to-tenth use transition probability.

The extent to which cigarettes and SLT are used separately and concurrently is shown in table 2. Consistent with results from other studies, a strong relationship is evident between smoking and SLT use, for both lifetime and current use. First, a majority of males (60.2%) have used both cigarettes and SLT. Only about 1 of 3 males who have never tried SLT have tried cigarettes; 6 of 7 males who have tried SLT have also tried cigarettes. Fewer than 1 of 10 males who do not use SLT weekly smoke weekly, but more than 1 of 3 males who use SLT weekly also smoke weekly. Of the 25.5% of the boys who use tobacco at least once a week, 7.6% use cigarettes only, 11.7% use SLT only, and 6.2% use both.

Among females, 29.5% have used both cigarettes and SLT. Over 50% of the females who have never tried SLT use cigarettes, but more than 9 of 10 who have tried SLT have also tried cigarettes. On average, fewer than 1 in 5 girls who do not use SLT weekly smoke weekly, but more than 1 of 2 who are weekly SLT users smoke weekly.

Onset of Smoking and Smokeless Tobacco Use

The results presented to this point have described prevalence of current use, lifetime use, and the frequency of occurrence of certain onset events for smoking and SLT separately and together. These results have described the extent to which various smoking events occurred but not at what ages they occurred. Attention is now focused on the ages at which the onset events occurred, with emphasis on a description of the age-specific onset rates for first, tenth, and first weekly use for smoking and SLT. First, smoking and

TABLE 2.—Relationship between smoking and SLT use, %

Sex	Use/onset	Cigarettes only	SLT only	Cigarettes and SLT	Neither
Males	Lifetime use				
	Ever	9.5	10.8	60.2	19.4
	>Five times	10.2	18.4	22.3	49.3
	Current use				
	≥Once/mo	7.8	14.6	11.1	66.5
	≥Once/wk	7.6	11.7	6.2	74.5
	Onset of use				
	First	9.6	10.7	60.5	19.2
	Tenth	9.4	19.0	21.4	50.1
	First weekly	9.0	17.7	13.3	59.9
Females	Lifetime use				
	Ever	39.1	1.6	29.6	29.7
	>Five times	33.7	0.6	5.3	60.4
	Current use				
	≥Once/mo	24.0	0.8	2.0	73.3
	≥Once/wk	18.5	0.8	0.7	80.1
	Onset events of use				
	First	38.9	1.6	29.8	29.6
	Tenth	32.4	0.5	5.3	61.8
	First weekly	27.7	0.9	3.5	67.9

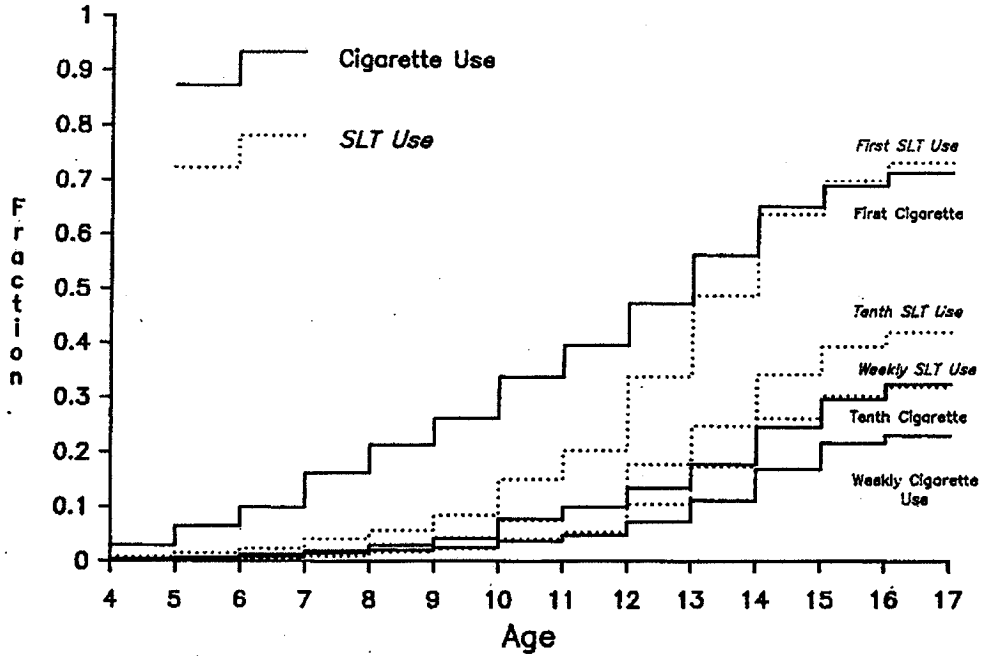

FIGURE 1.—Onset curves for smoking and SLT for 840 adolescent males.

SLT are considered separately and then together. We used basic methods of presenting and analyzing time-to-event data. The onset curves for first, tenth, and weekly use for cigarettes and SLT are shown in figures 1 and 2 for males and females, respectively. The onset curves indicate that the rates are greatest (onset curves increase the fastest) during certain age ranges shown in table 3.

It is clear that substantial differences exist between the age ranges when smoking and SLT onset occur. For males and females, initial SLT use occurred later than initial smoking. For males, tenth and weekly SLT use did not occur later than tenth and weekly use of cigarettes. Rather, the onset rates were similar until the boys were 11 years old, after which more boys achieved tenth and weekly SLT use than tenth and weekly smoking. For females, tenth and weekly SLT use occurred later than tenth and weekly use of cigarettes.

Relationship Between Smoking Onset and Onset of Smokeless Tobacco Use

The relationship between the onset of smoking and that of SLT use in adolescents was investigated by a number of methods.

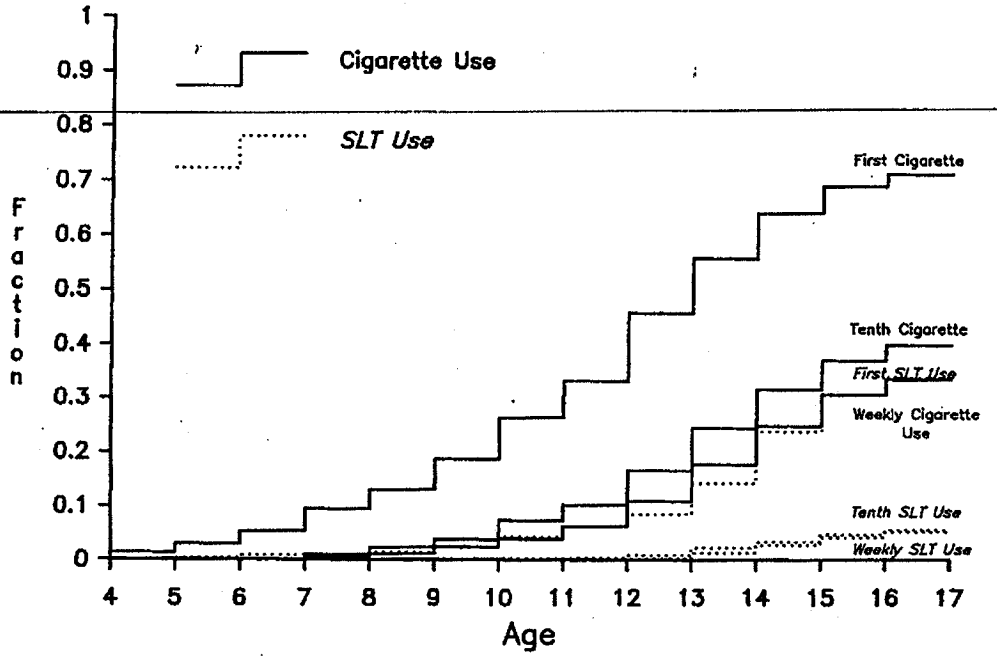

FIGURE 2.—Onset curves for smoking and SLT for 791 adolescent females.

TABLE 3.—Age ranges for high onset rates

Sex	Use: First — Age range, yr	First — Percent onset[a]	Tenth — Age range, yr	Tenth — Percent onset[a]	First regular — Age range, yr	First regular — Percent onset[a]
Males						
Smoking	6–14	55	9–15	26	11–15	14
SLT	9–14	55	11–15	30	11–15	25
Females						
Smoking	8–14	51	9–15	33	10–15	27
SLT	12–16	26	11–15	5	12–16	5

[a] Percent onset is for age range indicated.

First, joint distributions were computed for the age of occurrence of an event in the smoking onset process and that of the corresponding event in the SLT onset process. Time-to-event censoring was handled by inclusion of a "never started" category. From the joint distributions (not shown) of: 1) age at first use of cigarettes and at first use of SLT, 2) age at tenth use of cigarettes and age at tenth use of SLT, and 3) age at regular use of cigarettes and at regular use of SLT, a number of conclusions can be obtained.

One summary point of the joint distribution of ages of initiation of smoking and SLT use is the extent to which the smoking event occurs before the SLT use event, and vice versa, among those experiencing both smoking and SLT use events. As shown in table 4, smoking and SLT each occurred first in a substantial number of males. Among boys who used both, 25% tried SLT first and 60% tried cigarettes first. Fifteen percent first tried both at the same age. In contrast, the vast majority of females tried cigarettes first (76%) rather than SLT first (12.5%).

Finally, the following question is addressed: How are the age-specific onset rates for regular smoking related to the prior occurrence of steps in the SLT onset process for the 840 boys and 791 girls? Conversely, how are the onset rates for regular SLT use related to the prior occurrence of steps in the smoking onset process for both sexes? We investigated these questions using time-to-event regression methods developed by Cox (*14*). Data for all participants are included in these analyses; those not experiencing the end point of interest (e.g., weekly smoking, in table 5) are treated as censored.

The occurrences of steps in the SLT onset process are strongly related to increases in subsequent onset rate for weekly smoking. From runs (i.e., individual analyses) 1 and 4 of table 5, the weekly smoking onset rate is 1.65 ($P = .002$) and 2.13 ($P < .001$) times as large for males and females, respectively, after initial SLT use has occurred compared with before initial SLT use. From runs 2 and 5, the weekly smoking onset rate is 1.83 ($P = .002$) and 3.25 ($P = .021$) times as large for males and females, respectively, after weekly SLT use began compared with before weekly SLT use.

Furthermore, evidence suggests that *each* of the SLT steps, initial and weekly use, contributes to the risk of subsequent weekly smoking. When both steps are included in the analyses for males (run 3), the occurrence of initial SLT multiplies the risk of smoking onset by 1.45 ($P = .047$), and the subsequent occurrence of weekly SLT use multiplies the risk of smoking onset by an additional 1.47 ($P = .08$) for a net multiple (1.47×1.45) of 2.13 times the smoking onset rate when no SLT event has occurred. For females (run 6), the relative risks are 2.04 ($P < .001$) and 1.80 ($P = .27$); not enough females use SLT regularly to provide the data needed in this data set for us to determine whether weekly SLT use provides an added risk of weekly smoking beyond the risk provided by initial SLT use.

The results for the converse relationship are similar (table 6). The occurrences of steps in the smoking onset process are strongly related to increases in the subsequent onset rate for SLT use. From runs 1 and 4 of table 6, the onset rate

TABLE 4.—Precedence of smoking vs. SLT among individuals using both, %

Use	Smoking event occurred first	SLT use occurred first	Simultaneous occurrence
Males			
First	60.0	24.9	15.1
Tenth	44.2	28.2	27.6
Weekly	43.4	31.0	25.6
Females			
First	76.3	12.5	11.2
Tenth	73.8	11.9	14.3
Weekly	60.7	14.3	25.0

TABLE 5.—Results of relative risk regression analyses of relationship of steps in onset process of SLT with onset of weekly smoking[a]

Run	Relative rate and 95% confidence interval of weekly smoking onset[b]: After initial SLT use	P	After weekly SLT use	P
Males				
1	1.65 (1.20, 2.29)	.002	—	
2	—		1.83 (1.24, 2.69)	.002
3	1.45 (1.00, 2.09)	.047	1.47 (0.95, 2.27)	.08
Females				
4	2.13 (1.50, 3.02)	<.001	—	
5	—		3.25 (1.20, 8.81)	.021
6	2.04 (1.42, 2.93)	<.001	1.80 (0.64, 5.07)	.27

[a] Analyses used data on 840 males and 791 females, of whom 188 and 247, respectively, attained weekly smoking.
[b] *Values in parentheses* represent 95% confidence intervals.

TABLE 6.—Relative risk regression analyses of relationship of steps in onset process of smoking with onset of weekly SLT use[a]

Run	Relative rate and 95% confidence interval of weekly SLT use[b]			
	After initial smoking	P	After weekly smoking	P
Males				
1	2.03 (1.56, 2.62)	<.001	—	
2	—		3.50 (2.55, 4.82)	<.001
3	1.65 (1.25, 2.18)	<.001	2.74 (1.95, 3.85)	<.001
Females				
4	6.72 (2.34, 11.92)	<.001	—	
5	—		4.57 (2.31, 9.06)	<.001
6	4.56 (1.49, 14.0)	<.001	2.63 (1.29, 5.40)	<.001

[a] Analyses used data on 840 boys and 261 events and 791 girls with 35 events.

[b] *See* table 5, footnote *b*.

for weekly SLT use is 2.03 ($P < .001$) and 6.72 ($P < .001$) times as large for males and females, respectively, after initial smoking has occurred than that before it occurred. This result for females is particularly striking: Females who have tried cigarettes are at almost seven times the risk for using SLT as those who have not. From runs 2 and 5, the onset rate for weekly SLT use is 3.50 ($P < .001$) and 4.57 ($P < .001$) times as large for males and females, respectively, after weekly smoking than before it occurred. Furthermore, evidence is clear that *each* of the smoking onset steps, initial and weekly use, contributes to the risk of subsequent weekly SLT use. When both steps are included in the analysis for males (run 3), the occurrence of initial smoking multiplies the risk of onset of weekly SLT use by 1.65 ($P < .001$), and the (subsequent) occurrence of weekly smoking multiplies the risk of onset of weekly SLT use by an additional 2.74 ($P < .001$), for a net multiple (1.65×2.74) of 4.5 times the SLT onset rate when no smoking event has occurred. The corresponding multiples for females (run 6) are 4.56 ($P < .001$), 2.631 ($P < .001$), and 12.0 (4.56×2.63).

DISCUSSION AND CONCLUSION

A consistently strong relationship is observed between the onset processes of SLT and smoking among adolescents. In particular, the occurrence of events in the smoking onset process is strongly related to increases in the subsequent onset rate for SLT use. Conversely, the occurrence of steps in the onset process of SLT use is strongly related to increases in the onset rate of subsequent smoking.

The finding that prior use of SLT is a risk factor for smoking indicates that prevention of its use may also help prevent smoking. Conversely, the finding that prior smoking is a risk factor for SLT use indicates that prevention of smoking may also help prevent SLT use. These results indicate the possible desirability of combining the prevention components of both within an overall intervention program. Such integration also makes practical sense in light of the tobacco common denominator between smoking and SLT use and the needs of schools for integrated interventions.

Several limitations of this investigation should be noted. The data used in these analyses on the onset processes for smoking and SLT use are recall data collected retrospectively from a cross-sectional survey. Resulting limitations include: 1) Recall bias may be present because the data are limited to those individuals who can remember, and the recall may be biased among those who remember. 2) The sample does not correspond to a defined cohort but is a modification (by in- and out-migration) of some identifiable original cohort. However, to the extent that in- and out-migrating students are similar in their SLT and smoking onset patterns, no bias would result.

Also, these data on occurrence of events in the smoking and SLT onset processes span a period (1975–1985) during which the prevalence of SLT use was increasing rapidly. As a result, the relationship between the onset of both during such a period necessarily includes the effects of temporal changes in prevalence.

These investigations illustrate how survival analysis methods, and in particular survival analysis regression methods, can help to provide insight into the onset of individual steps of the smoking onset process, the relationship between age and the onset rate of various tobacco use events, and the degree to which onset of different events are related. Results of such investigations can contribute to the design of health-promoting interventions by guiding the choice of component, delivery method, and age and grade at which they are provided.

Further research is indicated in several directions: how the effect of SLT use on subsequent smoking onset depends on age and inclusion of other aspects of the tobacco use onset processes including social, environmental, and motivation variables. Finally, cohort studies are needed.

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ATTACHMENT C

TRANSLATION OF SWEDISH NEWSPAPER (SVENSKA DAGBLADET) ARTICLE
PUBLISHED ON 4/19/2001

Snuff is Better than Nicotine Preparations against Tobacco Dependency

More smokers are successful in quitting smoking using snuff, than with available over-the-counter nicotine drugs. In addition, those who try to quit smoking find that snuff works better than nicotine drugs.
This is the conclusion, probably unexpected, reached in a survey by Temo, sponsored by the Swedish Cancer Foundation and the drug company, Parmacia, which has been selling nicotine drugs for a long time.
Surveyed were 2,002 people, half of whom were smokers and half of whom had quit smoking. Of those who had succeeded in quitting smoking, 33 percent had used snuff during the smoking cessation period, compared to only 17 percent who had used nicotine drugs. The remaining people managed without using any aids. Of 108 persons surveyed, who had used nicotine drugs, 76 percent indicated that the drugs had been a great help. However, of those 163 surveyed who had used snuff, 84 percent, or slightly higher, were satisfied and answered yes to the same question.
A similar tendency in favor of the "benefits" of snuff could be found among those who still smoke, but have tried to quit. Among those, 74 percent answered that snuff had been "very helpful" when they tried to quit smoking compared to 56 percent of those who had tried nicotine drugs.

Despite the fact that the smokers themselves seem to prefer snuff and that the number basis in the report is not especially impressive, the Cancer Foundation is using the material to attack snuff. In a press release, the Foundation warns that snuff is a "risky alternative" for those who want to quit smoking. This is a message, which the co-sponsor, Pharmacia, will probably appreciate. The manufacturers of nicotine drugs are in the middle of an intense marketing struggle with the tobacco industry, especially Swedish Match, which is attempting to introduce snuff as a smoking cessation tool, particularly in the US. This is a large tempting market for Swedish Match, where cheaper snuff can become a threat to the drug manufacturers.
"No, we are absolutely not trying to promote nicotine drugs," says Britt-Marie Lindblad, in charge of tobacco affairs at the Cancer Foundation. "It is not our task and, in general, snuff does not constitute a big issue for us."

She stated that, for the most part, the Cancer Foundation wants to warn that snuff is strongly addictive and will lead to continued abuse, which can be difficult to stop.
"Those who replace cigarettes with snuff are only switching from one stimulant to another," she noted, and also warned that some people will start using both cigarettes and snuff.
The survey indicated that 111 persons, or 11 percent of the smokers, are mixed users and that 16 percent of those, who used snuff to quit smoking, have continued to use snuff.
On the other hand, it is not mentioned that the nicotine drugs can also be addictive, especially the chewing gums and nasal sprays. In a report about smoking cessation from SBU (the State Committee for Evaluation of Medical Methodology), it is noted that there is a risk of continued dependence, but the long-term effects of these preparations have not been studied sufficiently.

A study indicates that between five and ten percent continued to chew nicotine gum for more

than a year. For nicotine spray, which produces rapidly increasing nicotine concentrations, the addiction risk is even higher. Up to 40 percent of those who quit smoking will continue to use the spray even after a year.
The reason cited for snuff being more addictive is that it contains higher levels of nicotine than the drugs. Also, one explanation for the relatively low effect of the drugs is that their nicotine levels are too low. The industry is continuously engaged in work to develop drugs with higher nicotine levels.
No one, at either the Cancer Foundation or at Pharmacia, wants to say how much money the company paid for the Temo survey.
Inger Atterstam
08-13 51 59
Footnote: Aside from Pharmacia, the companies, Novartis, SmithKline Beechman and ACO, sell approximately ten different nicotine drugs, which are currently on the market. Recently Glaxo Wellcome introduced a drug in pill form, which the company claims counteracts nicotine addiction.

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Fact: Cancer risk among snuff users completely debunked.
The health risks related to snuff use have long been a controversial issue. However, recently the cancer risk has been taken off the agenda and a new study does not indicate any increased risk of heart disease.

Based on a decision by EU regarding its new tobacco directive, the warning text on snuffboxes will be changed. The phrase "causes cancer" will be reduced to "hazardous to health". The Swedish Board of Social Affairs has played a major role in the efforts to remove the cancer warning, because this risk is not considered to have been proven.

As for the effects on heart and blood pressure, the controversy still exists. In a large study, which was recently reported in a leading American epidemiological journal, a research group in Umeå present the strongest evidence so far against heart risks. They studied 687 men who had myocardial infarction and 687 healthy control subjects. The comparison between the participants' smoking habits showed major increased risks linked to smoking, while snuff use did not indicate any increased risk. In other words, snuff did not seem to increase the risk of heart disease.
Inger Atterstam

Snus bättre än nikotinpreparat

RÖKAVVÄNJNING | Dubbelt så effektivt enligt Temoenkät

▶Fler rökare lyckas sluta röka med hjälp av snus än med de nikotinläkemedel som finns att köpa receptfritt på apoteken. Dessutom upplever de som försöker sluta att snus fungerar bättre än nikotinpreparaten.

Det är den sannolikt något oväntade slutsatsen som kommer fram i en enkät som gjorts av Temo, bekostad av Cancerfonden och läkemedelsföretaget Pharmacia som sedan lång tid säljer nikotinläkemedel.

2002 personer tillfrågades, hälften var rökare och hälften hade slutat röka. Av dem som lyckats sluta hade 33 procent använt snus vid rökstoppet, mot enbart 17 procent som brukat nikotinläkemedel. De övriga klarade sig utan hjälpmedel. Av 108 tillfrågade som använt nikotinpreparat angav 76 procent att de haft stor hjälp av medlen. Dock var något fler, 84 procent av de 163 utfrågade som använt snus, nöjda och svarade ja på samma fråga.

Liknande tendens till snusets "fördel" framkommer bland dem som fortfarande röker men som försökt sluta. Där anger 74 procent att snuset varit till "stor hjälp" vid stoppförsöken mot enbart 56 procent bland dem som prövat nikotinläkemedel.

Trots att alltså rökarna själva tycks föredra snus och att siffermaterialet i rapporten inte är särskilt imponerande använder Cancerfonden materialet för att gå till storms mot snuset. I en pressmeddelande varnas för att snus är ett "riskabelt alternativ" för den som vill sluta röka.

Det är ett budskap som medfinansiären Pharmacia sannolikt uppskattar. Tillverkarna av nikotinpreparat befinner sig i en intensiv marknadsföringskamp med tobaksindustrin och då speciellt Swedish Match som försöker lansera snus som rökstoppsmedel specifikt i USA. En stor hägrande marknad för Swedish Match där det billigare snuset kan bli ett bot mot preparattillverkarna.

– Nej, vi propagerar absolut inte för nikotinläkemedel, säger Britt-Marie Lindblad, tobaksansvarig vid Cancerfonden. Det är inte vår uppgift och överhuvudtaget är snus ingen större fråga för oss.

Hon förklarar att Cancerfonden framför allt vill varna för att snus är starkt beroendeframkallande och leder till fortsatt missbruk som kan vara svårt att ta sig ur.

– Den som ersätter cigaretter med snus går bara från ett njutningsmedel till ett annat, påpekar hon och varnar också för att vissa kan börja med blandbruk av både cigaretter och snus.

Enkäten visar att 111 personer eller 11 procent av rökarna är blandbrukare och att 16 procent av dem som använde snus för att sluta röka har fortsatt snusa.

Däremot nämns inte att nikotinläkemedlen också kan vara beroendeframkallande, särskilt tuggummin och nässpray. I en rapport om rökavvänjning från SBU (Statens beredning för utvärdering av medicinsk metodik) sägs att risk för fortsatt beroende finns, men att långtidseffekterna av dessa preparat är dåligt studerade.

En studie visar att mellan fem och tio procent fortsatte att tugga nikotintuggummin i över ett år. För nikotinspray som ger snabbt stigande **nikotinnivåer** är beroenderisken ännu större, upp mot 43 procent av dem som slutat röka fortsätter med sprayen efter ett år.

Den orsak som anges till att snus skulle vara mer beroendeframkallande är att det innehåller högre halter nikotin än läkemedlen. Samtidigt anses en förklaring till preparatens relativt låga effekt vara alltför låga nikotinnivåer. Inom industrin pågår därför ett utvecklingsarbete att ta fram medel med högre nikotinhalter.

Ingen vare sig på Cancerfonden eller hos Pharmacia vill uppge hur mycket pengar företaget betalat för Temoenkäten.

INGER ATTERSTAM
08 135 59 inger.attersta@svd.se

Fotnot: Utöver Pharmacia säljer företagen Novartis, SmithKline Beecham och ACO de cirka tio olika nikotinpreparat som finns idag. Nyligen introducerade Glaxo Wellcome ett läkemedel i pillerform som sägs motverka nikotinbegär.

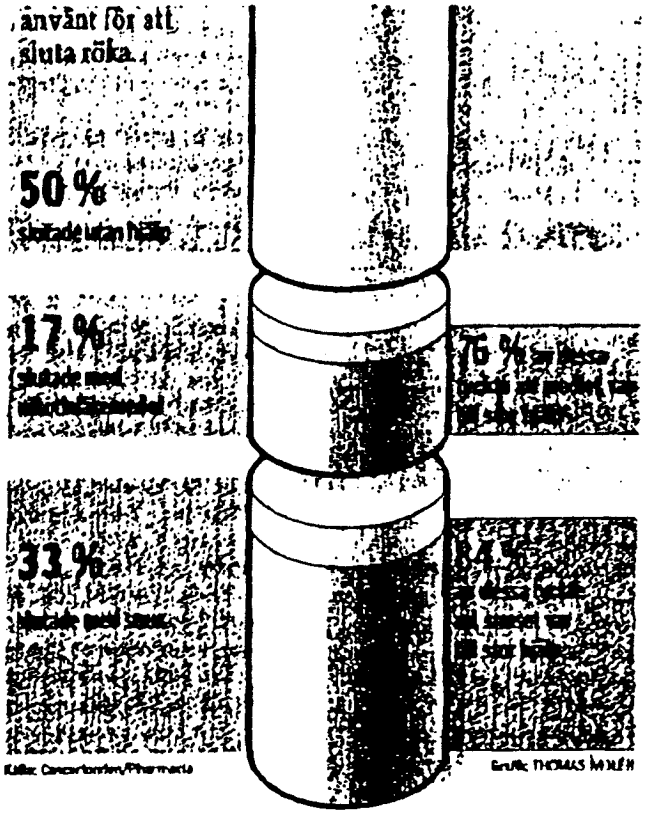
Att sluta röka

1000 personer som slutat röka tillfrågades om vilket hjälpmedel de

FAKTA | SNUS

Cancerrisk helt avförd

Hälsoriskerna med snus har länge varit en kontroversiell fråga. I dagarna har dock can-



cer avförts från dagordningen och en ny studie visar inte på någon ökad risk för hjärtsjukdomar.

Enligt beslut i EU:s nya tobaksdirektiv ska varningstexterna på snusdosorna ändras. Formuleringen "orsakar cancer" mildras till "farligt för hälsan". Inte minst svenska Socialstyrelsen har varit förkämpe för att ta bort cancervarningen, eftersom den risken inte anses bevisad.

När det gäller effekter på hjärta och blodtryck består oenigheten. I en stor studie som nyligen rapporterats i en ledande amerikansk epidemiologisk tidskrift redovisar en forskargrupp i Umeå de hittills starkaste bevisen mot hjärtrisker.

De har studerat 687 män som fått hjärtinfarkt och 687 friska kontrollpersoner. Jämförelser av deltagarnas rökvanor visar en stor ökad risk med att röka, medan snusning inte gav något utslag. Snus tycktes alltså inte öka risken för hjärtsjukdom.

INGER ATTERSTAM

Alkohol bra efter hjärtattack

CHICAGO ▶ Måttlig alkoholkonsumtion tycks inte bara förebygga hjärtinfarkt utan även förbättra överlevnadschanserna för dem som haft hjärtstillestånd. Det visar nya forskningsresultat från två olika studier i USA, som presenterades på tisdagen.

En måttlig alkoholkonsumtion tycks minska risken att dö inom några år efter ett hjärtstillestånd med cirka 30 procent, enligt dessa undersökningar.

- Vi kan behöva ompröva rådet att lägga om sina dryckesvanor till dem som haft en hjärtattack, sade Kenneth Mukamal, författare till en artikel i Journal of the American Medical Association, där de nya resultaten presenteras.

Mukamal och hans kollegor vid ett medicinskt center i Boston rapporterar att personer som drack en alkoholhaltig dryck om dagen minskade risken att dö inom fyra år efter hjärtattacken med 21 procent, jämfört med en grupp som inte drack någon alkohol alls. För dem som drack två gånger om dagen minskade risken med 30 procent.

Det tycks inte göra någon skillnad om alkoholen utgörs av öl, vin eller sprit - hur många centiliter alkohol det rör sig om per dag framgår inte. Studien i Boston stöds av en liknande som gjorts vid den medicinska fakulteten vid universitetet i Atlanta. Även där minskade risken för nya hjärtattacker vid måttlig alkoholkonsumtion.

De här resultaten är ingen uppmaning till hjärtpatienter att börja dricka alkohol, betonar forskarna. Det är snarare ett lugnande besked till dem som klarar måttlighetsdrickande, att de kan fortsätta med detta även efter en hjärtattack. TT-AFP

nyheter

19/4 2001

SENASTE NYTT
4/5 2001
18:36
Taxi lovar bekämpa diskriminering
18:29
Magnus Gustafsson borta från Houston
17:07
16-åring åtalas för mobbning

Alla senaste nytt

Snus bättre än nikotinpreparat mot beroende av tobak

Fler rökare lyckas sluta röka med hjälp av snus än med de nikotinläkemedel som finns att köpa receptfritt på apoteken. Dessutom upplever de som försöker sluta att snus fungerar bättre än nikotinpreparaten.
Det är den sannolikt något oväntade slutsatsen som kommer fram i en enkät som gjorts av Temo, bekostad av Cancerfonden och läkemedelsföretaget Pharmacia som sedan lång tid säljer nikotinläkemedel.
2 002 personer tillfrågades, hälften var rökare och hälften hade slutat röka. Av dem som lyckats sluta hade 33 procent använt snus vid rökstoppet, mot enbart 17 procent som brukat nikotinläkemedel. De övriga klarade sig utan hjälpmedel. Av 108 tillfrågade som använt nikotinpreparat angav 76 procent att de haft stor hjälp av medlen. Dock var något fler, 84 procent av de 163 utfrågade som använt snus, nöjda och svarade ja på samma fråga.
Liknande tendens till snusets "fördel" framkommer bland dem som fortfarande röker men som försökt sluta. Där anger 74 procent att snuset varit till "stor hjälp" vid stoppförsöken mot enbart 56 procent bland dem som prövat nikotinläkemedel.

Trots att alltså rökarna själva tycks föredra snus och att sifferunderlaget i rapporten inte är särskilt imponerande använder Cancerfonden materialet för att gå till storms mot snuset. I en pressmeddelande varnas för att snus är ett "riskabelt alternativ" för den som vill sluta röka.
Det är ett budskap som medfinansiären Pharmacia sannolikt uppskattar. Tillverkarna av nikotinpreparat befinner sig i en intensiv marknadsföringskamp med tobaksindustrin och då speciellt Swedish Match som försöker lansera snus som rökstoppsmedel speciellt i USA. En stor hägrande marknad för Swedish Match där det billigare snuset kan bli ett hot mot preparattillverkarna.
- Nej, vi propagerar absolut inte för nikotinläkemedel, säger Britt-Marie Lindblad, tobaksansvarig vid Cancerfonden. Det är inte vår uppgift och överhuvudtaget är snus ingen större fråga för oss.

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Fakta: Cancerrisk för snusare helt avförd

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Inge- Atterstam

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Inger Atterstam
08-13 51 59

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tillbaka

ATTACHMENT D

COMMENTARY

Harm reduction, public health and human rights:

Smokers have a right to be informed of significant harm reduction options

Lynn T. Kozlowski, Ph.D.

Department of Biobehavioral Health

Pennsylvania State University

Nicotine and Tobacco Research, in press

Running title: Harm reduction and human rights

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COMMENTARY

Harm reduction, public health and human rights: Smokers have a right to be informed of genuine harm reduction options

Lynn T. Kozlowski, Ph.D.

Department of Biobehavioral Health

Pennsylvania State University

Abstract

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 need also 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 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, & 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.

Ferrence *et al.* (2000) noted one of the important questions is "Would there be a net benefit to society if novel products reduced risk but increased use?" (p. x). Later in the book, Henningfield and Fant (2000) indicate 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 discussant in a later chapter urges 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 (IOM) 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" (p. x). The Executive Summary has as its last 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 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 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 their 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 IOM Report (Stratton *et al.* 2001). The IOM 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 desirable, the feasibility or practicability of the IOM 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 (Swedish moist snuff) reduces tobacco harm dramatically in comparison to cigarettes (Ramstrom, 2000; Henningfield & Fagerstrom, 2001). Rodu & 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, Holman, Milne, *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, Ramstrom, 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 IOM report (Stratton *et al.*, 2000) notes, ". . . the use of snus in Sweden has generally not been associated with oral cavity cancer" (p. 428). The IOM Report also reports that "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 are also no secondhand smoke or fire risks from snus. The findings are mixed on whether snus contributes to cardiovascular disease (Ramstrom, 2000; Henningfield & Fagerstrom, 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* than cigarettes to individual users.

Medicinal nicotine products (nicotine replacement therapies) such as gum, patch, nasal spray, and inhaler are also 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, Taiwan, United States, Spain, and Sweden (Corrao, Guindon, Sharma, & Shokoohi, 2000). On current epidemiological evidence, these products appear to reduce risk in comparison to 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 IOM 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 IOM 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 pregancy, but these problems should still likely be less than for cigarettes (Benowitz, 1998, Stratton et al, 2001). I would estimate that medicinal nicotine 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 significantly less dangerous than cigarettes.

There are supposed harm reduction products that have been proven to not reduce harm to individuals. The lower-tar cigarette appears to not reduce toxic smoke delivered to smokers (e.g., Jarvis *et al.*, 2001; Kozlowski & O'Connor, 2000; Kozlowski, O'Connor, & Sweeney, in

press; USNCI, 1996; Benowitz *et al.*, 1983) or mortality (e.g., Burns *et al.*, in press). Newer cigarette-like products (e.g., Eclipse®, Accord®) at best make smaller changes in the product (smaller than Snus or MN in comparison to cigarettes), and likely make concomitantly small changes, if any, in risk. Careful testing such as prescribed by the IOM Report (Stratton *et al.*, 2001) would be needed to establish the magnitude, if any, of risk reduction from the products.

The human right to health relevant information arises out of the principle of autonomy

Several ethical traditions (legal, medical, 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 (e.g., 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 is 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 IOM 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, 8-4). (Emphasis 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 1,000), then use would have to increase over 1,000 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.

Some other issues that might prevent public health advice about snus and medicinal nicotine as harm reduction products

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 proven 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 advise on harm reduction products 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 IOM 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 of human rights

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Insert Figure 1 here

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 part of governments to not be providing honest information about the dangers of cigarettes (Mann et al, 1999). Low-tar cigarettes are designed to reassure smokers and keep them smoking (e.g., Kozlowski & Sweeney, 1997), but do not reduce health risks to smokers (Burns *et al.*, in press). 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 ofHealth 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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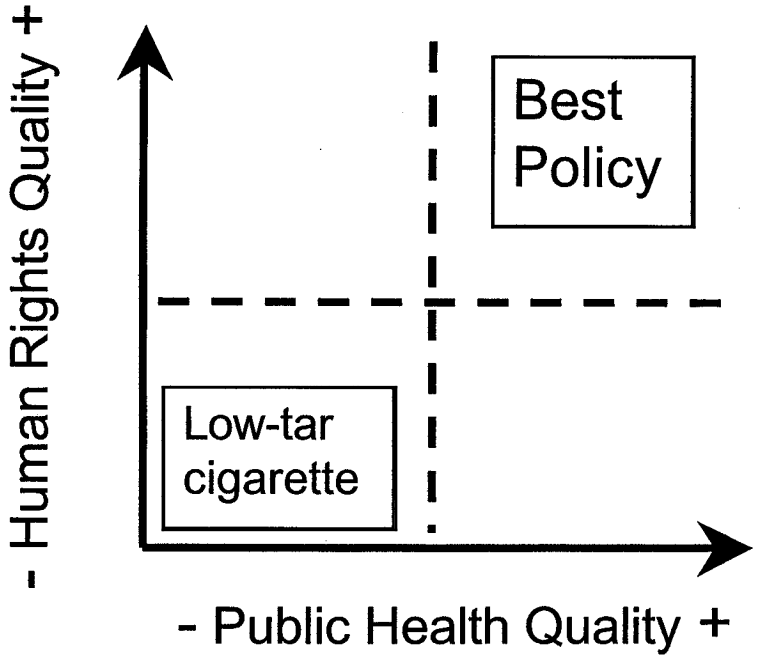
Figure Legend

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. (See text for more details.)


- Human Rights Quality +
Best Policy
Low-tar cigarette
- Public Health Quality +

ATTACHMENT E

21 of 43 DOCUMENTS

THE HARTFORD COURANT

July 11, 2002 Thursday, 7 SPORTS FINAL

SECTION: CONNECTICUT; Pg. B9

LENGTH: 723 words

HEADLINE: STATE RIPS PLAN TO LABEL **SNUFF** 'SAFER' TOBACCO

BYLINE: GARRET CONDON; Courant Staff Writer

BODY:

Early in his career, veteran ballplayer and broadcaster Joe Garagiola roomed during spring training with a teammate who, before retiring, would spread newspapers on the floor around his bed so he could chew while reclining and spit on the floor.

After eight or nine years of chewing tobacco himself, Garagiola quit when his young daughter -- who was studying the effects of tobacco in school -- asked him if he was going to die. "That was it for me," he said.

These days, Garagiola, 76, speaks out against smokeless tobacco as part of the National Spit Tobacco Education Program. He appeared Wednesday at a press conference with oral cancer survivor Gruen Von Behrens of Stewardson, Ill., and state Attorney General Richard Blumenthal.

Their target was Greenwich-based UST Inc. and its subsidiary, United States Smokeless Tobacco Co. In February, UST asked the Federal Trade Commission to allow it to tell consumers that smokeless tobacco products -- such as UST's Copenhagen and Skoal -- are safer alternatives to cigarette smoking.

"It's almost criminal," Dr. Michael Egan, president of the state dental association, said of UST's request.

Von Behrens, 25, said he began using smokeless tobacco at 13 and was diagnosed with oral cancer at 17. Today, 30 operations later, his lower face is severely disfigured and half of his tongue has been removed, along with his teeth, half of his neck muscles and nearby lymph nodes.

"Don't use it," Von Behrens said, as he broke into tears. "It ruined my life."

Blumenthal said he hoped the outcry against UST might persuade the company to withdraw its request -- or the commission to reject it. He said that he and other attorneys general would also consider legal action against UST. After the press conference, Blumenthal acknowledged that smokeless tobacco is probably less dangerous than cigarettes but said the comparison is misleading, because smokeless tobacco is such a hazardous product. Spit tobacco users are up to 50

times more likely than nonusers who don't smoke to get oral cancer, which kills 8,000 Americans a year.

Blumenthal said that calling **snuff** and related products safer than cigarettes is like saying that it's safer to drive 100 mph on a winding, country road than to drive 140 mph.

There's a growing debate in the public health community over tobacco harm reduction; the idea is that, short of getting people to quit, measures can be taken to reduce the damage done by cigarettes. For example, several "safer" cigarettes -- with reduced levels of certain cancer-causing compounds -- are under development.

Richard Verheij, executive vice president and general counsel of UST, said that his firm sees smokeless tobacco as a potential component in a harm-reduction strategy and has asked the FTC how it might best inform consumers.

One researcher cited by Verheij, Lynn Kozlowski, professor and head of the Department of Biobehavioral Health at Pennsylvania State University, has done research on smoking for more than 25 years. Kozlowski -- who said he has never taken tobacco company funding -- said that smokeless tobacco does not cause lung cancer or respiratory illness. These account for about 60 percent of the deaths from smoking. And although smokeless products increase the risk for oral cancer, he said, there is evidence that cigarette use poses a much higher risk of oral cancer.

"It is bad for you," Kozlowski said of **snuff** and other spit tobacco products. "It's not a safe alternative, but it is a much, much safer alternative to cigarettes." For hard-core smokers who haven't been able to quit using medicinal nicotine, such as patches and gum, smokeless tobacco might help, he said.

But Gregory Connolly, director of the Tobacco Control Program of the Massachusetts State Department of Public Health, said that the narrow comparison misses the broader picture. Smokeless tobacco makers and cigarette manufacturers together sell nicotine addiction, he said.

There is little evidence that smokeless tobacco helps smokers quit, but plenty to show that it is a gateway to cigarettes, he said. Kids who chew tobacco or use **snuff** are three times more likely to become smokers, he said. Adults who use smokeless tobacco are two-and-a-half times more likely to smoke. Use of the product by pregnant women could affect unborn children.

LOAD-DATE: July 18, 2002