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February 5, 2002

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

Re: Request for Advisory Opinion

Dear Secretary Clark:

U.S. Smokeless Tobacco Company ("USSTC"), a subsidiary of UST Inc. ("UST"), requests that the Commission, pursuant to section 1.1 of its Rules of Practice, issue an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative as compared to cigarette smoking. Such action by the Commission would address an issue of significant public interest to adult tobacco consumers, USSTC, and other smokeless tobacco manufacturers.

For decades, the public health community in the United States has asserted that cigarette smoking is the most deadly epidemic of modern times. For almost as long, the message of the public health community to cigarette smokers has been monolithic: stop all use of tobacco. Over the past several years, however, an increasing number of public health advocates have voiced doubts about what some have called the "quit or die" approach to smoking cessation. Rather than rely entirely on programs intended to achieve total cessation of tobacco use, this segment of the public health community is urging that a more pragmatic goal be adopted -- that of tobacco "harm reduction." One method of achieving tobacco harm reduction, according to a growing number of researchers, is to encourage those cigarette smokers who do not quit to switch to smokeless tobacco products.

The FTC may wish to consider holding a workshop to address the appropriateness of conveying tobacco harm reduction information as part of smokeless tobacco advertising. A workshop would assist in educating the Commission prior to the issuance of an advisory opinion, and would facilitate public discussion of this novel and important issue.

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I. Introduction

Since the Surgeon General's Report in 1964,¹ there has been substantial public health discussion about the potential health effects of tobacco use. Various public health organizations have identified the risks of cigarette smoking as including cancer (*e.g.*, lung, oral cavity, esophagus, larynx, pancreas, bladder, kidney), chronic obstructive pulmonary disease, myocardial infarction, and stroke.² The Surgeon General has indicated that the ideal way to avoid such health risks is to abstain from cigarette smoking.³ Nonetheless, 47 to 50 million adults in the U.S. continue to smoke cigarettes.⁴ This number represents approximately 25 percent of all U.S. adults.⁵

The Surgeon General determined in 1986 that use of smokeless tobacco products "can cause cancer."⁶ Moreover, federally-mandated rotating warnings on smokeless tobacco product packaging and advertising state that smokeless tobacco "may cause mouth cancer," "may cause gum disease and tooth loss," and "is not a safe alternative to cigarettes."⁷ There is, however, a

¹ U.S. Department of Health Education & Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964).

² Stratton K, Sherry P, Wallace R, Bondurant S (eds.). *Clearing the smoke. Assessing the science base for tobacco harm reduction.* Institute of Medicine. National Academy Press, Washington, D.C., 2001, at pp. 367-68.

³ U.S. Department of Health & Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (1994); *see also Smoking As A Health Hazard*, American College of Cardiology Position Statement, available at <http://www.acc.org/clinical/position/72565.pdf>.

⁴ The National Center For Chronic Disease Prevention and Health Promotion ("National Center For Chronic Disease Prevention") estimates that 47 million adults in the United States smoke cigarettes. *Targeting Tobacco Use: The Nation's Leading Cause of Death*, Tobacco Information and Prevention Source ("TIPS") (2001). The U.S. Department of Health and Human Services ("HHS") estimates that more than 57 million Americans currently smoke cigarettes. *Preventing Death and Disease From Tobacco Use*, Fact Sheet (Jan. 8, 2001). Other reports suggest that the number of smokers in the United States is between 46.5 and 50 million. *Cigarette Smoking Among Adults - United States, 1999, MMWR Highlights* (Oct. 12, 2001) Vol. 50, No. 40; *Treating Tobacco Use and Dependence*, U.S. Public Health Service, Fact Sheet (June 2000).

⁵ The National Center For Chronic Disease Prevention estimates that the adult smoking rate was 23.5 percent in 1999. *Cigarette Smoking Among Adults - United States, 1999, MMWR Highlights* (Oct. 12, 2001), Vol. 50, No. 40. HHS estimates that 25 percent of all adults smoke. U.S. Public Health Service, *Treating Tobacco Use and Dependence*, Fact Sheet (June 2000).

⁶ U.S. Department of Health & Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986).

⁷ Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408.

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growing body of scientific literature that supports the conclusion that cigarette smokers who do not quit can reduce their health risks substantially if they switch to smokeless tobacco products.

USSTC requests that the Commission issue an advisory opinion supporting the use of statements in advertising that provide the public with truthful and substantiated information about the harm reduction that a growing number of public health advocates believe can result from switching from cigarettes to smokeless tobacco products.⁸ The benefits of making such information available to consumers would be twofold: it would provide ready access to scientific opinion that otherwise would be difficult or costly to obtain, and it would help adult consumers make better educated choices about the tobacco products they use.⁹ As the federal agency with authority over tobacco advertising, the FTC should act affirmatively to provide guidance in this area.

USSTC believes that the types of information it proposes to communicate in advertising

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new pouch product -- Revel -- is currently in test market. USSTC maintains manufacturing and processing facilities in Franklin Park, Illinois, Hopkinsville, Kentucky, and Nashville, Tennessee.

In 1997, USSTC was the only smokeless tobacco company to support the proposed tobacco resolution. When the proposal failed to pass the Congress, USSTC became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement (“STMSA”) with Attorneys General of various U.S. states and territories. Pursuant to the STMSA, USSTC is providing a total of \$100 million, over a 10-year period, to the American Legacy Foundation for programs to reduce youth usage of tobacco and combat youth substance abuse, and for enforcement purposes.¹¹ Moreover, USSTC agreed to limitations on its advertising and marketing efforts, even though this put USSTC at a competitive disadvantage with other smokeless tobacco manufacturers.¹²

III. Proposed Statements Conveying Information About Tobacco Harm Reduction Would Be Truthful and Non-Deceptive

A. Statements in Advertising

Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Act), in part, “to inform the public of any dangers to human health resulting from the use of smokeless tobacco products.”¹³ Among other things, the Smokeless Act requires that all smokeless tobacco product packaging and advertising (except billboard advertising) display one

¹¹Youth usage of smokeless tobacco, as reported in surveys conducted by various federal government agencies and by the University of Michigan, has declined substantially in recent years. For example, the authors of last year’s report on the University of Michigan’s Monitoring the Future national survey noted that “[t]he use of smokeless tobacco by teens has been decreasing gradually from recent peak levels in the mid-’90s, and the overall declines have been substantial.” Johnston LD, O’Malley PM, Bachman JG. *Monitoring the Future national results on adolescent drug use: Overview of key findings 2000*. (NIH Publication No. 01-4923). Bethesda, MD: National Institute of Drug Abuse, p. 34 (2001).

¹² These restrictions include, among other things, eliminating outdoor advertising of smokeless tobacco products, such as billboards and signs in arenas, stadiums, shopping malls, video-game arcades, and on public transit. In addition, USSTC voluntarily limited itself to one brand-name sponsorship in any 12-month period, and agreed to discontinue distribution to the public of non-tobacco merchandise, such as caps and T-shirts, bearing the brand name, logo, or trademark of any smokeless tobacco product.

¹³ 15 U.S.C. § 4401(a)(1).

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At the same time, it should be noted that some critics reject “reduced harm” strategies, favoring only those public health strategies aimed at preventing or stopping tobacco use altogether.²³ And a recent report of the Institute of Medicine calls for more testing of the harm reduction benefits of smokeless tobacco products before urging their use as part of a tobacco harm reduction strategy.²⁴

USSTC’s proposed statements, of which the above text is a possible example, accurately portray the views of public health researchers about the risks of smokeless tobacco as compared to cigarette smoking. The statements also would convey that a growing number of researchers advocate that smokers who do not quit be encouraged to switch to smokeless tobacco products. USSTC has taken care not to overstate the evidence or its significance. In addition, it acknowledges the Surgeon General’s conclusion concerning smokeless tobacco products,²⁵ while informing the public about the views of public health researchers who contend that smokeless tobacco is a reduced risk alternative to cigarette smoking.²⁶

²³ *Id.* at 8-9.

²⁴

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IV. The FTC Should Provide an Advisory Opinion to USSTC to Encourage the Communication of Useful and Accurate Information to Adult Consumers

A. *The FTC Has Jurisdiction and is the Appropriate Agency to Consider USSTC's Proposed Statements and to Issue an Advisory Opinion*

USSTC respectfully requests that the FTC provide an advisory opinion permitting advertising which incorporates information regarding the current debate about tobacco harm reduction, such as the exemplar statement set forth in section III.A. above. USSTC currently does not make cross-category comparative statements in its advertising.

The Commission may issue advisory opinions with respect to an intended course of action when “[t]he matter involves a substantial or novel question of fact or law and there is no clear Commission or court precedent” or “[t]he subject matter of the request and consequent publication of Commission advice is of significant public interest.”²⁷

The Commission is the appropriate agency to provide guidance on the proposed comparative statements for smokeless tobacco products. It has direct authority over smokeless tobacco advertising under the Federal Trade Commission Act and the Smokeless Act. Further, the FTC is uniquely experienced in addressing the kind of health-related statements at issue here and in providing guidance to business. For example, in its *Enforcement Policy Statement on Food Advertising*, the Commission provided guidance on the use of nutrient content and health claims in food advertising,²⁸ and more recently it provided guidance on dietary supplement advertising claims.²⁹ These and other business and consumer education efforts by the Commission³⁰ have provided a measure of certainty to companies seeking to advertise certain attributes of their products, and provided information to consumers in an unsettled legal environment. Commission guidance with respect to comparative health risk statements for smokeless tobacco products would provide similar benefits to business and adult consumers.

USSTC recognizes, of course, the widespread interest within the government regarding issues relating to tobacco products generally, and understands the FTC may wish to consult with

²⁷ 16 C.F.R. § 1.1 (a)(1)(2).

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agencies within the Department of Health and Human Services, among others, in developing the requested advisory opinion.³¹

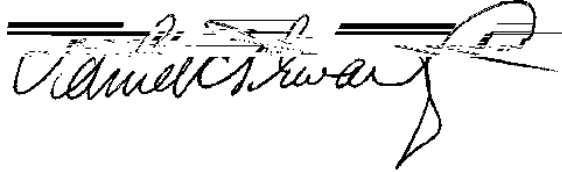
- B. *An Advisory Opinion is Warranted Because Cross-Category Comparative Reduced Risk Statements Present Novel Legal Issues for Which There is No***

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We appreciate your attention to this matter. Please contact me at (202) 508-6025, or my colleague, Dana Rosenfeld, at (202) 508-6032, for any further information you may require.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Daniel C. Schwartz", is written over a horizontal line. The signature is fluid and cursive, with a long, sweeping tail that extends to the right.

Daniel C. Schwartz

Enclosures

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
Mary K. Engle, Acting Associate Director, Division of Advertising Practices
Gerard Butters, Assistant Director, Bureau of Economics

**An Overview of Significant Issues Relating to Smokeless
Tobacco in the Context of Tobacco Harm Reduction**

Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. This is why many public health leaders believe that what has come to be called “harm reduction” must be included as a subsidiary component of a comprehensive public health policy toward tobacco.¹

Tobacco “harm reduction” is defined in the IOM Report as follows:

For the purposes of this report, a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants. Many different policy strategies may contribute to harm reduction. However, this report focuses on tobacco products that may be less harmful or on pharmaceutical preparations that may be used alone or concomitantly with decreased use of conventional tobacco.²

It is clear from this definition of “harm reduction” that, in the view of the IOM, it is not necessary to demonstrate that a product is “safe” or “harmless” in order for that product to play a role in tobacco harm reduction.³

The IOM Report had the following to say with respect to smokeless tobacco products:

Smokeless tobacco products are associated with oral cavity cancers, and a dose-response relationship exists. However, the overall risk is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk. It may be

¹ Stratton K, Shetty P, Wallace R, Bondurant S (eds.). Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine. National Academy Press, Washington, D.C., 2001, at p. 201.

² Id. at p. 2.

³ It should be noted that it is USSTC’s position that smokeless tobacco has not been shown to be a cause of any human disease, and nothing in this review should be interpreted as a concession by USSTC to the contrary. It is not necessary, however, to agree with USSTC’s position on the smokeless tobacco and health issue in order to accept the proposition that smokeless tobacco has a significant and legitimate role to play in a public health strategy aimed at tobacco harm reduction.

use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. These publications were authored or co-authored by over 50 researchers or public health advocates and appeared in approximately 40 different scientific journals or books, most having been published over the past several years.

Dr. Brad Rodu, a Professor in the Department of Pathology at the University of Alabama at Birmingham and a Senior Scientist at the UAB Comprehensive Cancer Center, and several of his colleagues, are the most widely published researchers on the issue of smokeless tobacco and tobacco harm reduction. They have authored nearly a dozen publications and Dr. Rodu has published a book entitled “For Smokers Only – How Smokeless Tobacco Can Save Your Life,” in which he maintains that smokeless tobacco is “98 percent less dangerous” than cigarette smoking.

Dr. Rodu’s analysis is based on two assumptions. First, he accepts the view of the Centers for Disease Control and Prevention that cigarette smoking is responsible for approximately 419,000 deaths each year in the United States, as follows:⁶

⁵ Bates C. Clearing the smoke or muddying the water? (Editorial) *Tobacco Control* 2001; 10: 87-88.

⁶ Centers for Disease Control and Prevention. Cigarette smoking – attributable mortality and years of potential life lost. *MMWR* 1993; 42: 645-649.

Cancers	
- Lip, oral cavity, pharynx	6,475
- Esophagus, larynx, kidney, bladder, etc.	24,927
- Trachea, lung, bronchus	116,920
Cardiovascular diseases	179,820
Respiratory diseases	84,475
Pediatric diseases	1,711
Burns	1,362
Environmental tobacco smoke	3,000
TOTAL	418,690

Second, Dr. Rodu calculates that if all 46 million cigarette smokers in the United States switched to smokeless tobacco there would be “at worst, 6,000 deaths from oral cancer” each year.

Dr. Rodu has summarized his analysis as follows:

If all smokers were instead addicted to smokeless tobacco, only 12,000 new cases of oral cancer (with a 50 percent survival rate) could be expected each year. This is only one-twentieth of all cancers that now result from smoking, and one-tenth of smoking related lung cancer cases! I haven't even mentioned the reduction in heart disease and emphysema deaths yet. *If all 46 million smokers used smokeless tobacco instead, the United States would see, at worst, 6,000 deaths from oral cancer, versus the current 419,000 deaths from smoking-related cancers, heart problems, and lung disease.*⁷

Dr. Rodu and one of his colleagues have also performed an analysis from which they conclude that a cigarette smoker's life is shortened by 7.8 years as a result of his smoking, compared to 15 days for a smokeless tobacco user:

We estimated the life expectancy of 35-year old white males with three patterns of tobacco use: non-users, cigarette smokers and smokeless-tobacco users.

* * *

The results indicate that the average remaining life expectancy of a 35-year old smokeless-tobacco user is 45.92 years, only 0.04 year less than that of a non-user. . . . This 15-day reduction in life expectancy is in sharp contrast to the 7.8 years lost by smokers.⁸

IV. Recommendation That Cigarette Smokers Who Do Not Quit Should Switch to Smokeless Tobacco

A growing number of tobacco harm reduction proponents recommend that those cigarette smokers who do not quit should switch to smokeless tobacco products. Examples of researchers or public health advocates who recommend this course of action are as follows:

As early as 1980, LR Kirkland, a physician at Emory University Hospital, made the following proposal in the *New England Journal of Medicine*:

I urge physicians to encourage snuff and chewing tobacco as alternatives to cigarettes. No one disputes the role of snuff and similar products as the cause of oral leukoplakia, but there is a vast difference in the frequencies of oropharyngeal carcinoma and cigarette-induced lung cancer. If five new “dippers” are created to avert creation of one new cigarette smoker, then progress has been made.⁹

In 1985, four British researchers made the following observation in the *Lancet*:

⁷ Rodu B. For smokers only. How smokeless tobacco can save your life. Sulzburger & Graham Publishing, Ltd., New York; 1995 at p. 131.

⁸ Rodu B, Cole P. Tobacco-related mortality. (Letter to the Editor). *Nature* 1994; 370: 184.

⁹ Kirkland LR. The nonsmoking uses of tobacco. (Letter to the Editor). *NEJM* 1980; 303: 165.

Unlike tobacco smoking, use of wet snuff carries no risk of lung cancer, bronchitis, or emphysema, and no risk of cardiovascular disease has been demonstrated.

* * *

If all smokers in Britain switched to [smokeless tobacco] sachets about 50 000 premature deaths per year might eventually be saved at an annual cost of less than 1000 deaths from mouth cancer.¹⁰

Since 1995, Dr. Rodu and his colleagues have strongly recommended that “inveterate” cigarette smokers switch from cigarettes to smokeless tobacco products:

A switch to a safer delivery system, smokeless tobacco, will allow the 46 million smokers in this country (and the people they live with) to live longer, healthier lives.¹¹

What do switchers accomplish? Our research shows that they will live, on average, as long as those smokers who quit nicotine altogether. They reduce their risks for smoking-related illness and death, which is the goal of all existing smoking cessation efforts. There is, of course, no debate about the ideal way to achieve this goal: complete tobacco abstinence. But that ideal is not always attainable since many smokers are unable to give up nicotine. Switching to smokeless tobacco is a small compromise with the ideal which reaps large individual and public health gains.¹²

More recently, Dr. Lars Ramström, Director of the Stockholm Institute for Tobacco Studies, published an article entitled “Snuff – An Alternative Nicotine Delivery System,” in which he made the following statement:

While snuff use may entail some health risks, there is good evidence that these are substantially lower than those associated with smoking. Switching from smoking to snuff use would therefore represent a reduction in health risk.

cessation products driven out of the marketplace. Since tobacco products are not regulated, we should be very cautious in arguing that one product is “safer” than another. It is a dynamic environment where all tobacco manufacturers will work together to promote each other’s products and addiction to nicotine. We should be very careful in choosing our tobacco bedfellows.¹⁵

V. **Individual Risk Versus Population Risk**

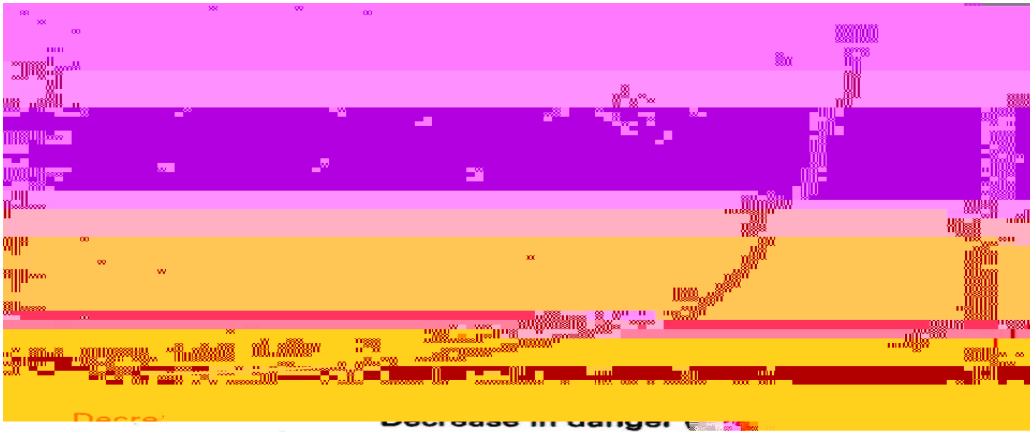
One concern raised by some in the public health community with respect to “reduced risk” tobacco products is that while a product might reduce the health risk to an individual, the aggregate public health impact on the population might be negative. Thus, for example, it is argued that if a “safer” cigarette reduced the health risks associated with cigarette smoking by 10 percent, but resulted in a 20 percent increase in cigarette use (either through new smokers or by causing some smokers who otherwise would have quit to continue smoking), the aggregate public health impact would be negative. Professor Kenneth E. Warner of the University of Michigan gives the following example:

[C]onsider the implications of Star Enterprise’s advertising that its new cigarette, Advance, yields fewer nitrosamines than conventional cigarettes. Informed that most cigarette smoke contains nitrosamines and that nitrosamines are carcinogenic, would smokers preparing to quit flock to the new cigarette instead, believing that it would greatly reduce their risk of smoking-induced lung cancer? The net health consequences are unclear: for those smokers who would have continued smoking anyway, switching to Advance might well reduce risk. For smokers who would have quit, or former smokers induced to start smoking again by the availability of this purportedly “safer” product, the active marketing of a low-nitrosamine cigarette clearly would *increase*

¹⁵ Connolly GN. Suckers today; smokers tomorrow? *Tobacco Control* 2001; 10: 304.

risk. The net impact would depend on the unpredictable balance between such effects.¹⁶

Professor Lynn Kozlowski, Head of the Pennsylvania State University Department of Biobehavioral Health, has developed a “risk/use equilibrium” chart¹⁷ to assess the issue of individual risk reduction versus aggregate population impact. The chart compares the “decrease in danger (%)” displayed on the horizontal axis to the “multiplier to achieve equal risk” on the vertical axis.



According to Professor Kozlowski’s analysis, a tobacco product which reduces risk by only 10 percent raises a difficult public health issue because an 11 percent increase in use of the product would offset the risk reduction in the population as a whole, and an increase in excess of 11 percent would result in a negative public health impact on the population as a whole. On the other hand, a tobacco product which results in a reduced risk in excess of 90 percent presents a

¹⁶ Warner KE. Reducing harm to smokers: Methods, their effectiveness and the role of policy. In: Rey Department 5, h 9 increase

relatively easy public health issue since the increase in usage necessary to offset the reduction in risk is so substantial – more than 1,000 percent – that it is highly unlikely to occur.

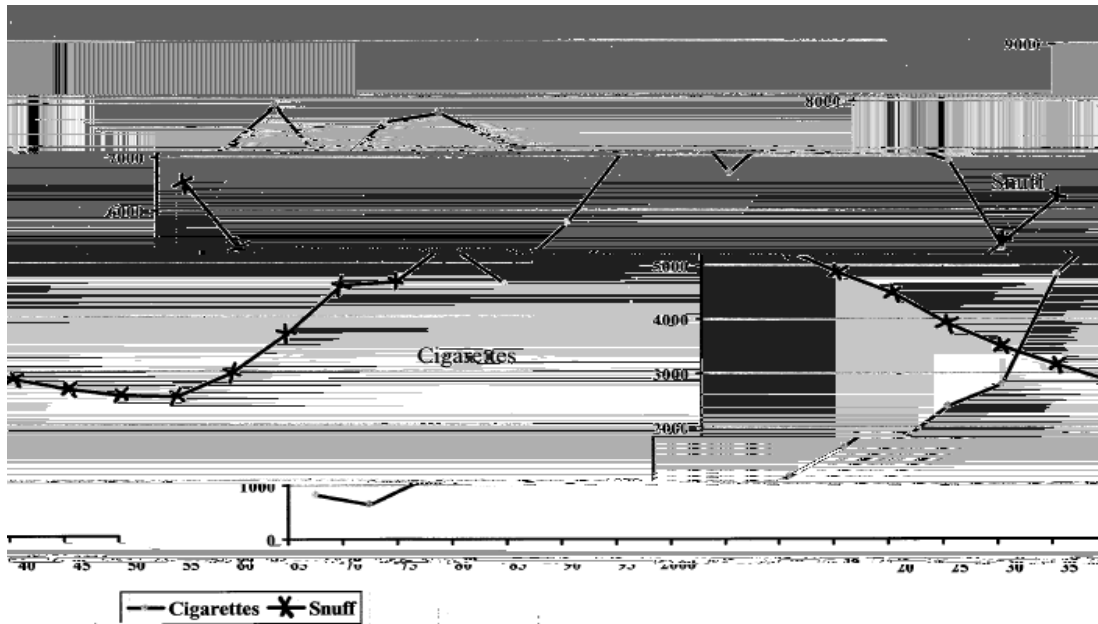
Given the predominant view in the public health community that the risk of adverse health effects associated with smokeless tobacco products is slight compared to that of cigarette smoking, researchers believe it is highly unlikely the public health benefit of cigarette smokers switching to smokeless tobacco would ever be offset by increased usage of smokeless tobacco.

VI. The Swedish Experience

Some proponents of encouraging “inveterate” cigarette smokers to switch to smokeless tobacco products point to the history of cigarette smoking and smokeless tobacco use in Sweden as support for their view. Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any Western country, and the daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes (18.2 percent daily smokeless tobacco users versus 17.1 percent daily cigarette smokers).¹⁸ The following chart¹⁹ illustrates the changing pattern of tobacco use in Sweden during most of the past century, including the fact that smokeless tobacco use has overtaken cigarette smoking in recent years for the first time since World War II.

¹⁸ Henningfield JE, Fagerström KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control* 2001; 10: 253-257, at p. 254.

¹⁹ Adapted from Swedish Match’s Third Quarter Results, October 23, 2001, as posted on Company’s web site. The figures cited reflect reported taxable shipments of snuff and cigarettes, measured in tons.



Tobacco and health researchers have linked Sweden’s low rate of “tobacco-related mortality” to its high prevalence of smokeless tobacco use and low prevalence of cigarette smoking:

Sweden, with a long tradition of smokeless tobacco use (16% of adult males use smokeless tobacco daily) and the highest penetration of NRT [nicotine replacement therapy] use, is the only European country that has reached (19%) the World Health Organization’s target of 20% smokers in the adult population by the year 2000; about 35% of all nicotine consumed comes from nonsmoked deliver[y] forms. The tobacco-related mortality in Sweden is by far lower than in any other European or North American country, although nicotine consumption may not be lower than in other countries.²⁰

Last year’s *New Scientist* article summarized the Swedish experience in the context of tobacco harm reduction:

²⁰ Balfour DJK, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996; 72: 51-81, at p. 71.

[S]mokers [in Sweden] aren't faced with the quit-or-die dilemma. Instead of using a nicotine replacement therapy with the aim of quitting both smoking and ultimately nicotine, they can continue using tobacco as a recreational drug, safe in the knowledge that it probably won't kill them. It's all down to a product called "snus," a form of moist ground tobacco that you pop between your lip and gum.²¹

* * *

The "Swedish experiment," as it has come to be known, has inspired some health campaigners to press for a more enlightened approach to the smoking epidemic. It's a concept they call "harm reduction." "If you look at Sweden, we have a living example of the concept in action," says Clive Bates, director of ASH.²²

Some have raised a question as to whether the Swedish experience is applicable to the United States, asserting that Swedish moist snuff products contain lower levels of so-called tobacco-specific nitrosamines (some of which have been reported to be laboratory carcinogens)

led to a movement to advocate the practice as a less dangerous alternative to smoking and an aid to nicotine withdrawal in those addicted to smoking.²⁴

This view is supported by a report issued in 1997 by the Swedish National Board of Health and Welfare, which concluded:

Recent data suggest that the differences [in TSNA levels reported

VII. Conclusions

Among the conclusions that can be drawn from this review and the attached compilation of statements from the scientific literature are the following:

1. Smokeless tobacco products have a significant and legitimate role to play in a public health strategy aimed at tobacco harm reduction.
2. There is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.
3. There is growing support in the public health community for including smokeless tobacco as a component of a comprehensive tobacco harm reduction strategy by encouraging those cigarette smokers who do not quit to switch to smokeless tobacco products.

**Statements Published in the Scientific Literature Asserting or Supporting the View
that Smokeless Tobacco Use Involves Significantly Less Risk
of Adverse Health Effects Than Cigarette Smoking**

1. Anderson A. Can't quit, won't quit. (Editorial).

3. Asplund K. Snuff – how dangerous is it? The controversy continues. (Editorial). *J Intern Med* 2001; 250; 457-461.

We are confronted with extremely difficult questions: Are there circumstances that could justify doctors to recommend the use of smokeless tobacco? What about the smoking patient who asks if he/she should try snuff dipping instead? And even more challenging: in pragmatic public health work, is snuff friend or foe?

* * *

Obviously, from a medical point of view, the only reasonable norm is nonuse of tobacco. The goal should be a tobacco-free society. On the route towards this goal, we face enemies that are more perilous than others. My personal opinion is that we should not squander our forces. We should concentrate them on the fight against cigarettes – they are the overwhelming threat to people’s health, snuff being only a mini-monster in comparison. (pp. 459 – 460).

4. Bates C. Clearing the smoke or muddying the water? (Editorial). *Tobacco Control* 2001; 10: 87-88.

While I do not wish to see a rush of novel tobacco products making health claims, there are immediate real problems arising from the “self serving caution” of regulators. For example, this applies to the refusal of some regulators to approve harm reduction indications for pharmaceutical NRT [nicotine replacement therapy], the regulatory barriers facing a nicotine gum manufacturer that wants to compete directly with cigarettes as a supplier of lifestyle branded nicotine, and the clumsy regulation of certain oral tobaccos that have substantially lower health risks than cigarettes. (p. 88).

5. Cole P, Rodu B. Analytic Epidemiology: cancer causes. *Cancer: principles & practice of Oncology*. Lippincott Williams & Wilkins, Pennsylvania 2001: 241-252.

CANCER OF THE ORAL CAVITY (OCC). This condition, including cancer of the pharynx, is caused by smoking with a RR [relative risk] of about 5.

* * *

Use of smokeless tobacco imposes a moderate RR of 2 for OCC. However, the risk may be declining because the suspect carcinogens in smokeless

tobacco, naturally-occurring tobacco-specific nitrosamines (TSNAs), have been reduced over the past two decades. In Sweden, where *per capita* consumption of smokeless tobacco is very high, TSNAs levels are undetectable and recent studies report no OCC attributable to the use of Swedish products. (p. 246).

During the last 20 years in the USA many anti-smoking campaigns shifted their focus from preventing deaths caused by smoking to preventing tobacco use. If we refocus attention on deaths from smoking we can learn a valuable lesson from Sweden, the only country which has met the World Health Organization's goal of a less than 20% prevalence of smokers. It also has Europe's lowest rates of lung cancer, larynx cancer, OCC, and bladder cancer. How were these benchmarks attained? There may be several explanations, but it is certainly relevant that Sweden has the highest *per capita* use in Europe of smokeless tobacco. (pp. 249 – 50).

6. Galanti MR, Wickholm S, Gilljam H. Between harm and dangers. Oral snuff use, cigarette smoking and problem behaviours in a survey of Swedish male adolescents. *Eur J Public Health* 2001; 11: 340-345.

The prevalence of smokeless tobacco use (moist snuff) in Sweden is among the highest world-wide and snuff is gaining popularity as a less harmful alternative to cigarettes. (Abstract, p. 340).

The use of Swedish oral tobacco (moist snuff) has not been consistently associated with relevant health hazards, and is therefore regarded as relatively safe compared to cigarette smoking. (p. 342).

7. Galanti MR, Nordgren P, Gilljam H. "Nicotine niche" or way out? The use of oral snuff among Swedish current and former smokers. *3rd SRNT Europe Conference* 19 – 22 September 2001, p. 52.

To date, there is no convincing evidence of major adverse health effects associated with the use of the Swedish smokeless tobacco "*snus*". It has also been claimed that *snus* availability may have substantially contributed to lower the adult smoking prevalence.

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

The most powerful means to reduce the diseases caused by tobacco use are to prevent the initiation of use and to help users to achieve complete and lasting abstinence. For tobacco users who are unwilling or unable to completely give up their tobacco use, the possibility is increasingly being considered that such persons might be able to reduce their risk of disease and premature mortality by reducing their exposure to tobacco toxins.

* * *

In Sweden, the tobacco marketing and regulatory situation has been different from that of most other countries in several respects, and Sweden has become one of the first developed nations to see a significant decline in tobacco attributable mortality. This decline has been associated with changing consumer preferences and regulatory policies that have contributed to a partial shift in nicotine intake from the most hazardous form (cigarettes) to less hazardous forms (snus form of smokeless tobacco and nicotine replacement medications). It is not clear to us how to apportion the contribution of the aforementioned specific factors in the reduction of overall tobacco attributable mortality risk. Nonetheless, we believe that the situation in Sweden might be considered a real world experiment in harm reduction that is in progress although we are concerned that not all of the signs are positive. (p. 253).

[R]eductions in smoking are possible in an environment that includes a range of accessible nicotine delivering alternatives to cigarettes. [W]e believe it is probable that for persons who sustain their nicotine intake, education about the dangers of smoking and the marketing of alternative products can contribute to shifts in the nature of nicotine product use. . . . [R]educed tobacco toxin exposure can lead to reduced premature mortality and this is not necessarily undermined by increasing prevalence of use of non-cigarette sources of nicotine. These effects and public health benefits have been predicted and discussed elsewhere.

. . . Swedish snus contains ingredients that are more toxic than would be permitted in foods or medicines, and there are adverse health consequences, including oral diseases and addiction, although the adverse consequences are less severe than those produced by cigarette smoking. (p. 255).

9. Johnson N. Tobacco use and oral cancer: A global perspective.

11. Warner KE. Reducing harm to smokers: methods, their effectiveness, and the role of policy. In: Rabin RL, Sugarman SD (eds.). *Regulating tobacco*. Oxford University Press 2001: 111-142.

Until recently the entire effort to help addicted smokers has rested on encouraging them to quit, to sever their ties to nicotine completely. Sweanor (1997) argues that this approach condemns millions of them to an early and avoidable grave. Among the alternatives to quitting smoking for those who cannot quit, as well as for those who do not want to quit but do wish to reduce risk, are reductions in the daily consumption of cigarettes and substitution of less harmful nicotine-delivery systems for cigarettes. Additional, more controversial possibilities include substitution of less dangerous tobacco products for cigarette smoking (e.g., smokeless tobacco or cigarettes modified to be less toxic) and the use of novel cigarette-like products developed by the cigarette manufacturers that are marketed as reducing risk. In each case, compared to the dangers posed by the unaltered smoking pattern, the alternative holds the potential of reducing the smoker's risk. (p. 114).

Substitution of Less Dangerous Tobacco Products For the nicotine addict who cannot find satisfaction in NRT products, switching from smoking cigarettes to less hazardous forms of tobacco consumption could conceivably reduce risk considerably. In recent years, Rodu (1995), an oral pathologist at the University of Alabama, and his colleagues (Tilashalski, Rodu, and Cole 1998; Rodu and Cole 1999) have argued in favor of converting "inveterate smokers" to smokeless tobacco use. His argument is straightforward, though not without its detractors (Tomar 1996): many confirmed smokers, he believes, can find smokeless tobacco an acceptable substitute for cigarettes, recognizing the risk-reduction benefits it confers in contrast to continued smoking. And smokeless tobacco use, although definitely not without disease risks of its own, is unarguably less risky than smoking. (pp. 118 – 19).

12. Bates C. Taking the nicotine out of cigarettes-why it is a bad idea. *Bulletin of the World Health Organization* 2000; 78: 944.

If removing nicotine will not work, what is the alternative? Regulators should be concentrating on cleaning up the delivery system, and tending to *increase* the amount of nicotine in the smoke relative to toxic smoke constituents such as tar and carbon monoxide. Regulatory pressure may be used to force selective reduction of tobacco toxins relative to nicotine by the use of chemically active filters, a switch from burning to heating tobacco, and greater use of oral tobacco, tobacco distillates and perhaps, ultimately, to nicotine delivery devices that do not use tobacco at all but, unlike current nicotine replacement therapies (patches and gum, etc.), deliver a psychoactive

and satisfying dose of nicotine to the addict. None of these approaches avoids all harm – far from it – but the evolution (rather than prohibition) of addictive nicotine delivery products represents an important strategy in reducing tobacco-related deaths in the 21st century. (p. 944).

13. Ramström L. Snuff – an alternative nicotine delivery system. In: Ferrence R, Slade J, Room R, Pope M (eds.). Nicotine and public health. The American Public Health Foundation, Washington D.C., 2000; Chapter 9: 159-178.

Experts from the Institute of Environmental Medicine at the Karolinska Institute . . . conclude that long-term use of snuff does not have any marked effects on the major risk factors for cardiovascular disease. (p. 167).

18. Huhtasaari F, Lundberg V, Eliasson M, Janlert U, Asplund K. Smokeless tobacco as a possible risk factor for myocardial infarction: A population-based study in middle-aged men. *J Am Coll Cardiol* 1999; 34: 1784-1790.

The present observations would show that, from a cardiovascular perspective, the deleterious effects of snuff dipping are much less than those of cigarette smoking. This is a complicated message. Faced with anti-smoking campaigns and restrictions on sales of cigarettes, it is tempting for the tobacco industry to turn to less controversial alternatives, i.e. various forms of smokeless tobacco. (p. 1789).

19. Rodu B, Cole P. Nicotine maintenance for inveterate smokers. *Technology* 1999; 6: 17-21.

[M]odern smokeless tobacco products have three major benefits to offer the inveterate smoker. First, although smokeless tobacco is perceived as hazardous, it poses only about two percent of the mortality risk of smoking. Even the risk of oral cancer—the one consequential health effect of smokeless tobacco—is only one-half that of continued smoking. Smokeless tobacco causes none of the other health effects of smoking, including lung cancer, emphysema, and cardiovascular diseases. Second, nicotine is absorbed from smokeless tobacco in a manner very similar to that from smoking, therefore the craving of inveterate smokers usually is eliminated. In fact, serum nicotine levels from smokeless tobacco use remain elevated longer than they do from smoking, and tobacco consumption is reduced. In part for this reason, the third benefit of smokeless tobacco is that it is less expensive than cigarettes. . . . A major consideration regarding smokeless tobacco relates to its image as socially unacceptable. However, newer products are packaged in small, single-dose paper pouches that are imperceptible during use. In a recent pilot study, 16 of 63 inveterate smokers used smokeless tobacco to quit, and the product was accepted by both men and women. (p. 19).

20. Dretchen K, Slade J, Kessler D, Koop CE, et al. Conference on tobacco dependence: innovative regulatory approaches to reduce death and disease: selected excerpts from conference proceedings. In: Warner KE, Peck CC, Woosley RL, Henningfield JE, Slade J, Page J. Tobacco dependence: Innovative regulatory approaches to reduce death and disease. *Food and Drug Law J Supplement* 1998; 53: 115-137.

I [Ken Warner] did want to mention just two interesting substances that we ought to be thinking about as we go through this discussion. One is Snus [Swedish snuff], which has been mentioned here previously. This is the smokeless tobacco that is in widespread use, for many decades now, in Sweden that is very low in cancer-causing nitrosamines, and quite high in

nicotine. The evidence is that it increases health risks compared to that of nontobacco users very little. There appears to be a slight oral cancer risk.

[I]t appears that Swedish users of smokeless tobacco (snuff), who ingest similar amounts of nicotine to smokers, do not have a higher incidence of coronary disease than nontobacco users. (p. 476).

It is interesting to note that Sweden, which has the lowest incidence of tobacco-related harm among developed countries, has unintentionally been used as a reduced smoking paradigm. Sweden has relatively few smokers. . . . However, approximately 28% of adult Swedes use nicotine daily, the explanation being that approximately one third of all nicotine consumed is in the form of moist snuff The practice of using snuff has not been found to

these studies cannot exclude such a relationship, no significant association between snuff dipping and cancer in humans can be established” and further that these findings “have raised doubt as to the scientific justification for the currently used hazard labeling, ‘Causes cancer.’” In light of new evidence, the agency also suggested that the Swedish government renegotiate the issue with the [Commission of the European Communities].

The total ban on oral snuff imposed by the Commission of the European Communities—but not on nasal snuff products or on any other tobacco product—does not seem to be based on rational scientific considerations. . . . This author agrees fully with the opinion of Hoffmann and co-workers (1981) at the American Health Foundation: “Although we concur with other scientists” . . . “that snuff use may be a feasible alternative to cigarette smoking, we feel that no efforts should be spared to reduce the concentration of alkaloid derived N-nitrosamines in snuff, since the use of this type of tobacco product has been associated with an increased risk for cancer of the oral cavity.” (Citations omitted, p. 13).

25. Ramström L, Uranga R, Hendrie A (eds.). *Social and economic aspects of reduction of tobacco smoking by use of alternative nicotine delivery systems (ANDS)*, Adis International Limited, United Nations. 1998: 17.

[I]t is now evident that the risk of death and disease is related to not only the amount but also the nature of tobacco exposure; for example, daily cigarette smoking is far more dangerous than occasional use of Swedish snuff.

26. Tilashalski K, Rodu B, Cole P. A pilot study of smokeless tobacco in smoking cessation. *Am J Med* 1998; 104: 456-458.

Traditional smoking cessation programs have had limited success and only among smokers who can achieve nicotine abstinence. Inveterate smokers may benefit from strategies that focus instead on providing nicotine by a means other than cigarette smoking. Smokeless tobacco is a potential alternative for inveterate smokers because we have estimated its adverse health effects may be as low as 2% of those of smoking. (p. 456).

27. Ahlbom A, Olsson UA, Pershagen G. Health hazards of moist snuff. *SoS-Report* 1997; 11: 3-29.

Taken together, the data suggest that long-term use of snuff does not have any marked effects on the major risk factors for cardiovascular disease. (p. 17).

The health hazards of snuff are in all likelihood smaller than those associated with smoking. (p. 20).

28. Bolinder G. Smokeless tobacco – a less harmful alternative? In: Bolliger CT, Fagerström KO. (eds.) *The Tobacco Epidemic: Progress in Respiratory Research*. Volume 28; Karger Publishing, Basel. 1997: 199-212.

[C]ompared with the extremely high risk of developing cancer due to tobacco smoking (according to the WHO, 33% of all cancers in the industrialized world are caused by smoking), it seems as if the risks associated with the use of smokeless tobacco are obviously of minor importance. (p. 203).

The risk of adverse health effects is evidently less serious in smokeless tobacco users than in smokers (p. 208).

29. Borland R. Minimizing the harm from nicotine addiction. *Health Promotion J Australia* 1997; 7: 138-141.

Tobacco smoke contains more than 4000 different chemicals, many of which are known poisons, mutagens and carcinogens. It is generally accepted that most of the damage from smoking is due to components in the tar, and to a lesser extent, the carbon monoxide (CO). The contribution of the nicotine is believed to be lower, but still considerable. The strongest evidence for this is that smokeless tobacco, which has little tar, appears to be less harmful than the smoked product. (p. 138).

30. Balfour DJK, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996; 72: 51-81.

If nicotine preparations could be developed that were acceptable to smokers, there is the possibility of eliciting a substantial reduction in tobacco smoking, while not necessarily maintaining complete abstinence.

Such use of NRT [nicotine replacement therapy], although controversial for those hoping for a total extinction of nicotine use, without doubt would do more service to mankind and public health than what NRT could contribute in

programs are not very successful, largely because conventional approaches offer no alternative to giving up nicotine entirely, an unattainable goal for many smokers. Furthermore, these programs are unnecessarily limited, as they do not accommodate the fact that there are now several ways to satisfy a tobacco user's desire for nicotine without the health effects of smoking. Smoking cessation programs may become more successful when their providers recognize that the benefits of quitting smoking can be achieved without quitting nicotine altogether. (p. 112).

34. Vigneswaran N, Tilashalski K, Rodu B, Cole P. Oral tobacco use. (Letter to the Editor). *Oral Surg Oral Med Oral Pathol Radiol Endod*

3. Smoking is the most dangerous nicotine delivery system. Lifelong cigarette smokers lose almost 8 years of life on average compared with nonusers of tobacco: in contrast, smokeless tobacco users lose only 15 days.
 4. One third of current smokeless tobacco users are former smokers.
36. Benowitz NL. Medical implications. In: Davis RM (ed). Smoking cessation: Alternative strategies. Session III: Implications of alternative treatment goals. In: *Tobacco Control* 1995; 4: (suppl 2): S44-S48.

A potentially useful analysis is the epidemiology of snuff use in Sweden. Snuff users have plasma or urine nicotine and cotinine levels as high or higher than cigarette smokers. A recent epidemiological study reported that snuff dippers had the same odds ratio for myocardial infarction as those who did not use tobacco. In comparison, the odds ratio for cigarette smokers was substantially higher than that of either snuff users or those who used no tobacco. (p. S46).

37. Rodu B. For smokers only. How smokeless tobacco can save your life. Sulzburger & Graham Publishing, Ltd., New York; 1995.

[S]mokeless tobacco products allow you, the hard-core and long-term smoker, to take back a measure of control over your health by indulging in a far safer form of tobacco use. (Introduction, p. 8).

A switch to a safer delivery system, smokeless tobacco, will allow the 46 million smokers in this country (and the people they live with) to live longer, healthier lives. (p. 18).

If we look at “safe” to mean relatively safe or “safer,” something the government warnings inately avoid here, then use of smokeless tobacco products is far safer than cigarette smoking. . . .

Statistical dangers of using smokeless tobacco do exist, but they are considerably smaller than the dangers related to smoking cigarettes. (p. 29).

What about smokeless tobacco use and the development of heart disease? Within the past two years a couple of studies regarding this issue have come from Sweden (the smokeless tobacco capital of the world). In the first . . . [t]I). In t.0il allohSowyrd-c-8 but n t.0iI:

who were between 35 and 54 when the study started. . . . [T]he recorded risk for users of snuff was much smaller than for those who were either light or heavy smokers. In fact, the risk in smokeless tobacco users was the same as smokers who had quit from one to five years previously.

* * *

[R]egarding heart disease, it appears that *switching to smokeless tobacco is as beneficial as quitting smoking*.

What counts for you, then, is the fact that smokeless tobacco use carries fewer risks for all diseases than smoking, including . . . lung disease. (pp. 55 – 56).

If nicotine were responsible for circulatory problems, then users of smokeless tobacco, which contains as much nicotine, would suffer from heart disease and strokes at equivalent rates as smokers. However, there is strong evidence that this is not the case. Use of smokeless tobacco carries reduced risks for cardiovascular diseases compared with cigarette smoking. (p. 102).

If all smokers were instead addicted to smokeless tobacco, only 12,000 new cases of oral cancer (with a 50 percent survival rate) could be expected each year. This is only one-twentieth of all cancers that now result from smoking, and one-tenth of smoking related lung cancer cases! I haven't even mentioned the reduction in heart disease and emphysema deaths yet. *If all 46 million smokers used smokeless tobacco instead, the United States would see, at worst, 6,000 deaths from oral cancer, versus the current 419,000 deaths from smoking-related cancers, heart problems, and lung disease.*

* * *

Relative to cigarettes, smokeless tobacco products are a godsend. (p. 131).

[T]he average remaining life expectancy of a 35-year-old smokeless tobacco user is 45.92 years, which is merely four-hundredths of a year less than the nonuser of tobacco. Statistically speaking, use of full-bodied tobacco products with all the nicotine of cigarettes will cost the smokeless tobacco user only *fifteen days* of life! That's about 2,780 more days than the cigarette smoker lives. (p. 133).

As an alternative to cigarette smoking, smokeless tobacco is not perfectly safe, it is just *98 percent* less dangerous. (p. 181).

Since smokeless tobacco users live eight years longer than smokers, it isy four-hundredths of a yearj

38. Rodu B, Cole P. Would a switch from cigarettes to smokeless tobacco benefit public health? - Yes. *Priorities* 1995; 7: 24-30.

[S]mokeless tobacco use is 98 percent safer than cigarette smoking. Thus, it can save lives of smokers and of those persons who breathe second-hand smoke.

Contrary to a popular misperception, all forms of tobacco are not equally risky. Smokeless tobacco causes neither lung cancer nor other diseases of the lung, and users have no excess risk for heart attacks. In fact, the only consequential—but infrequent—adverse health effect of smokeless tobacco use is oral cancer. In 1981, writing in *The New England Journal of Medicine*, Dr. Deborah Winn and colleagues established that smokeless tobacco users are four times more likely to develop oral cancer than are nonusers of tobacco. However, this relative risk is only about one half the relative risk of oral cancer from smoking.

The number of deaths from smoking is almost 70 times higher than the number from smokeless tobacco use. In terms of life expectancy, the smokeless-tobacco user loses only about 15 days on average, compared with the eight years lost by the smoker.

Another major health benefit: smokers who switch to smokeless tobacco produce no passive smoke to harm others. The American Heart Association estimates that 40,000 Americans die annually from diseases related to second-hand smoke. No one dies from the secondary effects of smokeless tobacco use. Thus, this proposal could be recommended solely on the basis of lives saved through the elimination of the effects of passive smoking.

What do switchers accomplish? Our research shows that they will live, on average, as long as those smokers who quit nicotine altogether. They reduce their risks for smoking-related illness and death, which is the goal of all existing smoking cessation efforts. There is, of course, no debate about the ideal way to achieve this goal: complete tobacco abstinence. But that ideal is not always attainable since many smokers are unable to give up nicotine. Switching to smokeless tobacco is a small compromise with the ideal which reaps large individual and public health gains.

Substituting smokeless tobacco for smoking is a wise risk-reduction strategy because it reduces *all* smoking related risks and introduces no new risks.

Providing information about an alternative to smoking that is 98 percent safer is not only consistent with the highest standards of medical ethics, it is mandated by them.

39. Tilashalski K, Lozano K, Rodu B. Modified tobacco use as a risk-reduction strategy. *J Psychoactive Drugs* 1995; 27: 173-175.

A novel approach for smoking cessation has been proposed: that cigarette smokers unable or unwilling to quit change to smokeless tobacco (ST) use. In fact, surveys reveal that as many as 7% of former smokers have already modified their tobacco use to ST, which they perceive as less risky despite repeated warnings by medical authorities.

Data indicate that former smokers who now use ST have indeed chosen a safer mode of tobacco use that serves as a positive risk-reduction strategy. (Citations omitted, p. 173).

40. Vigneswaran N, Tilashalski K, Rodu B, Cole P. Tobacco use and cancer. *Oral Surg Oral Med Oral Pathol Radiol Endod* 1995; 80: 178-182.

Previous research has demonstrated that the relative risk of oral cancer with smokeless tobacco use is 4.2, about half of the risk from smoking (relative risk = 10 to 15). Mortality data from populations with sustained high-frequency smokeless tobacco use do not support the mistaken prediction of an epidemic of oral cancer with increasing smokeless tobacco use. In fact, the risks of smokeless tobacco use compare so favorably with those of smoking that smokers who switch to smokeless tobacco reduce their risks for all tobacco-related illnesses including oral cancer. Although some criticize this proposal as less than an ideal solution for the nation's smokers, full adoption of this strategy would eventually save over 400,000 lives each year. (Abstract, p. 178).

[L]arge scale vital statistics from Sweden and France strongly support the suggestion that if tobacco is to be used, it should be in the form of ST [smokeless tobacco] and not cigarettes. The population that uses ST in lieu of smoking is, in effect, protected from lung cancer and other major smoking-related diseases and suffers little or no increased risk of oral cancer. (p. 180).

A recent proposal has recommended ST use as an alternative for adult smokers who are unable or unwilling to stop smoking. Crucial to this proposal is the realization that ST use carries a lower risk of oral cancer than does continued smoking and has virtually no other consequential adverse effects. (p. 180).

A switch to ST use for inveterate smokers can be . . . justified – if not ethically mandated. Full adoption of this strategy would eventually save over 400,000 lives each year, a 98% reduction in deaths from *all* tobacco-related illnesses.

* * *

Although all tobacco use carries some risk, a reduction in risks for these inveterate smokers by a switch to ST will save lives. (p. 180).

* * *

By effective delivery of similar nicotine doses for only a fraction of the health risks associated with smoking, smokeless tobacco is a solution to the dilemma of total abstinence versus continuation of smoking. . . . Rather than condemning the addiction itself, this proposal focuses instead on smokers, providing them with a rationale to fundamentally change their addiction and related health risks. (p. 33).

42. Rodu B, Cole P. Tobacco-related mortality. (Letter to the Editor). *Nature* 1994; 370: 184.

We suggest that abstinence is not the only approach to reducing tobacco-related mortality: for smokers addicted to nicotine who would not otherwise stop, a permanent switch to smokeless tobacco could be an acceptable alternative to quitting. (p. 184).

43. Whidden P. Smokeless fire. (Letter to the Editor). *Nature* 1994; 371: 564.

A massive shift towards the use of oral tobacco by smokers would considerably cut the tens of thousands of deaths caused by tobacco-smoke pollution.

44. Kozlowski LT. Reduction of tobacco health hazards in continuing users: Individual behavioral and public health approaches. *J Substance Abuse* 1989; 1: 345-357.

There is no doubt that smokeless tobacco products are gram for gram less hazardous than smoked tobacco products. Smokeless tobacco products present no fire risks. . . . No added doses of smoke toxins (e.g. carbon monoxide, tar) get into the lungs of the user of oral or nasal snuff. There are no apparent lung cancer risks of using smokeless tobacco. It may be appropriate here to emphasize again that I do not suggest that smokeless tobacco products are safe. Nonetheless, these products are unquestionably less risky than smoked tobacco products.

One advantage of smokeless products is that it is easier to ration the dose. . . . In other words, when one limits smokeless tobacco to a certain amount per day, one does not have the same compensatory dosing problems found with smoked tobacco products. (Citations omitted, pp. 352-53).

45. Peto R. Control of tobacco-related disease. In: *The Value of Preventive Medicine*. The Ciba Foundation Symposium 110. Pitman, London. 1985; pp. 126-142.

As well as thinking about the composition of cigarettes, we should also think about the use of tobacco in a much less hazardous form, including perhaps not only the usual alternatives such as pipes and cigars, but also various forms of “smokeless” tobacco (including nasal snuff, chewing tobacco, and “dipping” tobacco—that is, powdered tobacco that is usually held between the gum and cheek). The exact hazards associated with such habits are not yet known, but the preliminary evidence thus far available suggests that they are unlikely to be substantial in comparison with the vast mortality now being produced by tobacco smoking (unless promotion of smokeless tobacco among the young engenders nicotine addiction that eventually leads to smoking). (Citation omitted, p. 127).

If this [snuff dipping] or some other such habit were to become widespread and did to any substantial extent replace smoking (particularly of cigarettes), then the net effect would be likely to be a reduction in tobacco-induced mortality. For, although snuff dipping causes a vast increase in the *relative* risk of cancer of the gum and cheek (together with the same sort of risks of cancers of other parts of the mouth that smoking produces), the *absolute* excess risks of death from oral cancer associated with the habit in the South-Eastern United States appear to be at most a few per cent of the total risk of death produced by cigarette smoking. Although the absolute risks in other populations might, of course, be considerably different (especially if some diseases other than oral cancer are found to be increased by tobacco “dipping”) the use of smokeless tobacco is still likely to be much less hazardous than is tobacco smoking, especially of cigarettes. (Citation omitted, p. 128).

46. Russell MAH, Jarvis MJ, West RJ, Feyeravend C. Buccal absorption of nicotine from

47. Kozlowski LT. Less-hazardous tobacco use as a treatment for the “smoking and health” problem. In: Smart RG, Cappell HD, Glaser FB, Israel Y, Kalant H, Popham RE, Schmidt W, Sellers EM (eds.) *Research Advances in Alcohol and Drug Problems*. Volume 8. Plenum Press, New York; 1984: Chapter 11, pp. 309-329.

This chapter will argue that the use of less-hazardous tobacco, if prohibitionistic impulses can be put aside, may have an important role in the treatment of the smoking and health problem. . . . The phrase “less-hazardous tobacco use” is meant to be inclusive. Cigarettes, for example, are the most hazardous tobacco products overall. . . . On the other hand, some less-hazardous tobacco products are less-hazardous in certain respects no matter how they are used: chewing tobacco, for example, carries no risks of fire and essentially no risk of lung disease. (p. 310).

There is really no dispute about whether smokeless tobaccos present fewer hazards to the user than do smoking tobaccos. Smokeless tobaccos expose the lungs to essentially no tobacco toxins. No carbon monoxide and no tar is produced. The oral cancers associated with oral smokeless tobaccos are substantially less lethal and are more easily diagnosed than lung cancers. In addition, smokeless tobaccos pose no problems of second-hand smoke and no risks of fire. (Citations omitted, p. 319).

48. Kozlowski LT. Pharmacological approaches to smoking modification. In: Matarazzo JD, Weiss SM, Herd JA, Miller NE, Weiss SM (eds.) *Behavioral Health. A handbook of health enhancement and disease prevention*. John Wiley & Sons, New York; 1984: Chapter 45, pp. 713-728.

Some less hazardous forms of tobacco use (smokeless tobaccos, pipes, cigars) are pharmacotherapies that can be self-applied easily by those who are poorly motivated to modify their smoking. (p. 714).

The use of smokeless tobaccos is not associated with lung cancer, chronic obstructive lung disease, or bronchitis. Oral smokeless tobaccos are associated with oral cancers, however, and manufactured nasal snuff may cause nasopharyngeal cancer, although direct evidence is lacking for such an effect.

* * *

Smokeless tobaccos not only act to eliminate the possible problems of passive smoking, they also eliminate the definite problems of passive fire-starting. (Citations omitted, p. 724).

49. Russell MAH, Jarvis MJ, Devitt G, Feyerabend C. Nicotine intake by snuff users. *Br Med J* 1981; 283: 814-817.

From our results snuff use may clearly be an efficient method of nicotine intake. This suggests that it might prove sufficiently acceptable to smokers, not only as a temporary substitute to help those who are trying to give up smoking but as a long-term alternative to continued cigarette smoking. . . .

Unlike tobacco smoke, snuff is free of tar and harmful gases such as carbon monoxide and nitrogen oxides. Since it cannot be inhaled into the lungs, there is no risk of lung cancer, bronchitis, and emphysema.

* * *

[T]he rapid absorption of nicotine from snuff confirms its potential as an acceptable substitute for smoking. Switching from cigarettes to snuff would substantially reduce the risk of lung cancer, bronchitis, emphysema, and possibly coronary heart disease as well, at the cost of a slight increase in the risk of cancer of the nasopharynx (or oral cavity in the case of wet snuff). Another advantage of snuff is that it does not contaminate the atmosphere for non-users. (p. 816).

50. Kirkland LR. The nonsmoking uses of tobacco. (Letter to the Editor). *NEJM* 1980; 303: 165.

Smokeless Tobacco and Health

The principal disease claimed to be associated with smokeless tobacco is oral cancer.¹

The purpose of this attachment is to provide an overview of the scientific studies published to date regarding smokeless tobacco and oral cancer.²

I. Overview

There are 34 epidemiological studies published in the scientific literature that report data or information regarding smokeless tobacco and oral cancer. Epidemiological studies – “case-control” or “cohort” studies – investigate diseases in human populations by statistical methods and identify factors that are statistically associated with the occurrence of those diseases. More than half of the epidemiological studies relating to smokeless tobacco and oral cancer (20 of the 34 studies) do not report a statistically significant association between smokeless tobacco use and oral cancer. Furthermore, the overwhelming majority of the more recent studies do not report a statistically significant association between smokeless tobacco use and oral cancer.³

¹ While claims have been made that smokeless tobacco may be associated with cancers at other sites, the 1986 Surgeon General’s Report concluded that the evidence relating to such cancers is “sparse” and that the results are “inconclusive.” 1986 Surgeon General’s Report at xxiii. Studies published since that time do not contradict that conclusion.

² This overview does -1.r6.0[48

In 1986, the Surgeon General's Report concluded that smokeless tobacco "can cause cancer." At the time of the Surgeon General's Report, the most frequently cited study supporting this conclusion was Winn et al. 1981 ("Winn"), a case-control study of mostly elderly women from North Carolina. However, as discussed below, substantial scientific research relating to smokeless tobacco and oral cancer has been conducted since the publication of the Surgeon General's Report, leading the European Union to eliminate the phrase "causes cancer" from smokeless tobacco warning labels.

II. Epidemiological Studies

Figure 1 below summarizes the epidemiological studies relating to smokeless tobacco and oral cancer. The left hand column lists those studies that report data or information indicating no statistically significant association between smokeless tobacco use and oral cancer in the population studied ("negative studies"). The right hand column lists those studies that report data or information indicating a statistically significant association between smokeless tobacco use and oral cancer in the population studied, or in a subgroup thereof ("positive studies").

1991, Johansson et al. 1991, Summerlin et al. 1992, Ashrafi et al. 1992, Patel et al. 1993.

Fig. 1 Epidemiological Studies Relating to Smokeless Tobacco and Oral Cancer

Negative	Positive
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or (iii) over the course of the last twenty years since the publication of Winn (70% of the studies are negative).

Moreover, Figure 1 shows that, at the time of the 1986 Surgeon General's Report, 50% of

our study.”⁷ In Lewin et al. 1998, the study population consisted of 545 head and neck cancers and 641 controls. The authors concluded that: “Overall, the use of oral snuff had little or no effect on risk.”⁸

Another large-scale, epidemiological study that focuses specifically on smokeless tobacco is Sterling et al. 1992. Sterling is one of the few U.S. epidemiological studies that is national in its scope, rather than limited to a particular state or a particular area of the country. It used the National Mortality Followback Survey and the National Health Interview Survey to compute risk estimates for mortality for all cancer, oral cancer, and cancer of the digestive organs for use of smokeless tobacco, controlling for potential confounding from smoking, drinking alcohol, and occupation. No statistically significant associations were found for any of these cancer groups.

The study most frequently cited at the time of the 1986 Surgeon General’s Report for the proposition that smokeless tobacco causes oral cancer was Winn et al. 1981. Winn is a retrospective case-control study conducted in the 1970s involving 232 cases comprised mostly of elderly women from the Piedmont region of North Carolina with oral and pharyngeal cancer and 410 controls. The authors, as well as other researchers, recognize that the study has limitations.⁹

One limitation is that the study group in Winn is not representative of smokeless tobacco consumers or the U.S. population in general. In addition, according to Dr. Deborah Winn, lead

⁶ Lewin et al. 1998 at 1367-68.

⁷ Schildt et al. 1998 at 344.

⁸ Lewin et al. 1998 at 1369.

⁹ See Lewin et al. 1998 at 1374; Sterling et al. 1992 at 229-30.

author of the study, virtually all of the snuff used in the study was of the “dry” type.¹⁰ This type of snuff has negligible usage and is not representative of smokeless tobacco products in the

statistically significant association only in a subgroup of the study population. In both studies, the subgroup is defined as females who do not smoke. Furthermore, in both studies, the number

cancer is based on five smokeless tobacco consumers. When an association is based on such a small number of individuals, the statistical significance may depend solely on the inclusion or deletion of one or two individuals among the cases.

Finally, none of the six positive studies published since Winn is generally cited in the scientific literature for the proposition that smokeless tobacco causes oral cancer. Rather, Winn and the 1986 Surgeon General's Report continue to be cited as support for that proposition.

III. European Community Warning

As a result of more recent studies published relating to smokeless tobacco and oral cancer, the European Union issued a directive in June 2001¹⁶ eliminating the warning "Causes cancer" from the warnings required on smokeless tobacco products sold in its Member States.¹⁷ Dr. Lars Ramstrom, Director of the Stockholm Institute for Tobacco Studies, recently explained the genesis of the change in the European Union smokeless tobacco health warning. He noted that a report issued in 1997 by the Swedish National Board of Health and Welfare ("NBHW"),¹⁸ which reviewed then recent studies relating to smokeless tobacco and oral cancer, caused the NBHW to "feel uneasy in its role as signatory of the legally prescribed [European Union] warning label on snuff packages: 'Causes cancer.' So the NBHW sent a letter to the Ministry of Health, drawing attention to the manifested lack of scientific basis for this warning label."¹⁹

¹⁶ Council Directive 2001.

¹⁷ The warnings have been changed from "Causes cancer" and "Tobacco seriously damages health" (Council Directive 1992 (*citing* Council Directive 1989)) to "This tobacco product can damage your health and is addictive." (Council Directive 2001).

¹⁸ Ahlbom et al. 1997.

¹⁹ Ramstrom 2000 at 169.

As a result of this and other submissions, the European Union issued its new directive on tobacco labeling, endorsed by both the European Council and Parliament, eliminating “causes cancer” from the health warning on smokeless tobacco products.

IV. Conclusion

The majority of the epidemiological studies relating to smokeless tobacco do not report a statistically significant association between smokeless tobacco use and oral cancer. The proportion of negative studies has been even higher since the publication of Winn and the 1986 Surgeon General’s Report and no study published since Winn has replicated its result. Against this backdrop, it is USSTC’s position that smokeless tobacco has not been shown to be a cause of any human disease.²⁰

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