American Association of Public Health Physicians

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Tobacco Control Task Force
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AAPHP Resolution and White Paper

The Case for Harm Reduction

for Control of Tobacco-related Illness and Death

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Abstract

"Tobacco Harm Reduction" is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous smokeless tobacco products.

In practical terms, enhancement of current policies based on the premise that all tobacco products are equally risky will yield only small and barely measurable reductions in tobacco-related illness and death. Addition of a harm reduction component, however, could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years. These projections are based on the expectation that a significant number of smokers will continue to smoke and the knowledge that risk of death from lung cancer continues for decades after the smoker has stopped smoking.

The literature review and bibliographic references that stand behind these projections are to be found in this AAPHP White Paper.

Executive Summary

"Harm Reduction" in the context of this executive summary is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced.

A simplified explanation of the risks of different tobacco products can be provided using a scale from zero to 100, with a score of 100 representing the average loss of 8 years of life due to cigarette smoking and a score of 0.001 representing the level of risk acceptable to the American public for other consumer products. This represents a five order of magnitude (one million times) difference in risk of death comparing cigarettes to foods and over-the-counter medications.

More than 90% smoking-related deaths are due to lung cancer, other pulmonary diseases, and cardiovascular diseases among smokers; and deaths in non-smokers from environmental tobacco smoke. Switching to smokeless tobacco would eliminate these risks. There is no disease for which the risk from smokeless tobacco is greater than the risk for smoking. Therefore, the theoretical maximum risk for a smokeless tobacco product would be about 10 (one order of magnitude less risk than cigarettes).

The problem with cigarettes appears to be the process of combustion itself, with direct inhalation of concentrated products of combustion. Some experts believe that such smoking of any plant material (even dried cabbage or lettuce) would yield high rates of cardiac and pulmonary disease and cancer, even without the carcinogens present in tobacco.

Case-control studies show that the highest risk smokeless tobacco product, powdered dry snuff, confers a risk rating of about 2. The best available data suggests that the lowest risk smokeless tobacco product (low nitrosamine snus) carries a theoretical risk rating of about 0.3. Thus, while reducing the risk of tobacco related death by more than 98%, (two orders of magnitude less risk) smokeless tobacco products are still 300 to 2,000 times more hazardous (two to three orders of magnitude more risk) than foods and over-the-counter medications.

Current tobacco control policies are based on the premise that all tobacco products are equally risky, and that smokers should quit or face death from tobacco related illness. This policy ignores what we know about the relative risk of smokeless tobacco products, and ignores what we know about the strength of the nicotine addiction.

In practical terms, enhancement of current policies will yield only small and barely measurable reductions in tobacco-related illness and death. Addition of a harm reduction component, however, could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years. These projections are based on the expectation that a significant number of smokers will continue to smoke and the knowledge that risk of death from lung cancer continues for decades after the smoker has stopped smoking.

Many who oppose tobacco harm reduction mistakenly believe that switching from cigarettes to smokeless tobacco will increase the risk of oral (mouth and throat) cancer. This is simply not true. There is no illness and no form of cancer for which any form of smokeless tobacco carries a risk higher than the risk from cigarette smoking. Both smoking and use of smokeless tobacco cause white patches in the mouth known as leukoplakia. Smoking-related leukoplakias account for 75% of oral cancer in the U.S.A. Smokeless tobacco related leukoplakias rarely progress to cancer.

Another common objection to tobacco harm reduction is based on the expectation that encouraging smokers to switch to smokeless tobacco will increase the numbers of teens initiating tobacco use and decrease the numbers of smokers who quit. Experience in Sweden shows that it is feasible to get smokers to switch to snus (a low risk form of smokeless tobacco consisting of moist snuff usually sold in miniature tea-bag-like pouches to be placed between the upper lip and gum) without increasing the number of children and youth initiating tobacco use and without decreasing the number of smokers who quit each year.

Even if a harm reduction approach doubles the number of people using tobacco products in the United States, the order-of-magnitude differences in risk of illness and death comparing smoking to smokeless tobacco products would still result in the same 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years.

Thus, it is our (The American Association of Public Health Physicians) perception that the current base of tobacco-related science is more than sufficient to support adding harm reduction as a component of programming intended to reduce tobacco-related illness and death.

While some have proposed limiting harm reduction to medicinal nicotine products, such a limitation would likely place the reduced risk products out of reach of rebellious teens, socially disadvantaged minorities, gays, and other high risk groups. We are therefore recommending that the approach to harm reduction be based on tobacco products sold in the same retail outlets as cigarettes, and at comparable prices.

All this considered, children and youth should be advised never to initiate tobacco use, and current tobacco users should be encouraged to quit. For smokers unable or unwilling to quit (that is, they are unable or unwilling to overcome their addiction to nicotine), encouraging them to switch to the lowest risk ST products would be an effective way for them to reduce their risk of tobacco-related illness and death.

The literature review and bibliographic references that stand behind this Executive Summary are to be found in this AAPHP White Paper.

This resolution and white paper were approved by the American Association of Public Health physicians at their general membership meeting in San Diego, October 26, 2008.

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Resolution on Tobacco Harm Reduction

Whereas there is substantial scientific evidence that selected smokeless tobacco (ST) products can satisfy the nicotine addiction of inveterate smokers while **eliminating most, if not all, risk of pulmonary and cardiovascular complications** of smoking and while reducing **the risk of cancer** by more than 95% and

Whereas transitioning smokers to selected ST products will eliminate **environmental tobacco smoke and fire-related hazards** and

Whereas current **"abstain, quit, or die"** tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine, and

Whereas there is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation and

Whereas health-related agencies and organizations, both within the United States and Abroad have already gone on record **endorsing Harm Reduction** as an approach to further reducing tobacco related illness and death, and

Whereas current federal policy requires tobacco product labeling that leaves the **incorrect impression that all tobacco product present equal risk**; and

Whereas certain **tax policies** put ST products at a competitive disadvantage, compared to cigarettes; and

Whereas harm reduction approaches to reducing tobacco related illness and death promise to be more **politically and financially viable** than alternative approaches because harm reduction approaches can secure the support of many tobacco-industry-related stakeholders.

Be it Therefore Resolved that the **American Association of Public Health Physicians** go on record as **favoring Harm Reduction** as a component of public health efforts to reduce tobacco-related illness and death and

Be it further **Resolved** that such efforts shall encourage the **following approaches**:

1. Product labeling to inform consumers of the relative risk profiles of the various classes of tobacco products.
2. Governmental and health-organization sponsored health education to educate consumers to the risk profiles of the various classes of tobacco products
3. Revision of taxation schemes at federal, state, and local levels to reflect risk profiles and costs to society of the various classes of tobacco products
4. Regulation of the manufacturing and marketing of the various classes of tobacco products reflective of their respective risk profiles and costs to society

Be it further **Resolved** that **funds be established** through taxation of tobacco products to facilitate government-sponsored (as opposed to tobacco company sponsored) **research and program evaluation** to refine our understanding of the relative risk profiles of the various classes of tobacco products, market trends, and the impact of governmental policy and programming on tobacco product consumption.

Whereas # 1 – Evidence of Lower Risk

Health Risks of Cigarette Smoking

As background for this literature review, the following summary data is provided from the Centers for Disease Control (CDC) web site. [1,2]

"Cigarette smoking is the leading cause of preventable death in the United States and produces substantial health-related economic costs to society." [1]

About 438,000 U.S. deaths are attributable each year to cigarette smoking. [2] Of these, about 38,000 are due lung cancer or ischemic heart disease due to exposure to environmental tobacco smoke. [2]

Table 1.
Annual Smoking-Attributable Deaths in the United States among 45 Million Smokers

Cause of Death	Range of RR[1,2]	Estimated Numbers of Deaths per Year in the United States	
Cancer			
Mouth and throat	5-11	4,868	
Pancreas	2.3	6,509	
Lung	13-23	123,836	
Other		23,316	
All Cancer			158,529
Cardiovascular Diseases			137,979
Respiratory Disorders			101,454
All Deaths Among Smokers			397,962[2,4]
Environmental Tobacco Smoke			
Lung cancer		3,000	
Cardiovascular		35,000	
All Environmental Tobacco Smoke			38,000[3]
All			435,962[4]

1 RR = Relative Risk; the ratio of risk comparing users to non-users; an RR of 1 means no increased Risk; 1.2 means a 20% increase; 2.0 means double the risk, etc. Range reflects differences from different case-control studies.

2 CDC SAMMEC, http://apps.nccd.cdc.gov/sammec/login.asp

3 CDC, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a1.htm

4 Does not include small numbers of deaths from a variety of other causes

(note: Estimated numbers of deaths derived by CDC by a complex software package using data from research studies, national surveys, and death records)

ST Use- Cardiovascular Disease

Over the past 15 years, ten epidemiologic studies have examined the risk of cardiovascular diseases among ST users. Eight of the studies found that ST users had no increased risk for heart attacks or strokes [3-10]. The other two reported modestly positive associations, with ST users having relative risks compared to non-users (RRs) of 1.2 and 1.4 [11,12], which are lower than those of smokers.

In 2003, Asplund completed a comprehensive review of the cardiovascular effects of ST use [65]. He concluded that, in distinct contrast to smokers, ST users do not exhibit any significant differences from nonusers of tobacco with regard to the following measures of cardiovascular health: heart rate, blood pressure, cardiac output and maximal working capacity, levels of hemoglobin and hematocrit, leukocytes, antioxidant vitamins, fibrinogen, components of the fibrinolytic system, C-reactive protein and thromboxane A2 production. In addition, ST users did not show important smoking-associated vascular changes, including increased thickness of blood vessels and atherosclerotic plaque development. In summary, most of the medical and epidemiologic evidence documents that ST users do not have elevated risks for cardiovascular diseases.

ST Use- Pulmonary Disease

According to the 2007 statement on harm reduction by the Royal College of Physicians in London, "ST products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer." [14]

In February of 2008, a European Commission released a report on the health effects of ST products including the following statements:

> "Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU (The ASPECT Consortium 2004). There is no consistent evidence that any ST products cause any of these major respiratory diseases. Complete substitution of ST products for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking." [15]

In a 2007 paper on snus, Foulds and Kozlowski concluded: "Importantly, for two of the most prevalent smoking-caused diseases (lung cancer and chronic obstructive pulmonary disease), snus poses no risk." [16]

Oral leukoplakia

Oral leukoplakia is a term used frequently in discussions about ST use. In 1978 the World Health Organization defined oral leukoplakia as a "white patch or plaque that cannot be characterized clinically or pathologically as any other disease." (17) Later this definition was recognized as overly broad; in 1984 it was revised to distinguish leukoplakias associated with ST use from those associated with smoking (18). The distinctions were based on prevalence, the location in the mouth, the proportion showing microscopic features of dysplasia, and the rate of malignant transformation (18,19).

Oral leukoplakia is a rare condition, occurring in less than 1% of the general population. Smoking-related leukoplakias occur primarily in long-time smokers 40 to 60 years old (20,21), and they most

commonly involve the undersurface of the tongue and soft palate, locations accounting for 75% of oral cancer in the U.S. (21,22)

Leukoplakias are seen in up to 60% of ST users (23,24), within 6 months to 3 years of starting ST use (25,26). They primarily occur at the site of ST use (i.e. mucosa of the gingival and lip) and are largely a result of local irritation (25,27). The frequency of appearance depends on the type of ST that is used. Moist snuff is more strongly associated with leukoplakia than chewing tobacco, which is attributed to high pH among the former (26). However, leukoplakia is less frequently seen in users of pre-portioned pouches than in those using loose forms of moist snuff (28).

There are distinct differences in the prevalence of dysplasia in leukoplakias associated with ST and smoking. Dysplasia is seen infrequently in ST leukoplakias (less than 3%) (29-32). Furthermore, even when dysplasia is present in ST leukoplakia, it usually is found in earlier stages than in leukoplakias due to smoking (33,34), where it is seen in about 20% of cases (35).

ST leukoplakias only rarely progress to cancer. For example, one prospective study found no case of cancer in 1,550 ST users with leukoplakia who were followed for 10 years (36), and a second study reported no case of oral cancer among 500 regular ST users followed for six years (37). A retrospective study of 200,000 male snuff users in Sweden found only one case of oral cancer per year, an extremely low frequency (38). In a more recent study, a group of 1,115 snus users in Sweden who presented with leukoplakia in 1973-74 were followed for 27-29 years. The study documented that the lesions had completely disappeared in 62 persons who had quit snus permanently. Cancer record linkages revealed three cases of oral cancer, resulting in a standardized incidence ratio of 2.3 (95% CI = 0.5-6.7) (39).

Leukoplakias in smokers have a higher rate of malignant transformation. In 1984 a follow-up study reported that 17% of smoking leukoplakias transformed into a cancer over seven years (40).

In summary, leukoplakia occurs commonly in ST users, but it primarily represents irritation and only very rarely progresses to oral cancer. In 2008 a systematic review of the epidemiologic evidence came to the following conclusion:

> "Thirty-three epidemiological studies consistently show a strong dose-related effect of current snuff on oral mucosal lesion prevalence. In Scandinavia, users have a near 100% prevalence of a characteristic "snuff-induced lesion", but prevalence of the varied lesions reported in the USA is lower. Associations with chewing tobacco are weaker. The lack of clear association with former use suggests reversibility following cessation, consistent with experimental studies showing rapid lesion regression on quitting." (41)

ST Use- Cancer

Oral Cancer. ST use has been associated with cancer – most specifically oral cancer – for many decades. It is widely perceived – both by laypersons and medical professionals – that the association is strong and applies to all ST products. However, epidemiologic studies dating back to the 1950s provide convincing evidence that most ST products increase oral cancer risks only minimally.

Rodu and Cole reviewed 21 epidemiologic studies published from 1957 to 1998 [42]. Unlike previous reviewers, these authors derived relative risk (RR) estimates for cancers of the mouth and

associated upper respiratory sites related to use of chewing tobacco, moist snuff, dry snuff and a fourth category in which the type of ST was unclear or undetermined (ST unspecified). This study found that use of chewing tobacco and moist snuff were associated with only minimally elevated risks, while use of dry snuff conferred higher risks.

Chewing tobacco has been studied at least once in each of four decades from the 1960s to the 1990s. The data clearly show that chewing tobacco use is associated with only slightly elevated cancer risks; RRs for all anatomic sites are under 2 with confidence intervals including 1 (i.e. no perceptible increase in risk). The first study evaluating the risk of chewing tobacco appeared in 1962 [43]. There were two studies in 1977 [44,45], two in 1988 [46,47], and four studies from 1993 to 1998 [48-51].

As with chewing tobacco, summary RRs are only slightly elevated for moist snuff, with three RRs at or below 1 and the highest RR at 1.2. RRs for moist snuff were reported first in 1977 [44]. Another study appeared in 1988 [47], and five additional studies were published from 1993 to 1998, as this ST type came under intense scrutiny [48-52].

Two of the seven studies on moist snuff were Swedish, both appearing in 1998 [51,52]. These studies have received considerable attention among tobacco researchers, particularly in Europe, because they are viewed as showing no oral cancer risk for Swedish products. They formed the basis for the Swedish government's decision in 1999 to recommend that the European Union (EU) oral cancer warning labels be removed from ST products. An EU directive in 2001 accomplished that objective and specified a new warning, "This tobacco product can damage your health and is addictive" [53]. Notably, the other five studies contributing to the summary RRs for moist snuff were American, and they reported RRs very similar to those of the Swedish studies.

Summary RRs for dry snuff use are higher, ranging from 4 to 13, although the confidence intervals for these estimates are wide. The first study appeared in 1962 [43], followed by studies in 1981 [54], 1988 [46], and 1994 [49], spanning a period of 32 years.

Eight studies provided RRs for ST-unspecified, five of which appeared between 1957 and 1969 [55-59]. Additional studies appeared in 1992 [60], 1993 [48] and 1998 [61]. RRs for ST-unspecified range from 1.5 to 2.8, and most are statistically significant. For all sites the summary RR is 1.9 (CI=1.5-2.3), which is intermediate between the low risks reported for chewing tobacco (1.2, 1.0-1.4) or moist snuff (1.0, 0.8-1.2) and the higher risk for dry snuff (5.9, 1.7-20). The intermediate risks for this ST category probably reflect the use of either the lower- or higher-risk products among different groups within the studies.

Prior to the 2002 analysis by Rodu and Cole, the distinctive risk profiles of moist snuff and chewing tobacco on one hand, and dry snuff on the other, had gone unnoticed. In fact, the low oral cancer risk associated with chewing tobacco had been discussed briefly in only one article [62]. No distinction in risks had been made previously between dry snuff and moist snuff, even though these products are considerably different with regard to tobacco content and processing, as noted earlier.

The distinction between the higher risk profile of American dry snuff and the minimal risk conferred by chewing tobacco and moist snuff continues to be ignored in reports from governmental and other organizations. In 2007 the International Agency for Research on Cancer issued IARC Monograph 89 on ST products [63]. Although the publication distinguished between chewing tobacco, moist snuff and dry snuff in the section on ST use, no such distinction was made in the

section on health effects. Similarly, in 2008 the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) from the European Union issued a report on the health effects of ST products [64]. Differences in risk among American products were minimized, even after a communication from the present author (BR) providing the scientific basis for the distinction. On the other hand, in 2007 the Royal College of Physicians issued a report on tobacco harm reduction, which contained a section on the health risks of ST use [14]. That report clearly discussed oral cancer risks separately for American moist snuff, chewing tobacco and dry snuff, and it further stated that the 1981 Winn study [54], showing the highest risks for oral cancer, was based exclusively on women in the Southeast U.S. who used powdered dry snuff. It is difficult to understand why the IARC and SCENIHR reports failed to make a similar distinction, since the details of the Winn study were disclosed by Winn herself in an IARC publication [65] and in another scientific publication [66].

The majority of epidemiologic studies regarding ST use and oral cancer have limitations, many of which are typical for case-control studies, and some important for understanding unique oral cancer risks. Most of them did not control for confounding by two strong determinants of oral cancer, cigarette smoking and alcohol use. Positive confounding by smoking would occur if ST users smoke more than do nonusers of ST. This would result in artificially high risk estimates for oral cancer among ST users. On the other hand, negative confounding is plausible and would occur if smoking rates are lower among ST users than among nonusers of ST. This would result in artificially low risks for oral cancer among ST users.

Only three studies [51,52,54] controlled for alcohol use, where only positive confounding is likely. Thus, control for alcohol consumption in all studies probably would have reduced somewhat many of the estimates of mouth cancer risk associated with ST use.

However, even with these limitations, the results of these studies are reasonably consistent with regard to mouth cancer risks from long-term use of moist snuff and chewing tobacco. In their review Rodu and Cole concluded that "the abundance of data now available indicates that commonly used ST products increase the risk of oral and upper respiratory tract cancers only minimally." [42]

Since the 2002 review five epidemiologic studies, two from Sweden and three from the U.S., have been published [67-71]. In all of these studies ST use was not associated with a significant increase in mouth cancer risk. In 2004 a group of epidemiologists concluded that the evidence linking ST use and oral cancer was "not decisive" [72]. These investigators commented that many claims in the media "overemphasize the risk of oral cavity cancer [from ST use], reaching beyond the scientific data."

In 2007 a meta-analysis concluded that "ST, as used in America or Europe, carries at most a minor increased risk of oral cancer." [73]

Pancreas cancer. Since 2004 four epidemiologic studies have evaluated the risk of pancreas cancer among ST users; two were based in the U.S., one in Norway and one in Sweden. An American study published in 2004 revealed that ever ST users had a RR of 1.4 (95% CI = 0.5 – 3.6) for pancreas cancer, compared with non-users of tobacco [74], and the RR was 1.1 (95% CI = 0.4 – 3.1) among exclusive ST users. The study did not control for diabetes or family history of pancreas cancer, which had been found in a previous report to be significant risk factors for the disease in this cohort [75].

In 2005 a study based in Norway found that ST users had a RR of 1.7 (95% CI = 1.1 – 2.5) [76], compared with nonusers of tobacco. However, this study was strongly criticized on a number of technical issues [77]. First, the investigators created a mixed referent group for the SLT analysis by combining never and occasional users (the designation of exposure groups, and especially of the referent group, greatly affects risk estimates in a study as small as this). They failed to provide risk estimates using the four customary SLT exposure categories that they described in their methods section: never users (referent group), regular current, occasional current, and regular former users. Second, they did not control for alcohol use. This was a critical error, as alcohol consumption was reported as the strongest risk factor for pancreas cancer in the earlier report of this cohort, with odds ratios up to 11 [78]. Finally, the study authors used an unusual procedure to adjust for the effects of smoking, which may have affected the risk estimates for ST users.

In 2007 a Swedish study found that Swedish construction workers who currently used ST had a RR of 2.1 (95% CI = 1.2 – 3.6) [71], compared with nonusers of tobacco. This study is one of a series produced by investigators at the Karolinska Institute.

In 2007 a case-control study involving 800 patients with pancreas cancer and 800 controls found that there was no association between ever-use of chewing tobacco or snuff and pancreatic cancer [79]. The adjusted odds ratio among chewing tobacco users was 0.6 (95% CI = 0.6 – 1.4), and the adjusted odds ratio for snuff users was 0.5 (95% CI = 0.1 – 1.5), when compared with never-users of tobacco. The results were adjusted age, sex, race/ethnicity, cigarette smoking, history of diabetes, alcohol consumption, educational level, state of residency, and marital status. This study found that the odds ratio among ever smokers was 1.6 (95% CI = 1.2 – 1.9), and a dose-response effect based on pack-years was evident.

Comparison of the health risks of ST use with those of smoking

According to the most recent data from CDC, [1,2] only 34% of smoking-related deaths are due to cancer. Since the data in the literature reviewed above suggests that the only substantial health hazard of ST is related to cancer at sites other than the lung, substituting ST for cigarettes would reduce the death toll from tobacco products from 438,000 per year to less than 34,700. The more detailed studies, presented in the literature review in this report suggest that, with a focus on the lowest risk ST products, this death toll could be reduced to less than 2% of the overall cancer risk of smoking – a death toll of less than 3,000 per year.

One major issue related to the extreme health hazard posed by cigarettes has to do with the means by which the hazardous chemical substances are transmitted to the human body, and the related issue of other chemicals produced in the combustion process. Burning tobacco generates carbon monoxide, which, in conjunction with the nicotine, substantially stresses the heart and cardiovascular system. The combustion process also produces gasses and small particles that are then directly transmitted to the smaller bronchi and the alveoli of the lung – possibly the most delicate and vulnerable tissues in the human body. Some experts in this field feel that smoking of any biomass, even without the nicotine and tar of cigarette smoke, would produce similar pulmonary, cardiac, and even cancer-related rates of illness and death [80].

The established health risks associated with ST use are vastly lower than those of smoking. In the past 25 years, numerous peer-reviewed scientific and medical publications have acknowledged the differential risks between the two tobacco products.

As noted earlier, there are major differences between oral leukoplakias associated with smoking and those associated with ST use. Smoking-related leukoplakias most commonly involve the undersurface of the tongue and throat, locations that account for 75% of oral cancer in the U.S. Leukoplakia occurs in up to 60% of ST users, primarily at the site of ST use. It is the result of local irritation. Long term follow-up of large numbers of ST users show that ST leukoplakias rarely progress to cancer.

In 1980 Michael A.H. Russell and co-workers proposed that nasal snuff might serve as an effective substitute for cigarettes because it delivers nicotine effectively without the risks of tobacco combustion [81]. This article was cited shortly thereafter in a brief letter in the New England Journal of Medicine [82]. Russell et al. published follow-up studies on nasal snuff in 1981 [83] and on an oral ST product in 1985 [84]. Lynn Kozlowski, a prominent American smoking and nicotine addiction expert at Penn State University, noted in 1984 and 1989 that smokeless forms of tobacco conferred fewer risks to users and therefore might serve as effective substitutes for cigarettes [85-87]. Using established risk estimates from accepted sources, Rodu and Cole documented that ST use confers only about 2% of the health risks of smoking [88-90]. In addition, they established that the average reduction in life expectancy from long-term ST use was about 15 days, compared with a reduction of about 8 years from smoking [89].

In 1994 Rodu noted that ST use posed a lower risk for mouth cancer than smoking [88]. In 2001 this was confirmed by a comprehensive report on tobacco harm reduction by the Institute of Medicine, which stated that "the overall [oral cancer] risk [for ST use] is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk" [91].

By the late 1990s some influential organizations acknowledged the differential risks of ST use and smoking. For example, in 1997 experts meeting at the United Nations Focal Point on Tobacco or Health concluded that "it 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" [92]. That same year a scientific panel convened by the Swedish National Board of Health and Welfare concluded that "the health risks related to ST are with great probability lower than those related to smoking" [93].

In 2002 the Royal College of Physicians of London, one of the oldest and most prestigious medical societies in the world, issued a report called "Protecting Smokers, Saving Lives," which stated, "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." [94]

In 2004 a study funded by the NCI assembled an international panel of experts (including epidemiologists from the NIH and the ACS) to compare the risks of ST use with those of smoking. The study authors reported that, "In comparison with smoking, experts perceive at least a 90% reduction in the relative risk of low-nitrosamine ST use." The authors concluded that "This finding raises ethical questions concerning whether it is inappropriate and misleading for government officials or public health experts to characterize ST products as comparably dangerous with cigarette smoking" [95].

Phillips et al. have provided perhaps the most detailed and direct comparison of risks from use of Swedish or American ST products and from smoking, using a spectrum of risk estimates for ST use ranging from well-substantiated and plausible to highly speculative and implausible [96]. They

estimated that, compared with smoking, ST risks "in the range of 1% or 2%, and possibly less, are most consistent with the epidemiologic evidence. Perhaps most important, our calculation shows that comparative risk estimates as high as 5%, let alone 10% or more, cannot be justified based on the evidence."

Using the risk estimates described in detail above, the following table compares the number of deaths that would occur annually among 45 million ST users with the number of deaths that the CDC estimates among 45 million smokers.

Table 2
Annual Smoking-Attributable Deaths in the United States
45 Million Smokers or 45 Million ST Users

Cause of Death	Smokers			Smokeless Tobacco		
	Range of RR[1,2]	Estimated Numbers of Deaths per Year in the United States		Range of RR[1,3]	Estimated Numbers of Deaths per Year in the United States	
Cancer						
Mouth and throat	5-11	4,868		1.0-4.0	665[3]	
Pancreas	2.3	6,509		0.6-2.1	2,003[3]	
Lung	13-23	123,836		1.0	0	
Other		23,316		1.0	0	
All Cancer			158,529			2,668
Cardiovascular Diseases			137,979			0
Respiratory Disorders			101,454			0
All Deaths Among Smokers			397,962[2,5]			
Environmental Tobacco Smoke						
Lung cancer		3,000				
Cardiovascular		35,000				
All Environmental Tobacco Smoke			38,000[4]			0
All			435,962[5]			2,668

1 RR = Relative Risk; the ratio of risk comparing users to non-users; an RR of 1 means no increased Risk; 1.2 means a 20% increase; 2.0 means double the risk, etc. Range reflects differences from different case-control studies.

2 CDC SAMMEC, http://apps.nccd.cdc.gov/sammec/login.asp

3 Estimates derived from epidemiologic studies (see text)

4 CDC, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a1.htm

5 Does not include small numbers of deaths from a variety of other causes

(note: RR estimates are from case-control studies. Estimated numbers of deaths derived by CDC by a complex software package using data from research studies, national surveys, and death records)

The Health Benefits of Tobacco Cessation Versus Switching to ST

Some risk of smoking-related death lingers for many years after cessation. The reduction in life expectancy from smoking and the benefits to be secured from quitting vary with age, gender, pack-years smoked, co-morbidities and other factors. Working from the best available data from the CDC and other sources in 1996, Rodu and Cole estimated that, for an average male smoker 40 years old, quitting would result in regaining about 7.2 of the 7.7 years of life expectancy otherwise lost to smoking. If instead of quitting, the man switched to ST, he would still regain the 7.2 years. For the male smoker at age 60, the projected loss of life expectancy from smoking would be 6 years. If he quit or switched at that age, he would only regain 1.9 of those years. Again, there would be no measurable difference in life expectancy for quitting vs. switching. The data for women is similar in pattern, but with only about half the loss in life expectancy. In any of these cases, the difference in life expectancy between quitting and switching to a low risk ST product would likely be no more than a few weeks [97].

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Whereas # 2 – Elimination of environmental tobacco smoke (ETS) and fire-related hazards

It is obvious, but by no means insignificant, that transitioning smokers to selected ST products will entirely eliminate environmental tobacco smoke and fire-related hazards for both smokers and everyone else. According to the U.S. Environmental Protection Agency, ETS is responsible for 150,000–300,000 new cases of bronchitis and pneumonia in children aged less than 18 months, resulting in 7,500–15,000 hospitalizations, annually [1]. The California Environmental Protection Agency estimates that ETS causes approximately 3,000 lung cancer deaths and 35,000 heart disease deaths annually among adult nonsmokers in the United States [2].

In February of 2008, the European Commission released a report on the health effects of ST products that included the following statement:

> "Since ST products do not produce smoke they will not cause any of the health problems linked to passive smoke exposure in adults or children. Substitution of snus for smoked tobacco would therefore prevent the passive smoke-related diseases [3]

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Whereas # 3 – "Abstain, quit, or die" may have reached maximum achievable benefit

In a 2007 commentary published in the Lancet, Foulds and Kozlowski noted that:

> "Around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. In Sweden, primary use of [ST] is associated with reduced risk of cigarette smoking in adulthood. The Lancet papers published today, when added to mounting epidemiological evidence, indicate that we should not delay in allowing [ST] to compete with cigarettes for market share, and we should be prepared to accurately inform smokers about the relative risks of cigarettes, [ST], and approved smoking-cessation medications. In light of all the available evidence, the banning or exaggerated opposition to [ST] in cigarette-rife environments is not sound public-health policy." [1]

In a 2008 Lancet article, Britton and Edwards lamented the lack of progress against smoking and urged governments to incorporate tobacco harm reduction into tobacco regulatory frameworks:

> "In the 50 years since the health risks of smoking first became widely recognized, the political and public health responses to smoking at national and international levels have been grossly inadequate...A logical harm reduction approach for the millions of smokers who are unlikely to achieve complete abstinence in the short-term or medium-term future is to promote the substitution of tobacco smoking with an alternative, less hazardous means of obtaining nicotine...We believe that the absence of effective harm reduction strategies for smokers is perverse, unjust, and acts against the rights and best interests of smokers and the public health....The regulatory framework should therefore apply the levers of affordability, promotion, and availability in direct inverse relation to the hazard of the product, thus creating the most favourable market environment for the least hazardous products while also strongly discouraging use of smoked tobacco." [2]

Sweanor et al. assessed the global public health implications of tobacco harm reduction in a 2007 article in the International Journal of Drug Policy:

> "Were the world's 1.3 billion cigarette smokers acquiring their nicotine from clean delivery systems rather than through repeated inhalation of smoke, nicotine use would likely not rank much higher than caffeine use as a public health priority...The consumer who rejects (or cannot achieve) abstinence but will use a product that reduces risk by 90% should not be prevented from making that preferred choice. Indeed, it is exactly the forced choice between smoking and abstinence that reinforces the current dominance of cigarettes...The relative safety of ST and other smokefree systems for delivering nicotine demolishes the claim that abstinence-only approaches to tobacco are rational public health campaigns...Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century." [3]

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Whereas # 4 – Harm Reduction works and can be accomplished in a way that will not increase initiation or decrease cessation

Evidence that ST is an Effective Substitute for Cigarettes

In 2008 Rodu and Phillips provided the first population-level evidence that over a quarter of a million American men have quit smoking by switching to ST [1]. The study showed that switching to ST resulted in over twice the proportion of former smokers (73%) than the nicotine patch (35%), gum (34%), inhaler (28%) or nasal spray (0%). It is particularly striking that an estimated 359,000 smokers tried to stop smoking by switching to ST – and over a quarter of a million became former smokers – especially since Americans are largely misinformed about the health risks of ST use [2,3]. It is safe to assume that rates of switching would increase substantially if smokers knew that switching to ST achieves almost all of the health benefits as quitting tobacco and nicotine altogether [4].

The comparison between ST and pharmaceutical nicotine also proves enlightening, especially in a broad social context. Nicotine gum and the nicotine patch have been available since 1984 and 1992 respectively [5]. Both products achieved non-prescription status in 1996, and that year the manufacturer conducted a large promotional campaign in conjunction with the ACS Great American Smokeout [6]. In 1999 an estimated $200 million was spent on print and broadcast advertising for smoking cessation products [7].

In contrast to the heavy promotion and advertising of pharmaceutical nicotine products for smoking cessation in the late 1990s, the environment for ST products was quite negative. A ban on broadcast advertising of ST had been established as early as 1986 [8], so the estimated $170 million spent on advertising in 1999 was restricted largely to print media [9]. Not only were manufacturers effectively prohibited from offering ST products as reduced-risk options for smokers, a counter-marketing program was launched by congressional legislation in 1986, in the form of one of three mandatory warning statements on every package of ST sold in the U.S.: "This product is not a safe alternative to cigarettes" [8]. In addition, major efforts have been made by the American tobacco control community to impede any widespread transition from cigarettes to ST [2,3]. Despite the pro-pharmaceutical and anti-ST climate, an estimated 261,000 men had used smokeless tobacco to quit smoking by the year 2000. While this number is lower than the number who had successfully used the nicotine patch (about one million), it is comparable to the number who had successfully used either nicotine gum or antidepressants, and far more than the number who were successful with other pharmaceutical nicotine products.

Unfortunately, no information on switching to ST is available in subsequent NHIS surveys, because that option was removed when the Cancer Control module next appeared, in the 2005 NHIS [10].

One clinical trial, an open-label, nonrandomized pilot study, has been conducted assessing the efficacy of an ST product in helping cigarette smokers become smoke-free. The investigators used a low-intensity approach, consisting of a 20-minute lecture about the health effects of all forms of tobacco use, followed by information about and samples of pre-portioned single-dose tobacco packets available throughout the U.S. The investigators used exhaled carbon monoxide levels to validate participant self-reports regarding smoke-free status at the conclusion of the original study after one year [11] and after seven years of follow-up [12].

Of 63 subjects starting the study, 16 had successfully quit smoking by switching to ST after one year, and 12 were still smoke-free after seven years. At enrollment, the average cigarette consumption of the successful participants had been 1.5 packs per day. One year later average consumption of ST was 2.3 packages per week among the 13 successful quitters using ST (3 were tobacco-free). Four additional participants had used ST to reduce their cigarette consumption by at least 50%.

For the past 100 years, cigarette smoking has been the dominant form of tobacco consumption in almost all developed countries. One notable exception is Sweden, where smoking rates, especially among men, have been considerably lower than those of comparable countries for decades. (An ACSH article provides historical background on Swedish snus [13]). Over the past 50 years Swedish men have had the lowest rates of smoking-related cancers of the lung, larynx, mouth and bladder in Europe [14], and the lowest percentage of male deaths related to smoking of all developed countries [15,16].

A 2004 study revealed that if men in the (15-country) EU had the smoking prevalence of Sweden, almost 200,000 deaths attributable to smoking would be avoided each year [17]. In contrast, women in Sweden smoke at rates similar to women in other European countries. This is reflected in similar rates of smoking-related illnesses among women.

As Fagerström pointed out in a recent study, per capita consumption of nicotine from tobacco in Sweden is quite high and on par with other countries such as Denmark, the U.S. and Austria [18]. The difference between Sweden and the other countries is how nicotine is consumed. In Denmark, the U.S. and Austria, almost all nicotine consumption is derived from tobacco combustion. In contrast, ST use, in the form of snus, accounts for almost 50% of all contemporary nicotine consumption in Sweden. Snus use in Sweden is much more common among men than among women; over 60% of nicotine consumption among Swedish men is from snus. This is not a new phenomenon; for over a century, Swedish men have had among the world's highest per capita consumption of ST [19].

Beginning in 2002, an American-Swedish research group used a World Health Organization database to describe in detail the impact of snus use on smoking among the population in northern Sweden during the period 1986-2004 [20-22].

Among men, the prevalence of all tobacco use was stable during the study period, at about 40%. However, there were striking, and opposite, changes in prevalence of smoking and snus use. Smoking prevalence was 19% in 1986, and it was lower in all subsequent surveys, reaching 9% in 2004. The prevalence of exclusive snus use increased from 18% in 1986 to 27% by 2004. Snus use was the dominant factor in the higher prevalence of ex-smoking among men compared to women (prevalence ratio 6.18, 95% CI 4.96 – 7.70). (In other words, men were 6.18 times more likely than the women to be ex-smokers; CI = "confidence interval" This means that if we could have gathered data from all the men in Northern Sweden, there is a 95% chance the prevalence ratio would have been between 4.96 and 7.70)

Among women the prevalence of all tobacco use also was steady at 27 to 28%, and women smoked at higher rates than men in all surveys. But these studies showed that snus use was associated with lower smoking rates among women in 1999 and 2004. Smoking prevalence was about 25 to 27% in

1986, 1990 and 1994, but declined to 21% in 1999, and 16% in 2004. The prevalence of snus use was 0.5% in 1986 and increased to 1.9% in 1990, 2.0% in 1994, 5.1% in 1999 and 8.9% in 2004.

In these reports snus use was not associated with smoking initiation, as the prevalence of smoking among former snus users was low in all survey years (3-4%). The evidence showed that among adult men in northern Sweden the dominant transition is from smoking to snus, not vice versa.

In 2003, Gilljam and Galanti reported the results of a telephone survey of current and former smokers in Sweden [23]. They reported that using snus increased the probability that male smokers would be smoke-free by 50% (OR 1.54, 95% CI = 1.3-2.5). (OR = "odds ratio" can be interpreted in a similar manner as relative risk)

In 2003 Foulds et al. reviewed the evidence relating to the effects of snus use on smoking and concluded, "Snus availability in Sweden appears to have contributed to the unusually low rates of smoking among Swedish men by helping them transfer to a notably less harmful form of nicotine dependence." [24] The investigators noted that "in Sweden we have a concrete example in which availability of a less harmful tobacco product has probably worked to produce a net improvement in health in that country".

In 2005 Furberg et al examined tobacco use data from the Swedish Twin Registry, finding that regular snus use was associated with smoking cessation, not initiation, among almost 15,000 male participants [25]. Both regular and occasional snus use were protective against having ever smoked.

In 2006 Ramström and Foulds examined data from a 2001-02 nationally representative Swedish social survey [26]. They found that snus use among men was significantly protective against smoking initiation (OR = 0.3, CI 0.2-0.4). They also found that snus was the most commonly used cessation aid among men (used by 24% of men on their most recent quit attempt). Men who used snus as a quit-smoking aid were more likely to quit successfully than those using nicotine gum (OR=2.2, CI=1.3-3.7) or the patch (OR=4.2, CI=2.1-8.6), which was also true for women.

Evidence that Harm Reduction Will Not Increase Initiation

Data from research studies in Sweden and the U.S. do not show that widespread use of ST serves as a gateway to smoking, especially among youth. A 2003 policy statement published in *Tobacco Control*, coauthored by Clive Bates, former director of Action on Smoking and Health (U.K.) and five other eminent tobacco research and policy experts, dismissed the notion that ST use led to smoking in Sweden: "To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco related disease in Europe" [27]. Foulds reached a similar conclusion: "This review suggests...that in Sweden snus has served as a pathway from smoking, rather than a gateway to smoking among Swedish men" [28].

A 2005 study examined tobacco use among 15- to 16-year old schoolchildren in Sweden over a 15-year period, from 1989 to 2003 [29]. The investigators found that the prevalence of regular snus use among Swedish boys increased from about 10% to 13% from 1989 to 2003, but the prevalence of regular smoking was very low and declined, from about 10% to under 4%. The prevalence of snus use among girls was very low, and the prevalence of smoking was about double that of boys

over the entire period. The authors concluded that snus use did not appear to be a gateway to smoking among Swedish youth but instead was associated with low smoking prevalence among boys.

Other recent studies based in Sweden have come to similar conclusions. In 2005 Furberg et al. investigated whether snus use was associated with smoking initiation or smoking cessation using data from the population-based Swedish Twin Registry. They concluded that snus use was "inversely associated with initiation." [30]

In 2006 Ramström and Foulds examined data on tobacco use from a national Swedish survey. They found that "Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker..." [31] With respect to these findings, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks concluded that "The Swedish data...do not support the hypothesis that...snus is a gateway to future smoking." [32]

In the U.S., concomitant use of cigarettes is common among ST users [33]. However, investigators have not found credible evidence that ST use is a gateway to smoking among American youth. In 2003 Kozlowski et al. analyzed data from the 1987 NHIS survey and concluded that there was little evidence that ST use was a gateway to smoking, because the majority of ST users had never smoked or had smoked cigarettes prior to using ST [34]. The investigators noted that their results coincided with earlier work from Sweden and with a tobacco industry-sponsored survey from 1984 [35].

In 2003 O'Connor et al. examined data from the 2000 National Household Survey on Drug Abuse [36]. They described the impact of ST use on subsequent cigarette smoking initiation as "minimal at best." O'Connor et al. also examined data from the CDC's Teenage Attitudes and Practices Survey for evidence that ST use served as a gateway to smoking among youth [37]. They concluded that ST use was not associated with smoking initiation after appropriate control for confounding by well-recognized psychosocial predictors of smoking. This is in contrast to an earlier report that did not control for confounding and found a positive association [38].

Claims of a gateway effect persist, even with lack of credible evidence, prompting O'Connor et al. to note in 2005, "Continued evasion of the [harm reduction] issue based on claims that ST can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information" [39].

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Whereas # 5 -- Agencies and Organizations endorsing harm reduction

In 2002 Britain's Royal College of Physicians, one of the world's most prestigious medical societies, issued a report on tobacco regulation in the United Kingdom called "Protecting Smokers, Saving Lives." [1] As noted earlier, this report stated "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an implicit endorsement of tobacco harm reduction, acknowledging that some smokeless manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community."

In 2007 the Royal College issued an even stronger endorsement of tobacco harm reduction [2]. The report concluded:

> "...that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved... Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking."
>
> "Compiled by leading experts in the field, this report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved."
>
> "Harm reduction is a fundamental component of many aspects of medicine and indeed everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform to the way that nicotine products are regulated and used in society. The ideas presented are controversial, and challenge many current and entrenched views in medicine and public health. The principles behind them have the potential to save millions of lives. They deserve consideration."

In 2006 the American Council on Science and Health (ACSH) became the first American organization to endorse tobacco harm reduction. ACSH has been a recognized leader of smoking control for several decades. And it has held the tobacco industry accountable for its part of the devastating toll from tobacco. ACSH founder Elizabeth Whelan published a landmark anti-smoking book, *A Smoking Gun?: How the Tobacco Industry Gets Away with Murder* [3]. The mission of the ACSH is to promote sound science in regulation, in public policy, and in the courtroom and to assist consumers, via the media, in distinguishing real health threats from purely hypothetical ones. ACSH believes that strong support of tobacco harm reduction is fully consistent with this mission; there is a strong scientific and medical foundation for tobacco harm reduction, and it shows great potential as a public health strategy to help millions of smokers.

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Whereas # 6 – Incorrect Impression of equal risk

Americans are badly misinformed about the risks of ST use, especially in comparison with smoking. In 2005 a survey of 2,028 adult U.S. smokers found that only 10.7% correctly believed that ST products are less hazardous than cigarettes [1]. In another survey, 82% of U.S. smokers incorrectly believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes [2].

A 1999-2000 survey of 36,012 young adults entering the U.S. Air Force found that 75% of males and 81% of females incorrectly believed that switching from cigarettes to ST would not result in any risk reduction, while another 16% of males and 13% of females incorrectly believed that only a small risk reduction would occur. Only 2% of males and 1% of females correctly understood that a large risk reduction would occur by switching from cigarettes to ST [3]. That survey also found that the overwhelming majority of subjects believed that switching from regular to low-tar cigarettes conferred greater reduction in risks than switching from cigarettes to ST.

It is not clear how Americans have become so confused about tobacco risks. But it is clear that misinformation about ST products is available in copious quantities from ostensibly reputable sources, including governmental health agencies and health-oriented organizations. Phillips et al have made some of the most pointed comments about this phenomenon:

> "Certain health advocates believe it is acceptable to mislead people into making choices they would not otherwise make...Through the use of various tactics, advocates who oppose the use of ST as a harm reduction tool have managed to convince most people that the health risk from ST is several orders of magnitude greater than it really is. The primary tactic they use is making false or misleading scientific claims that suggest that all tobacco use is the same. . . . Apparently motivated by their hatred of all things tobacco, they are trying to convince people to not switch from an extremely unhealthy behavior to an alternative behavior that eliminates almost all of their risk" [4].

The tactic has worked in the U.S., as Americans, almost without exception and regardless of general and health education levels, believe that the risks from ST are similar to those from smoking. In particular, Americans incorrectly believe that switching from smoking to ST use will create a large increased risk for oral cancer. Phillips has characterized this popular misinformation as the "you might as well smoke" message, since it tells people that if they are using ST, they could switch to smoking with no increase in risk, while smokers considering switching to ST should not bother [5].

Phillips et al. systematically reviewed content about ST use on the web in 2003 and found that the risks of ST use are almost always conflated with those of smoking [6]. Roughly one-third of the time, there are explicit claims that ST is as bad as or worse than smoking. Most of the rest of the time the information is arranged to imply similar risks, though there is no such explicit statement. There are also a variety of specific claims that are not supported by the literature.

Government agencies, other organizations and members of the public health community have a moral obligation **not** to misinform smokers about products that have fewer risks than cigarettes. Nevertheless, researchers have exposed numerous cases of misinformation from governmental sources. For example, in 2003 Kozlowski and O'Connor criticized websites of the CDC and the Substance Abuse and Mental Health Services Administration for erroneously reporting that ST products were not safer than cigarettes, pointing out that "the misleading health information on ST fails to meet the government criteria against deception in research" [6].

At a 2003 U.S. House subcommittee hearing, U.S. Surgeon General Richard Carmona testified: "I cannot conclude that the use of any tobacco product is a safer alternative to smoking...There is no significant evidence that suggests ST is a safer alternative to cigarettes." [7] Scott Leischow, at that time the Chief of the Tobacco Control Research Branch at the NCI, presented similar testimony at a concurrent hearing [8]. Carmona's statement prompted Rodu, who also presented testimony at that hearing [9], to comment that the Surgeon General was "sadly ill-informed about the nation's No. 1 health problem, cigarette smoking." Rodu strongly criticized Carmona, writing that he should be compelled to "tell American smokers the truth about all available options for quitting. After all, the 10 million smokers who will die over the next two decades are, in a very tangible way, his responsibility and his legacy" [10].

In March 2004, Ken Boehm of the National Legal & Policy Center (NLPC), a non-profit organization committed to promoting open, accountable and ethical practices in government, filed a request under the Data Quality Act (DQA) for correction of a document from the National Institute of Aging (NIA) that contained misinformation regarding the relative risks of ST versus cigarettes. (This other DQA requests on ST can be seen at the U.S. Department of Health and Human Services website [11]) The request resulted in a change of wording from the original text: "Some people think ST (chewing tobacco and snuff), pipes, and cigars are **safer** than cigarettes. They are not." The revised wording from NIA was: "Some people think ST (chewing tobacco and snuff), pipes, and cigars are **safe**. They are not."

The claim that ST products are not "**safe**" is a tactic that can be traced back to the 1986 Comprehensive Smokeless Tobacco Education Act, which required as one of three warnings on all ST products: "This product is not a safe alternative to cigarettes." In 1995 Rodu criticized this warning as ludicrous and suggested that other consumer products like automobiles, lawnmowers, aspirin and red meat don't meet absolute criteria for safety [12]. A decade later, Kozlowski and Edwards criticized this type of uninformative warning in a study entitled, "'Not safe' is not enough: smokers have a right to know more than there is no safe tobacco product" [13]. These authors believe that smokers deserve more information:

> "The 'not safe' or 'not harmless' messages don't address the reality that some tobacco products are substantially safer than others... Saying tobacco 'isn't safe' isn't incorrect, but it isn't saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information."

Ken Boehm from NLPC summarized the arguments against misinformation:

> "This is the kind of evidence Americans should be able to review and make their own decisions. Despite the best efforts of the largest government bureaucracy in the history of the republic, Americans still prefer to do their own thinking. And as we do our own thinking on the merits of reduced-risk products such as ST, none of us needs misinformation supplied by our own government" [14].

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Whereas # 7 – Tax policy

Excise taxes represent a potentially valuable tool for tobacco harm reduction. In 2005, Kentucky Governor Ernie Fletcher described the rationale for a differential tax on ST products in comparison to cigarettes that reflects risk differences:

> "Increasing taxes on tobacco products should have a deterring effect on their use, and therefore result in healthier lifestyles for Kentuckians. The relative taxes on tobacco products in this proposal reflect the growing data from scientific studies that although ST poses some risk, those health risks are significantly less than other forms of tobacco products. It also acknowledges that some in the public health community recognize that tobacco harm reduction should be a complementary strategy to any public health policy toward tobacco products. Taxing tobacco products according to relative risks is a rational tax policy and may well serve the public health goal of reducing smoking-related mortality and morbidity and lowering health care costs associated with tobacco-related disease." [1]

This tax policy was enacted by the General Assembly of the Commonwealth of Kentucky in 2005 (KRS CHAPTER 136). In 2006 the American Council on Science and Health noted that "State legislatures should place higher taxes on more dangerous tobacco products than on less dangerous tobacco products. The state of Kentucky has already taken steps in this direction." [2] The Heartland Institute commented that "Another harm reduction strategy often recommended is that in recognition of ST's lesser risks, taxes to discourage tobacco use should focus on cigarettes, not ST. That approach is gaining some acceptance." [3]

Gartner and Hall, writing in PLoS Medicine in 2007, endorsed this concept: "[T]here is a strong prima facie case on public health and ethical grounds for recommending [ST] to inveterate smokers who want to reduce their health risks and for considering public policies (such as lower taxes for [ST] and public information campaigns) to promote its use by smokers." [4] In 2008 these Australian tobacco researchers urged their government to "reduce the absurdly high customs tax on ST products to make [them] more affordable and easier to import." [5]

In 2007 the National Center for Policy Analysis issued a report on excise taxation of tobacco, alcohol, gambling and other products, which noted the irrational tobacco excise taxes in some states:

> "If the true purpose of excise taxes on tobacco products is to recoup the external costs to society, states should levy lower taxes on smokeless products than on cigarettes. However, some states do the reverse. About a fifth of the states charge higher taxes as a percent of the manufacturer's or wholesale price than for cigarettes, including Massachusetts (90 percent for smokeless products versus 68 percent for cigarettes), Texas (35.2 percent versus 18.5 percent), Minnesota (70 percent versus 55.4 percent), Idaho (40 percent versus 25.7 percent) and Oklahoma (60 percent versus 46.4 percent), to name a few." [6]

In 2008 the Buckeye Institute for Public Policy Solutions suggested that these irrational tax policies may have unfortunate consequences:

> "Illnesses from cigars and ST such as chewing tobacco cost taxpayers almost nothing. These products are just not as dangerous as cigarettes. Because of this, they should have

> no special taxes levied on them...While all tobacco products pose some health risk, smoking cigars or using chewing tobacco causes far fewer health problems than smoking cigarettes. By raising the cost of these less dangerous products the anti-tobacco activists may well cause some people who used these products to satisfy their tobacco habit with cigarettes." [7]

In 2007, Kozlowski concluded that "The reviewed evidence indicates that ST products as effective nicotine-delivery systems can function as cigarette substitutes and cessation aids." He advocated for implementation of harm reduction using tax policy: "Econometric research indicates that if one desires the maximum reduction in cigarette sales with a tax increase on cigarettes, it is also important to make other substitutable nicotine-delivery systems ([nicotine replacement therapy] and ST) cost less than cigarettes." [8]

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Whereas # 8 – Political and financial viability of harm reduction

The tobacco industry and tobacco-related stakeholders are not of one mind, and do not speak with a single voice. The traditional practice within the medical and public health communities of considering cigarettes and the major cigarette companies as emblematic of the entire tobacco industry and all industry-related stakeholders is simply incorrect. Personal experience over a period of decades in dealing with these stakeholders has left one of us (JLN) with the impression that they are a very diverse group, highly competitive within their various market niches, and, as a general rule, intense dislike of Altria/Philip Morris – the makers of Marlboro Cigarettes is widely prevalent.

Scott D. Ballin, JD, in his role as Tobacco and Health Policy Consultant for the Alliance for Health Economic and Agricultural Development (AHEAD), has been, more than any other single individual, an advocate for productive dialogue between public health advocates, growers, and other tobacco-industry-related stakeholders. In his October 3, 2007 testimony to the House Health Committee Subcommittee on Energy and Commerce, he described the mission of AHEAD in the following terms:

> "The Alliance is an informal organization whose purpose is to educate, stimulate, and facilitate discussions with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, pharmaceutical and biotech interests about a spectrum of issues related to the production, processing, manufacture, sale, distribution, labeling, marketing and use of tobacco and tobacco products. The Alliance is an outgrowth of the *Southern Tobacco Communities Project* established in the mid-1990's through a grant from the Robert Wood Johnson Foundation that brought the public health community and growers together to engage in a civil dialogue about tobacco. That dialogue led to the issuance of a set of *Core Principles* in 1998 and the presidential commission report **Tobacco at a Crossroads** in May of 2001. The Steering Committee members serve as individuals, each of whom has significant and unique experiences in dealing with tobacco related issues."[1]

AHEAD has published a detailed report entitled *Tobacco and Tobacco Products At a Crossroads in the 21st Century: Reducing Harm from Tobacco and Tobacco Products; Can Tobacco and Tobacco Product Modification Play a Role?; Seeking Civil Solutions in an Uncivil Environment.* [2] This report is well worth reading for anyone interested in considering productive dialogue between the public health community and tobacco-industry stakeholders in pursuit of common objectives under which tobacco industry stakeholders can thrive while protecting the health of the public.

The concept of political and financial viability of a harm-reduction approach is based on the idea that encouraging the use of lower risk tobacco products to reduce tobacco-related illness and death will give growers something to grow, manufacturers and vendors products to manufacture and sell, etc. As noted before, this can be done in a way that will not reduce the effectiveness of other programming intended to reduce initiation of tobacco use by children and youth, and not reduce effectiveness of efforts to encourage smokers to quit.

References

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2. Ballin SD: entitled *Tobacco and Tobacco Products At a Crossroads in the 21st Century: Reducing Harm from Tobacco and Tobacco Products*. August 2006 http://www.tobaccoatacrossroads.com

Note Regarding Pharmaceutical versus Non-Pharmaceutical Harm Reduction Products

Some writers in this field feel that harm-reduction nicotine delivery products should be limited to "medicinal nicotine" products produced by or on behalf of pharmaceutical firms. [1]

We disagree. It is our opinion that, if such products are to effectively reach populations at highest risk for cigarette-related illness and death – high school dropouts, disadvantaged minorities, gays and others – products will have to be accessible through the same retail outlets that sell cigarettes, and at comparable prices.

1. Kozlowski LT, Strasser AA, Giovino GA, Ericson PA, Terza JV: Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. Tobacco Control 2001:10: 201-203

Note on the Need for Additional Research

The prevailing public health policy that could be summarized with the phrase "avoid all use of tobacco products; abstain, quit or die" has sorely inhibited research into many topics related to tobacco and health. It has created a situation in which company-sponsored research is always suspected of major bias, and government-sponsored research has been largely limited to studies that support the impression that all tobacco use is so harmful that none should be considered.

As a result, the best we can do is to extrapolate the expected hazards from other forms of smoking tobacco products (cigars, pipes, water pipes, etc) to be similar in risk to cigarettes, and seriously question the public health value and impact of inhalable nicotine products being marketed or developed as harm-reduction alternatives. While snus have an enviable track record of safety over many decades of use in Scandinavian countries, there is no such track record for many of the non-pharmaceutical nicotine delivery devices now either on the market or coming to market.

The only practical means by which the needed research can be done will be the passage of federal legislation for federal oversight of tobacco products that realistically recognizes both the prevalence and power of the addictiveness of nicotine and a willingness to consider all feasible options to reduce tobacco-related illness and death. Such legislation should include provision by which one or more funds can be developed that will enable governmental sponsorship of unbiased research into all possible approaches to reducing tobacco-related illness and death.

That having been said, it is important to repeat the perception by the authors of this paper and the organizations supporting the resolution herein – that currently available scientific findings are more than adequate to vigorously pursue harm reduction as one aspect of our continuing efforts to reduce tobacco-related illness and death. We do not need more research to justify such an approach. What we need is new legislation and policy and program development to translate this knowledge into effective public health programming, while we pursue additional research to further refine our public health efforts.

Bios and Financial Disclosure Statements

Joel L. Nitzkin, MD, MPH, DPA, FACPM, is a public health physician who has spent most of his career working for local and state health departments. Following graduation from medical school in 1966, he had a one-year rotating internship at Parklawn Memorial Hospital, in Dallas, TX, followed by a two-year tour of duty in the CDC's Epidemic Intelligence Service. In 1970 he secured a Master's Degree in Public Health from the University of California at Berkeley. From 1970 to 1976 he directed the communicable and chronic disease programming at the Dade County Health Department, in Miami, Florida. While there he completed his credentialing in the medical specialty of Preventive Medicine and pursued his Master's Degree and Doctorate in Public Administration at Nova University, in Fort Lauderdale. From 1976 to 1989 he served as Director of the Monroe County Health Department, in Rochester, New York. It was while in Rochester that Dr. Nitzkin became deeply involved in tobacco control as a public health priority, with Monroe County adopting what was, in its time (1983), one of the strictest clean indoor air ordinances. From 1989 to 1992, Dr. Nitzkin served as the Assistant Secretary for Public Health (State Health Officer) for the state of Louisiana. Since 1992, he has been in the private practice of public health as policy consultant. For four of these years he was full time faculty at the LSU School of Medicine as follow-through to a consulting project. Since the late 1990's Dr. Nitzkin has served as the Chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. Dr. Nitzkin has never sought nor secured any financial or other support from any tobacco-related enterprise.

Brad Rodu, DDS, is Professor of Medicine and holds an Endowed Chair, Tobacco Harm Reduction Research, School of Medicine at the University of Louisville in Kentucky. An oral and maxillofacial pathologist by training, he was on the faculty at the University of Alabama at Birmingham (UAB) from 1981 to 2005, with appointments in several departments in the Schools of Medicine, Public Health and Dentistry.

For the past 15 years Dr. Rodu's research has focused on tobacco harm reduction, including prevalence studies of tobacco use, epidemiologic models of the health risks and life expectancy of tobacco users, and laboratory analyses of tobacco products. He also conducted research in Sweden, where tobacco harm reduction has been realized and has resulted in a profound effect on public health. His research has been published in a broad range of medical and scientific journals such as Nature, The American Journal of Medicine, Epidemiology, Cancer, Journal of Clinical Oncology, Nicotine and Tobacco Research and Tobacco Control.

From 1993 to 1999 Dr. Rodu's research on tobacco harm reduction was conducted with only very limited financial support from general accounts at UAB, and no external support whatsoever. During that time Dr. Rodu and his colleagues established the scientific foundation of tobacco harm reduction with publications in professional medical journals and in the general press.

From 1999 to 2005 UAB Dr. Rodu's research was supported by a research grant from the United States Smokeless Tobacco Company (USSTC) of Greenwich, Connecticut to UAB. The agreement between USSTC and UAB broke new ground with regard to industry-sponsored university research. The award was completely unrestricted; the agreement specified that UAB had no obligation to USSTC regarding consequential work products. The grantor had no scientific input or other influence regarding the nature of the research projects or activities and did not have access to

research reports prior to their publication. In other words, the structure of this agreement exceeded UAB guidelines with regard to financial support from external sources, and it imposed absolutely no restrictions on academic freedom in the undertaking and communication of funded research. A scientific advisory board oversaw the program.

In 2005 Dr. Rodu joined the University of Louisville. Financial support for the endowed chair and research activities was made possible by grants from USSTC and Swedish Match (based in Stockholm, Sweden with North American operations based in Richmond, Virginia). These grants are also unrestricted, which ensures the scientific independence and integrity of research projects and activities. The chair was also funded in part by the State of Kentucky Research Challenge Trust Fund, a program that makes it possible for public universities in Kentucky to attract and retain the nation's top scholars and researchers.

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