Available online at www.sciencedirect.com

SCIENCE DIRECT®

Addictive Behaviors 31 (2006) 1190–1200

ADDICTIVE BEHAVIORS

The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: Estimates of a panel of experts

David T. Levy [a,*], Elizabeth A. Mumford [b], K. Michael Cummings [c], Elizabeth A. Gilpin [d], Gary A. Giovino [c], Andrew Hyland [c], David Sweanor [e], Kenneth E. Warner [f], Christine Compton [b]

[a] *Pacific Institute for Research and Evaluation, Calverton, Maryland, and Department of Economics, University of Baltimore, Baltimore, MD, United States*
[b] *Pacific Institute for Research and Evaluation, Calverton, MD, United States*
[c] *Department of Health Behavior, Roswell Park Cancer Institute, Buffalo, NY, United States*
[d] *Cancer Prevention and Control Program, Cancer Center, University of California, San Diego, La Jolla, CA, United States*
[e] *Faculty of Law and Faculty of Medicine, University of Ottawa, Ottawa, Canada*
[f] *School of Public Health, University of Michigan, Ann Arbor, MI, United States*

Abstract

Objective: To predict the impact on tobacco use in the US of a "harm reduction" policy that requires that the smokeless tobacco product meet low nitrosamine standards, but could be marketed with a warning label consistent with the evidence of relative health risks.
Methods: Low nitrosamine smokeless tobacco (LN-SLT) and cigarette use are predicted by a panel of experts using a modified Delphi approach. We specify a thought experiment to isolate the changes that would occur after the new LN-SLT policy was implemented.
Results: The panel predicted that the new policy would accelerate a decrease in smoking prevalence from 1.3 to 3.1 percentage points over 5 years compared to the current SLT product policy, with greater effects on males than females. Introduction of the new product was also predicted to result in modest additional use of SLT overall, with the greatest increases among males who initiated tobacco use under the new policy.

* Corresponding author. 14403 Sylvan Glade Dr., N. Potomac, MD 20878, USA. Tel.: +1 301 755 2733; fax: +1 301 755 2799.
E-mail address: Levy@pire.org (D.T. Levy).

doi:10.1016/j.addbeh.2005.09.010

Conclusion: An overall consensus was reached that the introduction of a new LN-SLT product under strict regulations would increase SLT use, but reduce overall smoking prevalence. This reduction would likely yield substantial health benefits, but uncertainties surround the role of marketing and other tobacco control policies.

Keywords: Tobacco control; Smokeless tobacco; Harm reduction

1. Introduction

In 2001, the Institute of Medicine laid the foundation for tobacco-related research assessing *potentially reduced exposure products* or PREPs that might reduce the risks associated with using tobacco (Stratton, Shetty, Wallace, & Bondurant, 2001). These products include regulated medicinal nicotine delivery products (nicotine patches, gums, inhalers, lozenges, and sprays) intended to reduce consumer exposure to tobacco toxicants (Shiffman et al., 2002; Stratton et al., 2001), as well as several categories of unregulated tobacco products, such as cigarettes with claims of low nicotine content (e.g., Quest™) or cigarettes designed to reduce the harmful byproducts of tobacco by heating rather than burning the product (e.g., Omni™).

PREPs may reduce the harms that would otherwise occur from smoking more hazardous cigarettes, but other possibilities emerge. Three potential benefits are to delay or reduce the onset of tobacco; to facilitate smoking cessation; and to reduce the relative harm from smoking by changing the balance of consumption from smoking to products with lower health risks (Sweanor, 2003). Balancing the potential benefits, concerns have been raised that these products serve as an inducement to use other addictive nicotine delivery products, which are themselves harmful and might serve as a gateway to cigarette smoking. They may also replace abstinence from tobacco products. For example, a former smoker may be enticed to smoke again by the message that the product is relatively "safe". The intensity of discussion surrounding these issues highlights the importance of developing policies toward alternative tobacco products and government regulation.

Another example of a potential harm reduction product is low nitrosamine smokeless tobacco (LN-SLT) marketed for oral use, such as Swedish snus or Ariva Cigalets (Shiffman et al., 2002). In that a comprehensive study of the risks of various low-nitrosamine tobacco products relative to traditional cigarettes has not been conducted, a panel of experts was convened to assess the literature (Levy et al., 2004). With substantial agreement, the panel found that the health risks of these non-combustible tobacco products were substantially lower than those of conventional cigarettes (Levy et al., 2004).

Even if it is accepted that LN-SLT products have much lower risk than cigarettes, it does not necessarily follow that these products are an acceptable harm reduction alternative to cigarettes. In addition to product toxicity, the harm reduction potential depends on who uses the product, how much they use it, and how use of the product relates to use of other tobacco products. LN-SLT might be used instead of cigarettes or as a mechanism for quitting cigarette use. Alternatively, it may act to induce smoking initiation that would not otherwise have occurred or replace cessation from cigarettes that would have occurred.

Evidence on the use of the LN-SLT snus is available from Sweden. Snus use has increased from about 10% of the adult male population in 1976 to 23% in 2002, while smoking prevalence fell from 40% to 15% over the same time period (Foulds, Ramstrom, Burke, & Fagerstrom, 2003). Nevertheless, a causal

relationship has been questioned, since the reduction in smoking rates might instead have resulted from more stringent tobacco control policies in Sweden (Tomar, Connolly, Wilkenfeld, & Henningfield, 2003). The applicability of the Swedish evidence to other countries raises additional issues. For example, LN-SLT may take on a different role in the United States, where smoking rates are currently about 21% compared to 40% in Sweden in 1976. Further, use patterns may depend on how the product is marketed and governmental regulations regarding its use.

Little is known about how consumers will respond to the introduction of LN-SLT products in countries other than Sweden. In particular, estimates of the current prevalence of non-LN-SLT products in the United States provide limited guidance regarding potential use of LN-SLT. Therefore, we consulted a group of experts on tobacco use to develop hypothetical "best estimates" under a carefully defined "harm reduction" policy scenario. The expert panel was charged with the task of estimating the impact on SLT and cigarette use in the United States over the next 5 years of a specific policy regime: The SLT product must meet low nitrosamine standards, but would be marketed with a warning label consistent with the evidence of relative health risks.

2. Methods

2.1. Specification of the problem

The purpose of the Panel convened for this study ("the Behavioral Panel") was to predict the use of the new LN-SLT product and conventional cigarettes relative to current levels of SLT use and smoking in the US. Recognizing the importance of tobacco control policies, we first specified the regulatory environment surrounding SLT products. All SLT products sold in the United States would be low-nitrosamine products meeting the *same* regulatory standards for manufacture, handling, and sale as specified by the Food and Drug Administration, effective July 2005. The product (e.g., Ariva, Swedish snus) would at least meet the Gothiatek standard for production and manufacturing (www.gothiatek.com). The product would also be accompanied by a warning label that states: "*This product is addictive and may increase your risk of disease. This product is substantially less harmful than cigarettes, but abstaining from tobacco use altogether is the safest course of action.*" To avoid confounding the effects of the new LN-SLT policy with other tobacco control policies, we specified that other tobacco control policies, including cigarette and smokeless tobacco taxes, clean air laws, media campaigns, and policies regarding the provision of cessation treatments, would remain at their current 2005 levels.

Because SLT use varies considerably by gender, we asked the Behavioral Panel to separately consider the male and female populations. It would also be important to distinguish those who initiated tobacco use under the new LN-SLT regime from those who initiated under the current (no LN-SLT) policy. To examine the effect of the new product and policy regime on those who initiate under the *new* conditions, we specified that the Panel consider those who were currently ages 16 through 20, the years during which Americans are most likely to initiate regular tobacco use and when their future use patterns are largely established. The Panel members were to estimate use patterns after 5 years, the year 2010, when those individuals would be ages 21–25 years and most initiation would have already taken place (U.S. DHHS, 1994). To examine the effect of the new LN-SLT policy on individuals who initiate under the *old* conditions, we asked the Panel to estimate use patterns of those who were currently ages 36–40 years, an

age period when cessation often occurs (U.S. DHHS, 1992; Burns et al., 2000), after 5 years. They would then be ages 41–45 years.

To provide a common base of comparison, we provided the Panel with predicted use patterns for the 21–25 and 41–45 year old age groups in the year 2010 in the absence of a policy change. The predictions were presented in nine mutually exclusive categories of use representing the matrix of never, current and former smoking and never, current, and former SLT use. We specified that the category of (LN-) SLT includes chewing tobacco and snuff. To simplify the analysis, we also specified that cigar or pipe smokers are considered never smokers/users unless they also smoke cigarettes or use SLT (Gilpin & Pierce, 2001; National Cancer Institute, 1998; Nelson, Davis, Chrismon, & Giovino, 1996). We avoided asking the Panel to estimate the specific transitional pathways (e.g., new LN-SLT users may have been smokers, SLT users, never smoker/SLT users, or other combinations), because of the myriad possibilities and the difficulty in developing consistent estimates.

To determine the baseline smoking and SLT prevalence rates, we begin with the most recent data from the 2001/2002 Current Population Survey—Tobacco Use Supplement (CPS-TUS; N = 170,000 individuals who answered the relevant questions in the combined June, November and February samples). Smokers were defined as those who had smoked more than 100 cigarettes in their lifetime and were currently smoking some days or all days, the standard definition of established smoking (CDC, 1994; Choi, Pierce, Gilpin, Farkas, & Berry, 1997). Because those data do not distinguish "ever" past use from "regular" past use, we also use data from the January and May 1999 TUS samples to determine the percentages of past, regular SLT users (details available on request).

To predict forward from 2002 to the year 2010, we used the *SimSmoke* model to determine the percentage change in smoking prevalence rates (Levy, Mumford, & Nikolayev, 2005). *SimSmoke* is a dynamic computer simulation model that begins with smoking rates in the base year, 1993, and projects future smoking rates based on initiation, cessation and relapse rates, subject to changes in the effect of tobacco control policies on those rates. We hold policies constant at their 2005 levels. Because the *SimSmoke* model does not predict rates of SLT use, we examined recent trends in those rates using the 1992/1993 through 2001/2002 TUS. Because use was quite low and data from earlier years failed to distinguish clear trends in SLT use between 1996 and 2001/2002, we conservatively assume that in the absence of an LN-SLT policy that smokeless rates remain constant between 2001/2002 and the year 2010.

2.2. The methodology

In evaluating the use of LN-SLT, we recognized that the data provided by individual studies was open to interpretation. In particular, the applicability of the studies to different environments (e.g., translation of the Swedish snus experience to the US) and the range of appropriate studies to consider (e.g., the use of smokeless tobacco in the US) were open to question. Given the degree of uncertainty, we selected a modified Delphi process (Crisp, Pelletier, Duffield, Nagy, & Adams, 1999; Dalkey & Helmer, 1963; Dunn, 1981; Everett, 1993; Hasson, Keeney, & McKenna, 2000; Powell, 2003). This method has been applied in numerous fields including health care and health policy since its development in the 1950s (Burnette, Morrow-Howell, & Chen, 2003; Hahn & Rayens, 1999; Kirigia, 1998; Rainhorn, Brudon-Jakobowicz, & Reich, 1994). It involves eliciting informed estimates from a panel of experts, sharing those estimates with the group, and trying to reach consensus in an iterative process.

The Delphi process was conducted through e-mail. Drawing on the collective expertise of the authors, a list of 17 potential panel members was developed. The experts were selected first based on their knowledge of the behavioral trends associated with both smokeless tobacco and cigarette use. From that pool of scientists, we purposefully excluded those who, while also experts, might be too strongly associated with a particular viewpoint (in terms of either their support or rejection of LN-SLT as an alternative to smoking). Based on financial constraints, assessment of bias and the requirements for expertise, the research team decided to recruit nine experts. Initially, letters were sent via e-mail to nine candidates prioritized by their expertise in the field and the need to maintain a balanced set of views. When a potential candidate declined to participate or did not respond in a timely fashion, s/he was replaced by a candidate chosen to maintain a balanced set of views. A total of 14 letters were sent, successfully obtaining the agreement of nine experts. However, two experts dropped out when the panel was ready to begin, leaving seven experts (three from the US, two from Sweden, and two from England) to serve on the Panel (Table 1).

In the initial contact, we told prospective Panel members the purpose of the project and informed them that these estimates would be used by the authors in an ongoing simulation analysis of the effects of a policy encouraging inveterate smokers to switch to LN-SLT. Behavioral Panel members were also aware of the research team's intent to submit a paper for publication describing the results. Panel members were informed that they would be identified as a member of the Panel, but personal identifiers regarding estimates and comments would be removed from all transmission of estimates to fellow Panel members and from all output of the study. Panel members committed to participate through several rounds of a Delphi process to reach a general consensus and were paid $600 upon completion of the process.

We distributed a list of published articles to Behavioral Panel members to provide some common base of knowledge. The original list was based on a review of the literature developed from a search of Medline and CDC's Office of Smoking and Health database, and reviews of the reference lists of published articles. We included articles on SLT use in the US as well as snus use in Sweden. Studies of SLT use in other countries were considered less relevant. Once committed to participating, Panel members were asked to review the list of references and to suggest additional articles; we added suggested articles that focused on SLT use. A package containing copies of each article on the final list was mailed to all Panel

Table 1
Behavioral Panel Members

1) Frank Chaloupka
University of Illinois at Chicago, Department of Economics, Chicago, IL, USA
2) Karl-Olov Fagerström
Fagerström Consulting, Helsingborg, Sweden
3) Hans Gilljam
Karolinska Institute, Stockholm, Sweden
4) Dorothy Hatsukami
University of Minnesota, Tobacco Use Research Center, Minneapolis, MN
5) Jack Henningfield
Pinney Associates, Bethesda, MD, USA
6) Martin Jarvis
University College London, Epidemiology and Public Health, London, UK
7) Ann McNeil
University College London, London, UK

members. The list of collaborating Behavioral Panel members was also provided at the outset of the process. A copy of the initial contact letter, the list of articles provided, the instructions and forms, detailed results from each round, and the summary of results are available from the first author.

In the first round, the research team provided the Panel members with a description of the process, including assumptions and instructions, and an Excel file to be filled in with their prevalence predictions. The Excel file contained four worksheets, distinguishing males and females ages 21–25 and 41–45 years. Following each round, the research team provided a summary of Panel members' responses to the full Panel for review and reassessment (with personal identifiers removed). In addition, after Round 1 the research team submitted questions to the Panel members to help determine areas of agreement and disagreement. Panel members were also asked about their level of confidence in their response: very confident, confident, or not very confident. For each round, Panel members were asked to respond within 1 week, although in practice the two completed rounds actually took 3–5 weeks.

3. Results

The seven Panel members participated in each of the rounds. We focus here on the final results achieved in Round 2 (see Tables 2 and 3). The overall results reflect some changes between Round 1 and Round 2, notably the estimates of projected SLT use went down slightly for all groups except females age 21–25 years (where it increased by 0.01 percentage point). Changes between rounds are expected as Panel members reflect on their colleagues' individual estimates and the full range of responses. Although the Round 2 results did vary some from Round 1, Panel members generally reported that their changes

Table 2
Results from Round Two (final) of the delphi process: predicted prevalence rates for age groups 21–25 years

Categories	Male					Female				
	2010 Current Policy	2010 LNSLT Policy Mean	Median	Min	Max	2010 Current Policy	2010 LNSLT Policy Mean	Median	Min	Max
Current smoker, never SLT user	23.3%	19.6%	20.0%	17.5%	20.5%	22.3%	20.6%	21.0%	19.0%	21.6%
Current smoker, former SLT user	2.6%	2.0%	2.0%	1.0%	3.2%	0.2%	0.2%	0.2%	0.1%	0.3%
Current smoker, current SLT user	1.6%	2.7%	2.8%	2.0%	4.0%	0.0%	0.3%	0.2%	0.0%	1.0%
All current smokers*	27.5%	24.4%	24.8%	21.5%	26.4%	22.5%	21.1%	21.3%	19.7%	22.1%
Current SLT user, never smoker	1.8%	3.6%	3.0%	2.7%	6.0%	0.1%	0.4%	0.2%	0.1%	1.0%
Current SLT user, former smoker	0.7%	2.2%	2.6%	0.0%	4.4%	0.0%	1.0%	1.0%	0.0%	3.0%
All SLT users**	4.1%	8.5%	8.8%	6.8%	11.0%	0.1%	1.7%	1.2%	0.2%	5.0%
Former smoker, never SLT user	7.3%	6.7%	6.5%	5.0%	8.5%	8.6%	9.1%	9.0%	8.2%	10.0%
Former smoker, former SLT user	0.7%	1.5%	1.3%	0.8%	3.0%	0.0%	0.3%	0.2%	0.0%	1.0%
Former smokers***	8.7%	10.4%	11.0%	8.0%	12.1%	8.7%	10.4%	10.0%	8.9%	13.0%
Former SLT user, never smoker	1.5%	1.6%	1.5%	1.0%	2.0%	0.0%	0.1%	0.0%	0.0%	0.2%
Never SLT, never smoker	60.5%	60.1%	59.7%	59.2%	62.0%	68.7%	68.1%	68.5%	65.0%	69.6%

Yellow rows are summations of selected previous rows. *All current smokers includes current smoker/never SLT user, current smoker/SLT user, and current smoker/ former SLT user. **All SLT users includes current SLT user/never smoker, current SLT user /current smoker, and current SLT user/ former smoker. ***Former smokers includes former smoker/never SLT user, former smoker/SLT user, and former smoker/ former SLT user.

Table 3
Results from Round Two (final) of the Delphi Process: predicted prevalence rates for age groups 41–45 years

Categories	Male					Female				
	2010 Current Policy	2010 LNSLT Policy Mean	Median	Min	Max	2010 Current Policy	2010 LNSLT Policy Mean	Median	Min	Max
Current smoker, never SLT user	22.9%	19.8%	20.0%	17.5%	21.0%	21.2%	19.3%	20.0%	16.0%	20.6%
Current smoker, former SLT user	1.3%	1.2%	1.3%	1.0%	1.5%	0.1%	0.1%	0.1%	0.1%	0.2%
Current smoker, current SLT user	0.5%	1.2%	1.0%	0.8%	2.0%	0.0%	0.5%	0.3%	0.1%	2.0%
All current smokers*	24.8%	22.2%	22.3%	20.5%	23.2%	21.3%	19.9%	20.2%	18.1%	20.9%
Current SLT user, never smoker	1.6%	2.5%	1.9%	1.8%	5.0%	0.1%	0.6%	0.2%	0.1%	3.0%
Current SLT user, former smoker	1.0%	2.3%	1.8%	1.0%	5.0%	0.0%	0.5%	0.2%	0.0%	1.5%
All SLT users**	3.1%	6.0%	5.6%	4.4%	8.9%	0.1%	1.6%	0.8%	0.3%	5.2%
Former smoker, never SLT user	25.2%	24.5%	25.2%	22.0%	27.0%	22.0%	22.1%	22.0%	21.0%	23.1%
Former smoker, former SLT user	1.3%	2.4%	2.2%	1.5%	4.0%	0.1%	0.2%	0.1%	0.1%	0.3%
Former smokers***	27.4%	29.2%	29.5%	26.0%	30.4%	22.1%	22.8%	22.7%	22.1%	23.4%
Former SLT user, never smoker	1.5%	1.6%	1.5%	1.5%	2.0%	0.1%	0.1%	0.1%	0.1%	0.2%
Never SLT, never smoker	44.7%	44.7%	44.5%	44.0%	46.0%	56.5%	56.5%	56.4%	55.4%	58.0%

Yellow rows are summations of selected previous rows. *All current smokers includes current smoker/never SLT user, current smoker/SLT user, and current smoker/ former SLT user; **All SLT users includes current SLT user /never smoker, current SLT user/current smoker, and current SLT user/ former smoker; ***Former smokers includes former smoker/never SLT user, former smoker/SLT user, and former smoker/former SLT user.

were slight and commented on the relative consensus apparent in the estimates. The difference between the minimum and maximum predicted prevalence of smoking and SLT prevalence was reduced for three of the demographic groups, with a very slight increase for females ages 21–25 years. The moderators determined that a third round would not yield substantial variation in the final estimates.

The data are summarized in terms of the average estimates provided by the Panel members, the median of predicted values for each category of tobacco use, and the minimum and maximum values reflecting the range of responses. Because mean and median values are close, we concentrate on reporting mean values of predicted use.

Relative to the 2010 predicted smoking prevalence without the introduction of a new LN-SLT product or policy, the estimated prevalence of total current smoking, regardless of LN-SLT use patterns, is predicted to decline under the new policy scenario for each of the four demographic groups. The relative percentage decrease in the mean estimated prevalence of current smoking is about 11% (3.1 percentage points) for males ages 21–25 years and 10% (2.6 percentage points) for their older counterparts. The estimated relative decrease in mean prevalence for females is about half that of males, or 6% (a 1.3–1.4 percentage point decline) for females in both age groups. The reduction in smoking prevalence (except for males ages 21–25 years) is primarily among never SLT users, but some of that reduction is offset by an increase in concurrent use of cigarettes and SLT.

The predicted decrease in overall current smoking under the new policy regime, as estimated by the seven Panel members, is offset by an estimated increase in the percentage of SLT users and, to a lesser degree, by an increase in the percentage of former smokers. Overall current SLT use is predicted to approximately double after 5 years of a new product and policy regime for both younger and older males. Male prevalence at ages 21–25 years is predicted to be 8.5% relative to the old policy scenario

prediction of 4.1%, and for males ages 41–45 years, the predicted prevalence of SLT use is 6.0% relative to 3.1% without any policy changes. Among male current SLT users of both age groups, the increases are greatest among those who are also former smokers. Total formal smoking among males ages 21–25 years is estimated to increase by 1.7 percentage points, or 19% higher relative to the initial level. Among males ages 41–45 years, former smoking is predicted to increase by 1.8 percentage points, or 7% higher.

Predicted increases in SLT use among females are based on a smaller population of current users. The predicted prevalence of current SLT use among females ages 21–25 years is 1.7% under a new policy regime, compared to 0.1% under current policies. Most of the increase is among former smokers. Among females ages 41–45 years, the predicted SLT prevalence also increases to about 1.6% compared to negligible use under current scenarios, with most of the increase among former smokers. Former smoking is estimated to increase by 1.7 percentage points among females age 21–25 years, and 0.7 percentage points among females age 41–45 years.

Following Round 1, the Moderator asked Panel members to comment on their level of confidence in each of their predicted values. Overall, four Panel members reported themselves "confident" or "very confident" in their estimates, with two of these four having higher confidence regarding their estimates for the females versus the males. A fifth Panel member felt confident in his/her estimate regarding male tobacco use rates, but not confident in his/her estimates for females. The remaining two Panel members reported less confidence in their estimates overall. Confidence levels did not appear to vary by the age group considered.

4. Discussion

An overall consensus was reached that the introduction of a new LN-SLT product introduced to the US market under strict regulations but with relevant health claims would *not* impede the decline in overall smoking prevalence. Indeed, all Panel members indicated that the new policy would likely accelerate the decline in smoking prevalence. Estimates of the decreases in predicted smoking prevalence compared to the current product/policy scenario range from 1.3% to 3.1% percentage points. There was a greater predicted impact on males than females.

Introduction of the new product/policy scenario was predicted to result in greater use of SLT overall, particularly among males ages 21–25 years who had recently initiated tobacco use, but also among older males and females. The increase in SLT use under the new regime predicted by the different Panel members ranged between 2.7 and 6.9 percentage points for males ages 21–25 years, which is considerably less than the increase observed in Sweden, albeit over a longer time period (Foulds et al., 2003). Panel members linked the increase in SLT use to the decrease in smoking prevalence as a means to achieve smoking cessation, especially among smokers ages 41–45 years.

Given the current, heated debates surrounding harm reduction as a tobacco control policy, the level of agreement that was reached in this study might be considered surprising. At least some of the past controversy may be regarding how the policy is defined and analyzed. We have specified a thought experiment in which we can isolate the primary changes that might occur after the new LN-SLT policy was implemented. We defined a specific policy regime regarding LN-SLT, and isolated the effect of that change from other policies. We limited the exercise to two age groups to distinguish the effects on those who initiated tobacco use after the policy was in effect from those who initiated in the pre-policy regime.

To limit demands on the Panel, they were not asked about other potentially relevant age groups, such as the cessation behavior of those initiating under the new regime at later ages.

While the research team sought to simplify the format to isolate the important changes, a potential limitation of this study is the complexity of the exercise. The research team provided a common set of studies to the Behavioral Panel members at the outset, but there may still be differences in individual members' interpretation of available data and application of this information to the complexity of nine tobacco use behavioral categories. Although not requested of the Panel, only one Panel member reported in detail the quantitative logic of his/her calculations. One Panel member pointed out that an increase in the category of never tobacco users might reflect residual adjustment of estimates in the final row to achieve overall 100% prevalence of all tobacco categories. A predicted decrease in the number of never smokers/SLT users among those ages 41–45 years by one Panel member raises such suspicions.

Another limitation of this study is that a relatively small number of Panel members participated compared to prior Delphi analyses (Crisp et al., 1999; Dalkey & Helmer, 1963; Dunn, 1981; Everett, 1993; Hasson et al., 2000; Powell, 2003). We limited our original pool of potential participants by the number of scientists who are experts on both smoking and smokeless tobacco use, and who would represent a balanced set of views. Financial limitations also constrained the size of the Panel. While we attempted to recruit a balanced Panel in terms of the range of views, the results unavoidably reflect the authors' selection of panel members and the self-selection of Panel members who agreed to participate. With a view that the issues relating to harm reduction are open to debate, the authors endeavored to select panel members and establish a framework that would be impartial."

The generality of the results, and especially their applicability to other nations and to other policies, is limited by the way that the policies were specified in this exercise. After Round 1, the Moderator raised three issues in a summation of the results that echoed issues raised by Panel members. First, in response to a Panel member's comment on the sensitivity of estimates to the expected level of tobacco industry marketing efforts, the Moderator asked Panel members to incorporate any changes expected in marketing by SLT and cigarette firms under the new policy. In Round 2 results, several Panel members mentioned aggressive advertising by SLT and cigarette manufacturers in describing changes in their responses. One Panel member pointed out that the U.S. places few limitations on marketing efforts, unlike the European Union. Another Panel member noted that marketing efforts might have a greater impact on the younger age group, and increased their estimate of expected prevalence of current SLT use among males ages 21–25 years by 61%. This Panel member noted that the effect of aggressive marketing on young females was less predictable but might elicit higher use among females ages 41–45 years to help quit smoking. Another Panel member mentioned potential increased use among females ages 41–45 years in response to marketing efforts that highlight smoke-free environment goals.

The second issue raised by the Moderator was that the levels of other tobacco control policies were assumed to remain constant at 2005 levels. This was one of the original assumptions of the exercise and should not have had much impact. However, in response to the Moderator's point, one Panel member emphasized "the targets are moving," referring to uncertainty about general trends as tobacco control policies change. This Panel member also raised the question of relative effectiveness of changes in public health efforts in contrast with developments in the tobacco industry's efforts. Although an important consideration, we did not ask Panel members to consider how the LN-SLT policy might impact other tobacco control policies, because we were concerned that the added complexity of the task might confuse interpretation of the results.

A third issue noted by the Moderator was in response to a Panel member's comments about Ariva. In the first round, one Panel member specified his/her assumption that the new LN-SLT product would be "as addictive and acceptable to consumers as snus is. This is not the case for products such as Ariva, which are lower dose—more akin to NRT." This Panel member suggested that the new policy would only gradually impact the tobacco market. Another Panel member commented that LN-SLT products such as Ariva or Stonewall are likely to be "appealing to smokers (ages 41–45 years) because they are cheaper and more palatable than NRT." In response to these comments, the Moderator emphasized that Ariva is only one example of an LN-SLT product mentioned in the project outline for illustrative purposes. Panel members did not specify this issue as having an impact on their Round 2 estimates although one Panel member indicated the uncertainty surrounding the available LN-SLT products on the market. Other issues surrounding the product were, however, mentioned. One Panel member commented that the health claim would have less impact on cultural norms in a country that is less influenced by norms in surrounding cultures (as are European nations in close proximity). By contrast, another Panel member expected smokers would heed the warning label and substitute LN-SLT heavily for smoking behavior.

In conclusion, the results from this study indicate that the introduction of a well regulated LN-SLT product is expected to reduce smoking and only modestly increase SLT use in the United States. Notably, the overall impact of the new policy regime is predicted to lead to virtually no change in overall tobacco use, i.e., the percent of males ages 21–25 years that use either SLT or cigarettes was predicted to increase from 30.0% to 30.2% while females ages 21–25 years decreased from 22.6% to 22.5%.

The results indicate that cigarette users would switch to smokeless with little change in overall tobacco use and with a limited degree of substitution of LN-SLT for cigarettes. If these results hold, the substantial reduction in health risks associated with LN-SLT use (Levy et al., 2004) should yield a net public health benefit through reduced mortality. Health benefits might also be expected from lower risks associated with the low-nitrosamine SLT compared to SLT now available in the US. However, a more complete analysis will involve making explicit a host of assumptions and the extent of uncertainty surrounding the estimates. Important to the effect of an LN-SLT product is the role of the regulatory framework (Stratton et al., 2001) and how the new LN-SLT policy impacts other tobacco control policies. Future work will consider the plausible range of behavioral and health effects through the development of a comprehensive simulation model.

Funding for this project was received from the Tobacco Control Research Branch of the National Cancer Institute's Division of Cancer Control and Population Sciences. David Levy and Elizabeth Mumford also received funding through grant UO1-CA-097450 of the National Cancer Institute's CISNET Program. We would like to thank Scott Leischow for his encouragement in developing this project.

References

Burnette, D., Morrow-Howell, N., & Chen, L. M. (2003). Setting priorities for gerontological social work research: A national Delphi study. *Gerontologist*, *43*(6), 828–838.

Burns, D., Anderson, C., Johnson, M., et al. (2000). Cessation and cessation measures among daily adult smokers: National-and State-specific data. *Population-based Smoking Cessation: A Conference on What Works to Influence Smoking in the General Population. Smoking and Tobacco Control Monograph No. 12.* N.C. Institute. Bethesda, MD, National Cancer Institute, National Institutes of Health: 113–304.

Centers for Disease Control and Prevention (1994). Cigarette Smoking Among Adults—United States, 1992, and Changes in the Definition of Current Cigarette Smoking. *MMWR*, *43*, 342–346.

Choi, W. S., Pierce, J. P., Gilpin, E. A., Farkas, A. J., & Berry, C. C. (1997). Which adolescent experimenters progress to established smoking in the United States. *American Journal of Preventive Medicine*, *13*(5), 385–391.

Crisp, J., Pelletier, D., Duffield, C., Nagy, S., & Adams, A. (1999). It's all in a name. When is a 'Delphi study' not a Delphi study? *Australian Journal of Advanced Nursing*, *16*(3), 32–37.

Dalkey, N., & Helmer, O. (1963). An experimental application of the Delphi method to the use of experts. *Management Science*, *9*, 458–467.

Dunn, W. (1981). *Public policy analysis*. Englewood Cliffs, New Jersey: Prentice-Hall.

Everett, A. (1993). Piercing the veil of the future. A review of the Delphi method of research. *Professional Nurse*, *9*(3), 181–185.

Foulds, J., Ramstrom, L., Burke, M., & Fagerstrom, K. (2003). Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control*, *12*(4), 349–359.

Gilpin, E. A., & Pierce, J. P. (2001). Patterns of cigar use in California in 1999. *American Journal of Preventive Medicine*, *21*(4), 325–328.

Hahn, E. J., & Rayens, M. K. (1999). Consensus for tobacco policy among former state legislators using the policy Delphi method. *Tobacco Control*, *8*(2), 137–140.

Hasson, F., Keeney, S., & McKenna, H. (2000). Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing*, *32*(4), 1008–1015.

Kirigia, J. M. (1998). Economic evaluation in schistosomiasis: Valuation of health states preferences. A research note. *Health Economics*, *7*(6), 551–556.

Levy, D. T., Mumford, E., Cummings, M., Gilpin, B., Giovino, G., Hyland, A., et al. (2004). The relative risks of a low-nitrosamine smokeless tobacco product compared to smoking cigarettes: Estimates of a panel of experts. *Cancer Epidemiology, Biomarkers and Prevention*, *13*(12), 2035–2042.

Levy, D. T., Mumford, E., & Nikolayev, L. (2005). Recent Trends in Smoking and the Role of Public Policies: Results from the SimSmoke Tobacco Control Policy Simulation Model. *Addiction*, *10*(10), 1526–1537.

National Cancer Institute (1998). Cigars: Health Effects and Trends. Bethesda, MD, National Institutes of Health, National Cancer Institute.

Nelson, D. E., Davis, R. M., Chrismon, J. H., & Giovino, G. A. (1996). Pipe smoking in the United States, 1965–1991: Prevalence and attributable mortality. *Preventive Medicine*, *25*(2), 91–99.

Powell, C. (2003). The Delphi technique: Myths and realities. *Journal of Advanced Nursing*, *41*(4), 376–382.

Rainhorn, J. D., Brudon-Jakobowicz, P., & Reich, M. R. (1994). Priorities for pharmaceutical policies in developing countries: Results of a Delphi survey. *Bull World Health Organ*, *72*(2), 257–264.

Shiffman, S., Gitchell, J. G., Warner, K. E., Slade, J., Henningfield, J. E., & Pinney, J. M. (2002). Tobacco harm reduction: Conceptual structure and nomenclature for analysis and research. *Nicotine & Tobacco Research*, *4*(Suppl 2), 113–129.

Stratton, K., Shetty, P., Wallace, R., & Bondurant, S. (2001). *Clearing the smoke: Assessing the science base for tobacco harm reduction.* Washington, DC, Institute of Medicine, National Academy Press.

Sweanor, D. (2003). Reducing toxicity exposure for the nicotine-dependent. *Addiction*, *98*(9), 1197–1198.

Tomar, S. L., Connolly, G. N., Wilkenfeld, J., & Henningfield, J. E. (2003). Declining smoking in Sweden: Is Swedish Match getting the credit for Swedish tobacco control's efforts? *Tobacco Control*, *12*(4), 368–371.

U.S. DHHS (1992). Smoking and health in the Americas: A Report of the Surgeon General, in collaboration with the Pan American Health Organization. Atlanta, GA, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

U.S. DHHS (1994). Preventing tobacco use among young people: A report of the Surgeon General. Atlanta, GA, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.