Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys

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ABSTRACT

Background In the USA, consumption of moist snuff continues to increase and cigarette manufacturers now control nearly its entire market. Manufacturers have developed new products that represent cigarette brand extension and in test marketing are promoting dual use of cigarettes and snuff. This study examined patterns of concurrent use of smokeless tobacco (ST) and cigarettes among young people and adults in the USA just before cigarette companies’ control of the nation’s ST market.

Methods Data were drawn from four US nationally representative surveys. Stratified analyses applied sampling weights and accounted for the complex sample designs.

Results Cigarette smoking was substantially more prevalent among young males who used ST than among those who did not. Among adult males, those who smoked daily were less likely than others to have used snuff every day. Men who used moist snuff daily had the lowest prevalence of daily smoking, but the prevalence of daily smoking was relatively high among men who used moist snuff less than daily. Unsuccessful past-year attempts by daily smokers to quit smoking were more prevalent among non-daily snuff users (41.2%) than among those who had never used snuff (29.6%).

Conclusions Although dual daily use of ST and cigarettes is relatively uncommon in the USA, concurrent ST use is more common among adolescent and young adult male smokers than among more mature tobacco users. Among adult males, daily smoking predominates and non-daily ST use is very strongly associated with current smoking. Adult male smokers who also use ST daily tend to have relatively high levels of serum cotinine and high prevalence of a major indicator for tobacco dependence.

BACKGROUND

Smokeless tobacco (ST) products include chewing tobacco, dry snuff and moist snuff. Consumption of chewing tobacco in the USA decreased from 47 million to 36 million pounds, and dry snuff from 3.5 million pounds to 2.2 million pounds from 2000 to 2006.1 However, during the same time period, consumption of moist snuff increased from 61.5 million pounds to 77.4 million pounds.1 Recently, cigarette and ST manufacturers have introduced a drier form of moist snuff called snus (20% moisture content vs 50% in traditional moist snuff), which is packaged in a pouch, often flavoured, and placed in the upper lip to reduce spitting. Snus has gained popularity among boys and men in Sweden, among whom its prevalence of use is greater than cigarette smoking.7 For decades, the US ST market was dominated by a small number of companies that sold only ST and had no financial interest in selling cigarettes. That situation changed with the acquisitions of the Conwood Company in 2006 by Reynolds American, Inc6 and the US Smokeless Tobacco Company (USSTC) in 2008 by Altria Group, the parent company for Philip Morris USA.4 Cigarette companies have also introduced new ST products, including moist snuff and snus, sold under cigarette brand names such as Marlboro and Camel. The recent entry by the cigarette industry into the US ST market, and expanded promotion of existing and new ST products, may have far-reaching public health implications. This new development has the potential to encourage increased ST use among young people and dual use of ST and cigarettes among smokers, while slowing reductions in smoking prevalence and undermining cessation.

Few studies have been conducted regarding the extent of dual use of ST and cigarettes in the USA,5–6 and none has examined detailed patterns across multiple population-based data sources. The purpose of this study was to examine patterns of concurrent use of ST and cigarettes among young people and adults in the USA. Data were primarily collected before the recent acquisitions of the US ST companies by cigarette manufacturers, and the analyses therefore may be viewed as a baseline measure of the extent of dual product use just before the entry of the major cigarette companies into the nation’s ST market. The analysis focused specifically on snuff, where possible. It also analysed levels of serum cotinine and markers of nicotine addiction such as time to first cigarette after waking among exclusive smokers and dual product users. Because use of ST in the USA is relatively rare among females, all analyses in this study were limited to males.

METHODS

Data sources

Data for this study were drawn from four US nationally representative surveys. We include four data sources because each survey has its particular strengths and limitations and no single data source adequately covers the full range of ages and variables related to dual use of cigarettes and ST. For example, the Current Population Survey Tobacco Use Supplement provides extensive detail on tobacco use, but is not anonymous and does not include people under age 16. School-based surveys such as the Monitoring the Future Study and the National Youth Tobacco Survey are anonymously
administered and reach younger people but provide more limited
detail on pattern of tobacco use. In addition to self-reported
data, the National Health and Nutrition Examination Survey
collects biological specimens that enables measurements such as
serum cotinine levels, but has a limited sample size for subgroup
analyses. These surveys use different sampling schemes, method-
ologies and questions to collect data on tobacco use and other
variables included in this study. The sources and variables
examined are briefly summarised below.

Current Population Survey—Tobacco Use Supplement
The US Bureau of the Census and the US Bureau of Labour
Statistics have conducted the Current Population Survey (CPS)
for more than 50 years to assess employment in the USA (US
CPS-66.pdf). The sample is drawn from the US civilian, non-
institutionalised population age 15 years or older. Data are
collected monthly through household interviews. Questions on
tobacco use were added as a National Cancer Institute-sponsored
Tobacco Use Supplement (TUS) to the monthly CPS in May
and August 2006 and January 2007, which are the most recent data
available at this time. Data for those 3 months were combined
and used to produce national estimates. Although CPS includes
both self-reported and proxy-reported data, analysis in this study
included only self-reported data. Further information on the CPS-
TUS is available at: http://riskfactor.cancer.gov/studies/tus-cps/.

Monitoring the Future Survey
Supported by grants from the National Institute on Drug Abuse,
the University of Michigan’s Institute for Social Research has
surveyed nationally representative samples of high school seniors
in the spring of each year since 1975 as part of the Monitoring the
Future (MTF) Survey. Beginning in 1991, surveys also have been
conducted among 8th- and 10th-grade students. Multistage
sampling designs were used to randomly select students in public
and private schools within the 48 contiguous states. Self-
administered questionnaires were distributed to students in
classrooms by trained personnel, and standardised procedures
were followed. This report uses MTF Survey data from public use
data tapes for 2005 and 2006. A detailed description of the MTF
survey is available elsewhere.9

National Health and Nutrition Examination Survey
The National Health and Nutrition Examination Survey
(NHANES) is a programme of studies conducted by the National
Center for Health Statistics to assess the health and nutritional
status of adults and children in the USA. As part of the NHANES,
venepuncture is performed to collect a blood sample from each
participant. The blood samples are subsequently assayed for
a wide range of biochemical substances, including cotinine,
a major metabolite of nicotine and a biomarker for nicotine
exposure. The NHANES is designed to be representative of the
civilian, non-institutionalised US population. The analyses in this
study included data from 1999 to 2006 for men aged 20 years and
older. Further details on NHANES are available at http://www.
cdc.gov/nchs/nhanes.htm.

National Youth Tobacco Survey
The National Youth Tobacco Survey (NYTS) has been conducted
by the Centers for Disease Control and Prevention since 1999 to
provide estimates of current use of tobacco products among US
middle school and high school students. The NYTS uses anony-
mous, self-completed survey instruments administered to
students in a multi-stage probability sample of public and private
schools and classes. Further information on the NYTS is available
at: http://www.cdc.gov/tobacco/data_statistics/surveys/NYTS/
index.htm. This study included data from the 2006 NYTS.

Analysis
Each of the datasets was analysed for a number of parameters
related to dual use of smokeless tobacco and cigarettes, including
► The prevalence of smoking, by smokeless tobacco use status
► The prevalence of smokeless tobacco use status, by smoking
status
► Number of cigarettes smoked per day by daily smokers, by
smokeless tobacco use status
► Sociodemographic characteristics of dual users
► Indicators of nicotine addiction, by smoking and snuff use
status
► Interest and attempts to quit smoking among daily smokers,
by snuff use status
► Biochemical markers of nicotine exposure, by smoking and
snuff use status.

Most analyses involved bivariate contingency tables, generally
stratified by demographic characteristics such as age or grade in
school. All datasets included in this study used complex sample
designs and applied sampling weights to account for differential
probabilities of selection and participation. Therefore, all statisti-
cal analyses were conducted on weighted data by using SAS and
SUDAAN software packages. p Values are reported for some
specific comparisons of means or proportions, and we reported
standard errors for estimated means and proportions to allow
readers to calculate confidence intervals for those estimates.

RESULTS
Young people
Patterns of dual use
Based on the 2004 NYTS, 7.6% of male middle school students
and 21.0% of male high school students smoked on at least one
of the 30 days preceding the survey (table 1). The prevalence of
cigarette smoking was substantially higher among young males
who used ST than among those who did not. For example, in the
2004 NYTS, 69.1% of boys in middle school who used ST every
day also smoked during the preceding 30 days; 53.8% smoked
every day. The pattern was similar for male high school students
in the NYTS: about 60% of those who used ST in the past
30 days also smoked, compared to 17% of those who did not use
ST. Although there were relatively few high school males in any
grade who used ST on a daily basis, 7th graders in the 2005–2006
MTF Survey (data not shown) who used ST daily had a much
higher prevalence of smoking one-half pack of cigarettes or more
per day (10.8%) than did those who did not use ST at all (1.3%).
The pattern was even more pronounced among 10th grade male
students: 22.7% of daily ST users also smoked one-half pack
of cigarettes or more per day, compared with 8.8% of less-than-daily
ST users and 1.7% of those who did not use ST at all. Males in
12th grade who used ST on a daily basis did not differ appreciably
on the prevalence of smoking one-half pack or more per day
(22.8%) from those who used ST but less than daily (25.9%), but
the prevalence of smoking one-half pack of cigarettes or more per
day was about five times greater among ST users than among
non-users (4.7%).

Based on the 2004 NYTS, 3.1% of male middle school
students and 9.5% of male high school students used ST on at
least one of the 30 days preceding the survey (table 2). ST use was
substantially higher among young males who smoked than
among non-smokers. For example, 27.7% of male middle school
students who smoked daily during the preceding 30 days also had
used ST during that time period, compared to 1.6% of those who had not smoked during the preceding 30 days. Differences between lighter smokers and heavier smokers in the prevalence of ST use were more pronounced among students in higher grades than in lower grades. For example, in grade 8 in the 2006 MTF Survey, 24.8% of males who smoked at least one-half pack of cigarettes smoked ST on some days or had never used it. Among men age 25 years or older in the 2006 CPS-TUS, 24.5% of males who smoked at least one-half pack of cigarettes of preceding 30 days

### Table 2 Smokeless tobacco (ST) use within the 30 days preceding the survey, by number of days of cigarette smoking within the preceding 30 days

<table>
<thead>
<tr>
<th>Number of days used smokeless tobacco in the preceding 30 days</th>
<th>Unweighted sample size</th>
<th>Number of days used ST of preceding 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 30 days</td>
<td>1–29 days</td>
</tr>
<tr>
<td>Middle school*</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>All 30 days</td>
<td>42</td>
<td>53.8</td>
</tr>
<tr>
<td>1–29 days</td>
<td>140</td>
<td>9.3</td>
</tr>
<tr>
<td>0 days</td>
<td>6327</td>
<td>0.7</td>
</tr>
<tr>
<td>Total</td>
<td>6509</td>
<td>1.2</td>
</tr>
<tr>
<td>High school†</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>All 30 days</td>
<td>105</td>
<td>32.1</td>
</tr>
<tr>
<td>1–29 days</td>
<td>348</td>
<td>26.3</td>
</tr>
<tr>
<td>0 days</td>
<td>5804</td>
<td>5.4</td>
</tr>
<tr>
<td>Total</td>
<td>6257</td>
<td>7.6</td>
</tr>
</tbody>
</table>

Male middle school students (grades 6–8) and high school students (grades 9–12). National Youth Tobacco Survey, 2004.

*\(p < 0.00001\).

† \(\chi^2 = 55.51\) (df = 4); \(p < 0.00001\).

#### Table 3 Smoking status of males aged 25 years or older, by snuff use status

<table>
<thead>
<tr>
<th>Smoker status</th>
<th>Unweighted sample size</th>
<th>Current daily</th>
<th>Current some day</th>
<th>Former</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% SE</td>
<td>% SE</td>
<td>% SE</td>
<td>% SE</td>
<td>% SE</td>
</tr>
<tr>
<td>Current daily</td>
<td>1100</td>
<td>7.3</td>
<td>0.9</td>
<td>7.7</td>
<td>1.0</td>
</tr>
<tr>
<td>Current some day</td>
<td>539</td>
<td>37.4</td>
<td>2.5</td>
<td>7.3</td>
<td>1.4</td>
</tr>
<tr>
<td>Former</td>
<td>5989</td>
<td>28.1</td>
<td>0.7</td>
<td>6.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Never</td>
<td>59665</td>
<td>14.9</td>
<td>0.2</td>
<td>3.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Total</td>
<td>67293</td>
<td>16.0</td>
<td>0.2</td>
<td>3.8</td>
<td>0.1</td>
</tr>
</tbody>
</table>


2.9% of non-daily smokers, 1.9% of former smokers and 1.3% of never smokers (table 4).

Selected sociodemographic characteristics of male daily smokers aged 25 years or older, by snuff use status, were analysed in the 2006–2007 CPS-TUS (data not shown). Daily dual product users were younger (mean = 42.45 years) than daily smokers who never used snuff (mean = 46.56 years; \(p = 0.005\)). Daily smokers who also used snuff on some days were significantly younger (mean = 38.58 years) than daily dual users (mean = 41.68 years; \(p = 0.002\)), former users (mean = 41.68 years; \(p = 0.002\)) and never users (\(p < 0.00001\)). Nearly all dual product users were white and were not of Hispanic ethnicity. Dual product use was most common in the southern region of the USA, including 53.6% of daily smokers who also used snuff daily and 45.2% of those who used snuff occasionally, compared to 38.0% of male daily smokers who had never used snuff. Daily product users also were over-represented in non-metropolitan areas. Among male daily smokers, the prevalence of concurrent snuff use was highest in Wyoming (11.8%), North Dakota (6.5%), Arkansas (5.9%) and West Virginia (5.6%) (data not shown).

#### Table 4 Snuff use status of males aged 25 years or older, by cigarette smoking status

<table>
<thead>
<tr>
<th>Smoking status</th>
<th>Unweighted sample size</th>
<th>Snuff use status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% SE</td>
<td>% SE</td>
</tr>
<tr>
<td>Current daily</td>
<td>10802</td>
<td>0.6</td>
</tr>
<tr>
<td>Current some day</td>
<td>2403</td>
<td>2.9</td>
</tr>
<tr>
<td>Former</td>
<td>19125</td>
<td>1.9</td>
</tr>
<tr>
<td>Never</td>
<td>34963</td>
<td>1.3</td>
</tr>
<tr>
<td>Total</td>
<td>67293</td>
<td>1.4</td>
</tr>
</tbody>
</table>

prevalent among daily smokers who also used ST daily (74.5%) and least prevalent among daily smokers who never used smokeless tobacco (63.8%).

Based on the 2006–2007 CPS-TUS, 30.0% of male daily smokers aged 25 years or older quit smoking for at least 1 day within the 12 months preceding the survey. Past-year quit attempts were more prevalent among non-daily snuff users (41.2%) than among daily smokers who had never used snuff (29.6%). That group also expressed a significantly greater degree of interest in quitting than did daily smokers who did not use snuff.

### DISCUSSION

Based on data from four large, US nationally representative surveys of young people or adults, the association between smokeless tobacco use and cigarette smoking is complex. The prevalence of smoking is generally quite high among men who use snuff on a less-than-daily basis and among former snuff users, while the prevalence of smoking is relatively low among men who use snuff every day. The pattern is quite different for young people: the prevalence of daily smoking is very high among male students in middle school and high school who use smokeless tobacco. This pattern is consistent with findings from an earlier US nationally representative prospective cohort study, which found that early dual users largely moved towards cigarette smoking later in life.11

A number of indications in this study reflect a potentially troubling pattern of smoking associated with non-daily ST use: ‘some day’ snuff users are more likely to be current daily smokers than any other group, and daily smokers who also use snuff on some days expressed greater interest in quitting smoking than the other groups but were more likely than any other group to have had unsuccessful quit attempts in the preceding year. This pattern of tobacco use may represent a partial substitution of smoking and a prolonging of dependence. Conversely, it is possible that smokers who have had unsuccessful quit attempts subsequently turned to snuff as a cessation strategy. Understanding the reasons for dual use clearly requires further research.

Although dual daily use of ST and cigarettes is relatively uncommon, that pattern is more common among adolescents and young adults than among more mature tobacco users. Although male dual daily users tend to smoke fewer cigarettes per day than male daily smokers who do not use snuff or use it less than daily, they tend to have the highest levels of serum cotinine and exhibit among the most prevalent indicator of dependence.

Interestingly, daily smokers who also used snuff on a non-daily basis had serum cotinine levels that were essentially equivalent to those of daily smokers who never used snuff, although there was no significant difference in the number of cigarettes they smoked per day. It is not known whether that pattern reflects their infrequency of snuff usage, greater compensation among smokers whose only source of nicotine was cigarettes, biological factors such differences in nicotine metabolism, or the relatively imprecise estimates that resulted from small sample sizes.

The landscape of tobacco use is rapidly changing in the USA. Per capita cigarette consumption has reached its lowest point in more than 60 years,12 smoking among high school students is at its lowest level since tracking began9 and smoke-free indoor regulations continue to proliferate.13 14 However, sales of moist snuff in the USA continue to increase each year.1 In stark contrast to the situation that existed in the USA until 2006, when almost the entire smokeless tobacco market was controlled by companies that did not manufacture cigarettes, cigarette manufacturers now control virtually the entire US snuff market. There is no indication that the major tobacco companies are planning to abandon cigarette manufacturing; on the contrary, they appear to be positioning traditional and new types of ST products as complements and as situational substitutes for cigarettes.15 The most recently available data suggest that dual product use is primarily concentrated in regions and subpopulations of the USA where ST use has been relatively prevalent for many years—for example, young males in southern and

### Table 5

Mean number of cigarettes smoked per day and mean serum cotinine level among male daily cigarette smokers* aged 20 years or older, by smokeless tobacco use status

<table>
<thead>
<tr>
<th>Smokeless tobacco use</th>
<th>Unweighted sample size</th>
<th>Cigarettes per day</th>
<th>Serum cotinine (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SE</td>
<td>Mean ± SE</td>
<td>Mean ± SE</td>
</tr>
<tr>
<td>Every day</td>
<td>11</td>
<td>17.06 ± 3.79</td>
<td>344.20 ± 40.02</td>
</tr>
<tr>
<td>Some days</td>
<td>22</td>
<td>17.75 ± 1.62</td>
<td>215.79 ± 22.69</td>
</tr>
<tr>
<td>Former</td>
<td>32</td>
<td>22.69 ± 1.70</td>
<td>276.74 ± 22.54</td>
</tr>
<tr>
<td>Never</td>
<td>761</td>
<td>17.50 ± 0.57</td>
<td>241.51 ± 4.90</td>
</tr>
<tr>
<td>Total</td>
<td>826</td>
<td>17.73 ± 0.51</td>
<td>244.72 ± 4.51</td>
</tr>
</tbody>
</table>

*Respondents were asked to rate their level of interest in quitting smoking on a scale from 1—10, where 1 = not at all interested and 10 = extremely interested.
† Significantly higher than for those who never used snuff, p < 0.0001.
‡ Significantly higher than for those who never used snuff, p < 0.0005.
### Table 6

Prevalence of selected indicators of addiction and quit attempts among male daily smokers aged 25 years, by snuff use status

<table>
<thead>
<tr>
<th>Indicator of addiction or quitting/snuff use status</th>
<th>Unweighted sample size</th>
<th>Percentage or mean ± SE</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First cigarette ≤ 30 minutes after waking</td>
<td>75</td>
<td>75.5 ± 5.6</td>
<td>0.005</td>
</tr>
<tr>
<td>Current daily</td>
<td>197</td>
<td>41.2 ± 4.3</td>
<td>0.046</td>
</tr>
<tr>
<td>Former</td>
<td>1638</td>
<td>14.1 ± 1.6</td>
<td>0.0014</td>
</tr>
<tr>
<td>Never</td>
<td>8816</td>
<td>29.6 ± 0.6</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>10727</td>
<td>30.0 ± 0.5</td>
<td></td>
</tr>
</tbody>
</table>

*Significantly higher than for those who never used snuff, p < 0.0001.
†† Significantly higher than for those who never used snuff, p < 0.0005.
‡‡ Significantly higher than for those who never used snuff, p < 0.0001.

National Health and Nutrition Examination Survey, 1999—2006. *Excludes persons using cigars, pipes, or nicotine replacement pharmacotherapy. † Significantly greater than for those who never used smokeless tobacco (p ≤ 0.006). ‡ Significantly greater than for those who never used smokeless tobacco (p < 0.02).
Appalachian states, northern plain states and in non-metropolitan areas. With tobacco companies such as Reynolds American, Philip Morris USA, Liggett and Lorillard focusing their test marketing efforts on areas with large college student populations, such as Columbus, Ohio and Austin, Texas and large urban areas with recent smoke-free indoor air laws, such as Indianapolis, Portland and Orlando, dual use of cigarettes and ST may become more prevalent in other regions.

Our findings are consistent with other US studies on dual use of ST and cigarettes. An earlier analysis of 1998 National Health Interview Survey data also found a high prevalence of smoking among men who used ST on some days, and indications that some men were using ST as a way to quit smoking. Similar to our findings, previous analyses of the 2002 and 2004 National Youth Tobacco Surveys found that a large proportion of young people who smoked also used other tobacco products. An earlier study of dual product users also reported profound levels of tobacco dependence. The present study extends these previous studies by examining these patterns in greater detail across multiple age groups and modes of data collection.

There are several limitations inherent in the use of the data-sets analysed for this study. First, all of the studies used cross-sectional designs, which limits the ability to examine longitudinal patterns of transition between usage of tobacco products. Differences in patterns of dual use between young people and adults may reflect birth cohort effects, and future patterns of tobacco use among adults may differ as today’s young people progress through life. In addition, all surveys, with the exception of NHANES, rely only on self-report to estimate prevalence and consumption of tobacco products. Self-reported levels of tobacco consumption may be prone to error. However, such measurement error would be expected to be non-differential with respect to use of other tobacco products—for example, we have no reason to believe that smokeless tobacco users would differ from non-users in the accuracy of the their reported daily cigarette consumption. Non-differential measurement error would tend to attenuate the strength of association between smokeless tobacco use and cigarette smoking.

In conclusion, analyses of data from four nationally representative surveys indicate that dual use of cigarettes and ST is relatively common among young males. The pattern is different among adult males, among whom daily smoking predominates and non-daily snuff use is very strongly associated with current smoking. Adult male smokers who also use snuff tend to have relatively high levels of serum cotinine and high prevalence of a major indicator for tobacco dependence. The major US cigarette companies now control nearly the entire US smokeless tobacco market and aggressively promote dual product use, which may portend a lessening in the decline in smoking, increased dual use, perpetuation of dependence and continued high levels of tobacco related death and disease.

What is already known on this subject?

In the USA, cigarette smoking is declining, consumption of moist snuff is increasing and cigarette manufacturers now control nearly the entire moist snuff market. Manufacturers have developed new products that represent cigarette brand extension and are promoting dual use of cigarettes and snuff. No previous US studies have examined detailed patterns of dual use across multiple population-based data sources on the eve of the cigarette industry’s takeover of the moist snuff market.

What this study adds?

This study found that the prevalence of daily smoking is very high among male students in middle school and high school who use smokeless tobacco. The prevalence of smoking is generally quite high among adult males who use snuff on a less-than-daily basis and among former snuff users, while the prevalence of smoking is relatively low among men who used snuff every day. The study also found that adult male daily smokers who also use snuff on some days expressed greater interest in quitting smoking than other groups but were more likely than any other group to have had unsuccessful quit attempts in the preceding year. Although male dual daily users tend to smoke fewer cigarettes per day than male daily smokers who do not use snuff or use it less than daily, they tend to have the highest levels of serum cotinine and exhibit among the most prevalent indicator of dependence. The association between smokeless tobacco use and cigarette smoking is complex, and aggressive marketing of moist snuff by cigarette manufacturers may lead to unpredictable and undesirable public health outcomes.

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Competing interests SLT serves as an expert witness for plaintiffs in product litigation brought against cigarette and smokeless tobacco manufacturers.

Ethics approval This study was approved by the institutional review boards of Harvard University and the University of Florida Health Science Center.

Contributors All authors included on this paper fulfill the criteria of authorship. We also confirm that there is no one else who fulfills the criteria but has not been included as an author.

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REFERENCES


