7.5.3-2: UPDATE - NONUSERS' BEHAVIOR - LITERATURE SUMMARY

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LIST OF ABBREVIATIONS

AOR	adjusted odds ratio
APC	annual percent change
CI	confidence interval
CPD	cigarettes per day
CTC	Communities That Care
CYDS	Community Youth Development Study
EC	electronic cigarette
ETP	emerging tobacco product
FDA	Food and Drug Administration
HRB	health-risk behavior
LGB	lesbian, gay, and bisexual
MDMA	3,4-methylenedioxymethamphetamine
MRTPA	Modified Risk Tobacco Product Application
NRT	nicotine replacement therapy
NYC	New York City
NYTS	National Youth Tobacco Survey
OR	odds ratio
OTP	other tobacco product
PATH	Population Assessment of Tobacco and Health
ST	smokeless tobacco
TUS-CPS	Tobacco Use Supplement of the Current Population Survey
UDB	unhealthy dieting behaviors
U.S.	United States
WTS	water pipe tobacco smoking
YRBS	Youth Risk Behavior Survey

7.5.3-2. LITERATURE SUMMARIZING THE EFFECT ON TOBACCO USE INITIATION AMONG NONUSERS

The Family Smoking Prevention and Tobacco Control Act and the Food and Drug Administration's Modified Risk Tobacco Product Application Draft Guidance (2012) Section VI (A) (3) require the following assessments of tobacco use initiation in nonusers:

- "The likelihood that consumers who have never used tobacco products, particularly youth and young adults, will initiate use of the [candidate] tobacco product;

- The likelihood that non-users who adopt the [candidate] tobacco product will switch to other tobacco products that present higher levels of individual health risk; and

- The likelihood that former users of tobacco products will re-initiate use with the [candidate] tobacco product."

To address the effect of the candidate product on tobacco use initiation, the Food and Drug Administration recommends submitting data from human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising. Results from these studies are summarized in Section 6.4. To supplement studies on consumer perception, this section summarizes the published scientific literature on smokeless tobacco (ST) use initiation in nonusers.

7.5.3-2.1. Literature Search and Review Process

A comprehensive literature review was conducted through December 2014 that reviewed the health and behavioral effects of ST (Section 7.5.1), and literature summaries were drafted in areas that are important in the assessment of a modified risk tobacco product candidate. A second literature review was conducted for the period of December 08, 2014, to February 06, 2017, to update the original search. During the new search, 1,029 citations were identified, and, after applying predetermined inclusion and exclusion criteria, 165 articles were deemed to be in scope. In general, the in-scope articles were peer-reviewed and included ST products commercially available in the U.S. A keyword assignment exercise was performed to determine how many of those articles provide information about the likelihoods listed in the previous section, which relate to initiation of tobacco use, the gateway effect of ST products, and relapse potential of ST products. There were 37, 10, and 1 articles, addressing each of these likelihoods respectively. However, as new references became available after December 2014, they were, initially, included in the original narratives if they added new information. To avoid presenting the same article in both the original and updated literature reviews, we excluded two articles addressing the initiation of tobacco use and one article addressing the relapse potential of ST products from the updated review.

This section is intended to supplement the previous literature review (Section 7.5.3-1) to provide a current, updated literature review of the aforementioned topics.

7.5.3-2.2. The Likelihood that Consumers Who Have Never Used Tobacco Products, Particularly Youth and Young Adults, Will Initiate Use of the Product

Noteworthy articles included in this literature review that address the initiation of ST use are highlighted in the following sub-sections, and all 35 articles are summarized in Table 7.5.3-2-1. Articles selected for discussion in the subsections below include those that used data from large, nationally representative samples and large samples from specific regions.

7.5.3-2.2.1. Prevalence of Smokeless Tobacco Use among Adolescents and Young Adults

Few of the studies reviewed for this update examined age of initiation of tobacco product use: all such studies were retrospective and relied on accurate recall of initiation age. Since prospective studies cannot easily be conducted, prevalence of tobacco use in an adolescent population can be used as a partial proxy for age at initiation. The best estimates of prevalence come from large, national studies of tobacco use. In this literature review, there were many articles that used data from these large studies to examine subpopulations instead of the general population. One article presented information on prevalence of adolescent ST use from a large, national study. Persoskie et al. (2017) used data from Wave 1 (2013 to 2014) of Population Assessment of Tobacco Health (PATH). The responses from youths (age: 12 to 17 years) indicated that 1.6 percent had used ST within the past 30 days, and an additional 3.2 percent had used ST outside of the last 30 days.

Chang et al. (Chang, Meza, & Levy, 2016) investigated the trends in ST use using data from nine waves of Tobacco Use Supplement of the Current Population Survey. The observation from the analysis was that the prevalence of ST use among adults (age: 18 years and older) decreased significantly, by 4.5% per year, from 1992 to 2003 but remained approximately constant from 2003 to 2011. Decreases in the prevalence of ST use from 1992 to 2003 were observed also in the subgroup of adult males (age: 18 years and older; 4.4% per year); and in the subgroup of young adult males (age: 18-24 years; 9.5% per year).

Smaller regional surveys of tobacco use in adolescents and young adults have conflicting information on the trend of ST use. Data from Minnesota Adolescent Community Cohort Study (Choi, Bestrashniy, & Forster, 2017) showed that, among young adults (age: 21 to 29 years) in Minnesota, the prevalence of ever-use of snus increased between 2011 and 2013, but the prevalence of past–30-day snus use decreased within the same period. When comparing the 2010-2011 period with the 2011-2013 period, the prevalence of ever-use of snus was also increased. In contrast, a study of New York City high school students (Elfassy, Yi, & Kansagra, 2015) reported increased ST use (defined as using at least once in the past 30 days) between 2001 and 2013 overall (1.1% to 4.4%, p < 0.001), among both nonsmokers of cigarettes (0.2% to 1.9%, p < 0.001) and among cigarette smokers (4.2% to 21.2%, p < 0.001). Over the same time period, prevalence of cigarette smoking declined from 17.6% to 8.2%.

7.5.3-2.2.1.1. Geographical Differences

Smaller, geographically focused studies reporting prevalence provide information on different regions in the United States. Cooper et al. (Cooper, Case, Loukas, Creamer, & Perry, 2016) observed that the prevalence rates of chew and snus use were 1.88% and 0.45%, respectively, among subjects (6th through 12th grade students in 27 counties in Texas) who did not use e-cigarettes or cigarettes. Morean et al. (Morean et al., 2016) reported that 2.8% of high school students in southeastern Connecticut were current ST users. Another cross-sectional study (Gilreath et al., 2016) reported that, among high school students (Grades 11 and 12) in southern California, 4.2% were ever-users of ST and 2.2% were current ST users. Prevalence rates for these groups, largely comprising suburban and urban subpopulations, contrasted with those from a rural population: Reichenberger et al. (Reichenberger, Hilmert, Irish, Secor-Turner, & Randall, 2016) reported that 18.3% of a population of 9th to 12th grade students in rural North Dakota were past–30-day ST users.

7.5.3-2.2.1.2. Variation of Prevalence by Age

Limited information on the changes in prevalence across the adolescent age range was reported in the literature reviewed. An analysis of the data from the 2012 National Youth Tobacco Survey (Lee, Hebert, Nonnemaker, & Kim, 2015) provided weighted estimates of exclusive and polytobacco use for various tobacco products. The weighted percentage of current, exclusive ST use was found to be 0.6% among middle school and high school students, and the prevalence rate increased with age: approximately 0.2% among 9- to 14-year-olds, 0.7% among 15- to 17-year-olds, and 1.9% among those aged at least 18 years.

Similarly, from Wave 1 data of PATH, Kasza et al. (Kasza et al., 2017) reported that the prevalence of past–30-day ST use was 1.6 percent among youths (age: 12-17 years) and that ST use among the 15- to 17-year-old group was higher than among the 12- to 14-year-old group. The finding that prevalence of current ST use among youth generally increases with age has also been reported in numerous regional studies (Anand et al., 2015; Lynne-Landsman, Maldonado-Molina, Komro, Kominsky, & Boyd, 2016; Neff et al., 2015).

7.5.3-2.2.1.3. Sex and Prevalence

In general, the prevalence of ST use was higher in males than it was in females during adolescence (Corey, Ambrose, Apelberg, & King, 2015; Gilreath et al., 2016; Kaufman, Land, Parascandola, Augustson, & Backinger, 2015; Lynne-Landsman et al., 2016; Parent, Bradstreet, Piper, Brace, & Parkman, 2016; Sutter, Nasim, Veldheer, & Cobb, 2016).

There was variability in the results from the different surveys and in the populations focused on for each. The largest population sample was used by Parent et al. (Parent et al., 2016), who evaluated the prevalence of chew/dip use from the national 2013 Youth Risk Behavior Survey (YRBS) of middle school and high school students. The outcome of this analysis was that 15% of males used chew/dip and 3% of females used chew/dip. In a survey of 2,097 11th and 12th grade students in southern California, Gilreath et al. (Gilreath et al., 2016) observed that 3.6% of males and 0.8% of females reported current use of ST. Among 684 adolescents (Grades 9 and 10) in the Cherokee Nation, males reported higher rates of chewing tobacco use (10%-16%) than females (2%-5%) (Lynne-Landsman et al., 2016).

A larger proportion of male ST users reported use of a flavored ST product than female ST users. Corey et al. (2015) noted in an analysis of the 2014 National Youth Tobacco Survey that among male middle school and high school students who used ST, 63.3% reported use of a flavored ST product; whereas, 40.7% of their female counterparts who used ST reported the same.

7.5.3-2.2.2.   Age at Smokeless Tobacco Initiation

A study to assess risk perceptions of adolescent and adult ST uses and nonusers was performed in four Ohio Appalachian counties with known higher ST use than that in other rural areas (Liu et al., 2015). Participants in the adolescent focus groups were at least 15 years old and recruited from public and vocational schools, and participants in the adult focus group were at least 18 years old and recruited from community colleges, colleges, churches, farm bureau agencies, and health department clinics. Among subjects who reported daily ST use or ST use on most days, there was a significant difference in the mean initiation age for adolescent ST users (11.7 ±2.0 years, n = 23) as compared with that for adult ST users (15 ±4 years, n = 38) (p = 0.001).

Among lifetime tobacco users from a group of first-year students at 11 colleges and universities in the tobacco-producing states of North Carolina and Virginia, 9% initiated tobacco use at age 13 years or younger, 61% initiated between the ages of 14 and 17 years, and 30% initiated at age 18 years or older (Sutfin et al., 2015). Furthermore, of lifetime tobacco users who used ST as their first tobacco product, 15% initiated at age 13 years or younger, 73% initiated between the ages of 14 and 17 years, and 12% initiated at age 18 years or older.

7.5.3-2.2.3.   Additional Factors Associated with Initiation of Smokeless Tobacco

Many studies used parameters in addition to age and sex to stratify results in order to test for other factors associated with the initiation of ST. Kaufman et al. (Kaufman et al., 2015), for example, reported that, among subjects who had reported neither cigarette nor ST use, females were significantly less likely than males to transition to ST-only use after 1 year; the same was found for Asian and black as compared with white subjects, and younger as compared with older subjects.

As discussed previously, prevalence among youth may be used as a partial proxy for age at initiation of ST use. An analysis of data from the 2013 YRBS (Parent et al., 2016) of middle school and high school students showed that white subjects (12%) had the highest prevalence of chew/dip use among high school athletes, followed by multiracial non-Hispanic (9%), multiracial Hispanic (7%), Hispanic/Latino (4%), Asian (4%), and black (3%) subjects.

Creamer et al. (Creamer, Perry, Harrell, & Diamond, 2015) analyzed data from the national YRBS from 1999 to 2013. The percentage of adolescents reporting use of various tobacco products was plotted over time and analyzed for any trends, with stratification by sex and race. From these analyses, the authors noted that there was a significant increase of ST use among non-Hispanic black high school students from 1999 to 2013 (p=0.01) but not among non-Hispanic white and Hispanic high school students in the same time span.

Timberlake (Timberlake, 2016) investigated the association between advertising receptivity and subsequent initiation of ST use among adolescent males from the Teen Longitudinal California Tobacco Survey conducted between 1993 and 1999, because it was one of the few surveys to examine both marketing and subsequent use of ST. The study demonstrated that the risk factors of risk taking/rebelliousness and intention to use ST were significantly and positively associated with ever-use of ST by 1996, but not regular use by 1999. Additionally, cigarette smoking and advertising receptivity were significantly and positively associated with both ST outcomes. Timberlake (Timberlake, 2016) also concluded that non-Hispanic whites were more likely to initiate or use ST regularly than Hispanics during the two longitudinal analyses (1993-1996 and 1993-1999).

7.5.3-2.2.4. Updated Findings

Data on prevalence and initiation of ST use in adolescents and young adults in publications included in the literature review conducted for the period of December 08, 2014, to February 06, 2017 are consistent with those from publications included in the initial literature review. The conclusions from the initial literature review have not changed based on the updated literature review.

A tabular summary of the literature addressing the initiation of ST is presented in Table 7.5.3-2-1.

Table 7.5.3-2-1: Literature Review for Smokeless Tobacco - Initiation

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Choi et al., 2017)	Trends in awareness, use of, and beliefs about electronic cigarette and snus among a longitudinal cohort of US Midwest young adults	Data are from a longitudinal study. The study used data on subjects' demographics, number of peers who smoke, smoking status, and EC use to assess trends. Objective: To assess the trends in awareness and use of, and beliefs about EC and snus among a cohort of young adults (age: 21-29 years, n = 2,622, 89.3%-90% non-Hispanic white, 46.8%-47.6% male).	Data were derived from the Minnesota Adolescent Community Cohort Study, collected annually during 2010-2013 period. Subjects were asked if they ever used snus and the number of days they used snus in the past 30 days. Data were adjusted for demographics, peer smoking, and smoking status.	There were slight increases in the proportion of the sample that had ever used snus (14.6% in 2010-2011 to 15.9% in 2012-2013). There was a slight decrease in past–30-day use of snus (from 3.2% in 2010-2011 to 2.4% in 2012-2013). When compared with subjects in 2010-2011, subjects in 2012-2013 were slightly more likely to have ever used snus in 2011-2012 and 2012-2013 ($p < 0.05$). There were no statistically significant changes in the proportion of the subjects who reported using snus in the past 30 days and in the number of days using snus in the past 30 days.	Strength: A longitudinal design that allowed authors to assess within-person changes over time. Limitations: (1) Attrition that might introduce bias; and (2) the U.S. Midwest sample in the study limited the study's ability to generalize findings to young adults in other U.S. regions.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Couch, Darius, Walsh, Chaffee, & Darius, 2016)	Smokeless tobacco decision-making among rural adolescent males in California	Data are from a cross-sectional study. Subjects (male high school students, Grades 9-12) were from rural high schools and were either enrolled in agriculture classes or participating in varsity football. Objective: To explore ST perceptions and other factors related to ST (dip/moist snuff or chewing tobacco) initiation and continued use among adolescent male ST users and never-users (n = 55, mean age: 16.5 years, 69% white, and 65% non-Hispanic/Latino) in rural California.	Subjects were asked about their ST use, ST awareness, initiation experiences, future intentions, perceptions of product appeal, social norms, health risks, acceptability, use patterns, and changes in use over time.	A majority of subjects reported ever-use of ST (58%); among ever-users of ST, 56% were current users, 31% were experimenters, and 13% were former users.	Limitations: (1) The study sample was not randomly chosen, and results may not reflect the opinions of all male adolescents or rural communities; and (2) synthesis of subject responses required subjective interpretation, which could have been influenced by researchers' prior expectations.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Courtemanche, Palmer, & Pesko, 2017)	Influence of the flavored cigarette ban on adolescent tobacco use	Data are from repeated, cross-sectional surveys in which subjects (n = 197,834, age: 11-19 years) were part of a nationally representative sample of middle school and high school students and were asked about their use of cigarettes, cigars, ST, and pipe in the past 30 days as part of the 1999-2013 NYTS. Objective: To estimate the association between the U.S. FDA's 2009 ban on flavored cigarettes and adolescents' tobacco use.	Subjects were asked about initiation and current use of a variety of tobacco products. Data including age, sex, race, tobacco price index, and unemployment rate for teens were collected.	There was a nonsignificant reduction in prevalence of ST use after the ban, from 4.2% to 4.1% (p = 0.806).	Strengths: The study used a large, nationally representative sample. Limitation: The study compared data from two different time periods to assess associations of the ban, and changes over time unrelated to the ban could have confounded the findings.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Goldbach, Mereish, & Burgess, 2017)	Sexual orientation disparities in the use of emerging drugs	Data are from a study with random selection of classrooms within 6th, 8th, 10th, and 12th grade. Subjects (n = 3,012; ages 11-18; 52.2% female, 37.8% African American, 28.3% white, 17.1 Hispanic/Latino) were middle school and high school students in one county in North Carolina. Objective: To investigate the use of risky substances among adolescents; and examine disparities between sexual minority and heterosexual adolescents in the use of novel and emerging substances.	Subjects were asked if "in their lifetime" and "in the past 30 days" they had smoked cigarettes, used ST, or smoked EC. Variables including age, sex, grade, race, and sexual orientation were assessed.	In the total sample, 6.7% reported lifetime ST use, and 2.9% reported past–30-day ST use. LGB adolescents (n = 157) reported significantly higher lifetime use (but not past–30-day use) of ST (AOR = 1.88, p < 0.05) than heterosexual adolescents.	Limitations: (1) Sexual minorities represented a small number of subjects, and the study aggregated LGB adolescents into a single group; and (2) the study may also have an underreporting of LGB adolescents, given social desirability biases in school-based survey research.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Kasza et al., 2017)	Tobacco-product use by adults and youths in the United States in 2013 and 2014	Data are from Wave 1 of a longitudinal study (PATH) in which subjects consisted of 32,320 adults (age: 18+ years) and 13,651 youths (age: 12-17, 51.3% male, 54.6% Non-Hispanic white). Tobacco products surveyed included cigarettes, EC, traditional cigars, cigarillos, filtered cigars, pipe tobacco, hookah, snus pouches, other ST (i.e., loose snus, moist snuff, dip, spit, or chewing tobacco), dissolvable tobacco, bidis, and kreteks. Objectives: To examine the prevalence of use of various tobacco products; the prevalence of current use (among adults) or use in the previous 30 days (among youths) for each tobacco product according to demographic subgroup; and the prevalence of multiple-product use or single-product use.	Estimates of the prevalence of use for each product were determined according to use category (e.g., current use or use in the previous 30 days) and demographic subgroup, and the prevalence of multiple-product use was explored.	Overall, 21.8% of youths had ever used tobacco, 13.4% had ever used cigarettes, 10.7% had ever used ECs, 7.5% had ever used cigars, and 4.8% had ever used ST including snus pouches. The overall prevalence of tobacco use in the previous 30 days among youths was 8.9%, with prevalence of 4.6% for cigarette use, 3.1% for EC use, 2.5% for cigar use, 1.7% for hookah use, and 1.6% for use of ST including snus pouches. As with ever-use, use in the previous 30 days was higher among youths 15-17 years of age than among those 12-14 years of age.	Strengths: The study used a (1) large sample size, and (2) nationally representative sample. Limitations: The data came from only the first wave of the PATH study.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Owusu et al., 2017)	The use of e-cigarettes among school-going adolescents in a predominantly rural environment of Central Appalachia	Data are from a cross-sectional study in which subjects (n = 894, age: 14-22 years [mean = 16 years], 57.8% female) were high school students in northeast Tennessee. Objective: To estimate the prevalence of EC use and examine association of EC use with two tobacco products among school-going adolescents.	Subjects provided information regarding their use of tobacco products, age of initiation, intention to quit, age, and sex.	Of the total study subjects, 5.3% were current ST users and 20.4% were ever-users of ST. Among EC users, 2.8% subjects were current users of EC and ST. Additionally, while 24.3% had ever used EC and cigarettes, 16.8% had ever used EC and ST products concurrently. The ever-use all of three products simultaneously was reported by 15% of the subjects. In the bivariate analysis, EC use was associated with current cigarette smoking, (OR: 38.33, 95% CI: 21.4-68.8), current ST use (OR: 14.92, 95% CI: 8.8-25.2), and being male (OR: 2.94, 95% CI: 1.9-4.6). After adjusting for covariates, odds of EC use were elevated in current ST users (OR: 7.92, 95% CI: 3.8-16.5).	Strengths: The study had a large sample size. Limitations: (1) Institutional constraints limited the study's ability to generate a truly representative sample; (2) the study was susceptible to recall and social desirability biases because the data were collected by self-reporting; (3) the results need to be interpreted in the context that the majority of subjects were under the age of 18 years; and (4) due to the agreement between the participating schools and the Department of Health, the study could not adjust for school differences.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Persoskie et al., 2017)	Measuring youth beliefs about the harms of e-cigarettes and smokeless tobacco compared to cigarettes	Data are from Wave 1 of a longitudinal study. Data derived from subjects (n = 13,651, age: 12-17 years, 54.2% Non-Hispanic white) who participated in the PATH study in 2013-2014. Objective: To examine validity of direct and indirect measures of perceived harm of EC and ST as compared with that of cigarettes.	Subjects provided information regarding their use of tobacco products (cigarettes, EC, or ST) and perceived EC and ST relative harm ratings.	Past–30-day product use was 4.6% for cigarettes, 3.1% for EC, and 1.6% for ST; non–past-30-day use was 8.8% for cigarettes, 7.5% for EC, and 3.2% for ST.	Strength: The study used a national sample and focused on youth. Limitations: (1) Indirect measures used were based on items with only five response options; (2) measures were based on single items that asked about global harm in general; (3) measures did not specify the frequency or intensity of product use to be assessed; and (4) data were only from Wave 1 of the PATH study.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Chang et al., 2016)	Trends and factors related to smokeless tobacco use in the United States	Data collected from nine waves of TUS-CPS from 1992-2011. Subjects' ages were grouped as follows: 18-24 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, 65-74 years, and 75 years and older. Objective: To investigate the time trends of ST use and to examine the factors associated with ST prevalence in the U.S.	The study analyzed trends in tobacco use, ST use by demographics (age, race, sex, education, residence, smoking status, and unemployment status), frequency of ST use, and factors associated with ST use.	Total adult (aged ≥18 y) ST use significantly decreased at an APC rate of 4.5% per year from 1992 to 2003 ($p < 0.05$). Prevalence of ST use has remained approximately constant since 2003. Similarly, ST use among adult males aged 18-24 years decreased from 1992 to 2003 (APC = –9.5%, $p < 0.05$), before remaining approximately constant from 2003 to 2011. Those who earn less than $14,999 per year and lived in the South had the largest significant decline in ST prevalence (APC = –6.3% and –5.6%, respectively). Former and never-smokers also had significant declines in ST use (APCs = –2.4%, 1992-2011 and –5.2%, 1992-2003, respectively).	Strength: (1) The data came from nationally representative surveys, and (2) it allowed for comparisons between self-reported data and market sales. Limitations: (1) Data are self-reported; (2) each survey data are cross-sectional; (3) the changes across survey years used definitions that may have introduced bias in estimations of ST use, in particular, the change from the regular use to ever-use screening question; and (4) tobacco companies have continued to introduce new ST products on the market, making the interpretations of trends difficult because of the variability in available products each year.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Cooke et al., 2016)	Predicting tobacco use across the first year of college	Data are from a longitudinal study in which subjects (n = 4,073, 60.1% female, 51% white) were freshman at Virginia Commonwealth University in 2011 (Cohort 1) and 2012 (Cohort 2). Surveys were administered in the fall and spring semesters for each cohort. Objective: To assess patterns of tobacco use across the first year of college, transitions in use, and associated predictors.	The study analyzed the frequency of tobacco use, subjects' demographics (sex and race/ethnicity), anxiety, depression, peer deviance, and stressful life events.	The percentage of ST use, grouped by the frequency of use, in the fall and spring semester, respectively was as follows: did not use (96.1% and 96.2%); used once or twice (1.6% and 1.5%); used 3 to 11 days per month (1.3% and 1.1%); and used 26 to 30 days per month (0.9% and 1.2%).	Strength: Data are from a longitudinal study. Limitations: (1) small sample size in the frequently using class; (2) the data cannot be generalizable to all tobacco users; and (3) there was the potential for recall bias, leading to either inflated or deflated reports of tobacco use.
(Cooper et al., 2016)	E-cigarette dual users, exclusive users and perceptions of tobacco products	Data are from a cross-sectional study in which subjects were 13,602 6th through 12th grade students attending public schools in 27 counties in Texas; 49.9% were female, and 43.9% were non-Hispanic whites. Objective: To examine differences in the characteristics of youth nonusers, cigarette-only users, EC-only users; and dual EC and cigarette users.	The study analyzed subjects' demographics (sex, school level, race, and mean grades), tobacco use categories, other current and lifetime tobacco use, harm perceptions of tobacco products and alcohol, and perceived peer use of tobacco products.	Among subjects who currently used neither ECs nor cigarettes, prevalence of chew and snus use was 1.88% and 0.45%, respectively; prevalence of current chew and snus use was significantly (p < 0.05) increased among EC users who did not use cigarettes (22.55% and 10.15%), cigarette users who did not use EC (41.12% and 15.20%), and EC/cigarette dual users (52.47% and 47.33%).	Strength: Data are from a large sample population. Limitations: (1) Cross-sectional study design prevents causal inferences; and (2) study subjects were limited to Texas youth.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Evans-Polce, Lanza, & Maggs, 2016)	Heterogeneity of alcohol, tobacco, and other substance use behaviors in U.S. college students: A latent class analysis	Data are from a follow-up of a longitudinal study in which subjects (n = 608; age: <21 years) were initially surveyed in their first semester of college at a large public university in the Northeast. The follow-up survey was conducted in their seventh semester, when the mean age of subjects was 21.5 years. Objective: To identify subgroups of college students with distinct profiles of traditional and alternative types of tobacco, alcohol, and other substance use and to examine how demographic characteristics and academic and social activities were associated with subgroup membership.	The study analyzed substance use measures, demographics, and social and academic activities.	Among subjects, 5.95% used ST. Latent class membership was estimated using seven dichotomous indicators of substance use behavior. In the class of nonusers of hookah tobacco (n = 42), 29.8% used ST. The class of polysubstance users (n = 34) was distinct in that each of the seven substances had a high (over 50%) probability of use, including ST (69.4%).	Limitations: (1) The study only assessed whether the substance was used or not, and (2) the study, by design, focused on undergraduate students at a single institution in 2010 and has limited generalizability.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Gilreath et al., 2016)	Patterns of alternative tobacco product use: emergence of hookah and e-cigarettes as preferred products amongst youth	Data are from a cross-sectional study. Subjects (n = 2,097) were 11th and 12th grade high school students (50% male; 51.7% Hispanic). The mean age was 17.3 years. Objective: To examine patterns of adolescent use of cigarettes, EC, cigars/cigarillo, hookah/waterpipe, and ST/dip/chewing tobacco in a population of southern California adolescents.	Subjects were asked about age at initiation and current use of cigarettes, cigars/cigarillos/little cigars, EC, hookah/waterpipe, and ST/dip/chewing tobacco. A variable with three levels (never, ever/lifetime, and current) was created individually for each of the five tobacco products.	Overall, 96.6% of the sample population reported never use of ST, 4.2% reported ever-use, and 2.2% reported current use. Among males, 90.1% reported never-use of ST, 6.3% reported ever-use, and 3.6% reported current use. Among females, 97.2% reported never-use of ST, 2.0% reported ever-use, and 0.8% reported current use.	Limitations: (1) the study was cross-sectional; (2) number of days used in the past 30 days was not included in the analysis because of sparseness in responses; and (3) the sample had a narrow age range of youth, and the racial/ethnic composition of the sample was largely Hispanic and non-Hispanic whites.
(Guydish et al., 2016)	Use of multiple Tobacco products in a national sample of persons enrolled in addiction treatment	Data are from a cross-sectional study in which subjects (n = 1,113) had a mean age of 38.3 years and half (49.4%) were women. Subjects were 55.3% white, 19.0% African American, and 11.9% Hispanic. To be eligible for the study, subjects must have been enrolled in addiction treatment. Objective: To explore use of tobacco products in relationship to marketing exposure among persons in addiction treatment.	The study analyzed demographic characteristics and use of tobacco products, exposure to tobacco advertising and counter-marketing, and perceived health risks of smoking.	Prevalence of weekly tobacco-product use is reported: 77.9% of subjects used cigarettes, 17.7% used EC, 5.2% used ST, 8.6% used little filtered cigars, and 4.6% used cigars.	Limitations: (1) rates of smoking and other tobacco use reported in the study might be representative only of publicly funded nonprofit programs serving uninsured patients or patients covered by Medicaid; and (2) patients in the sample were drawn from outpatients (30.9%), residential (38%), and methadone maintenance (31.1%) programs, while patients in addiction treatment programs nationally are distributed differently.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Haardorfer et al., 2016)	Polytobacco, marijuana, and alcohol use patterns in college students: A latent class analysis	Data are from a baseline survey of a multiwave longitudinal study. Subjects (n = 3,418; age: 18-25 years; 64.3% female; 63.2% white) were recruited from seven U.S. college campuses. Objective: To examine (1) profiles of substance use behaviors among young adult college students, with particular focus on use of various tobacco products, marijuana, and alcohol; and (2) sociodemographic, individual-level, and sociocontextual-level factors associated with use profiles among this sample.	The study analyzed use patterns of various tobacco products, sociodemographics, individual-level factors (depression; perceptions of harm and addictiveness), and sociocontextual factors (parental/friend use).	In the previous 4 months, 4.9% of subjects used ST. In the previous 30 days, 3.6% of subjects used ST.	Limitations: (1) The study sample was subject to selection bias and might not be generalizable to all young adults, and (2) the cross-sectional design limited the extent to which the study could make causal attributions or determine intraindividual trajectories of substance use over time.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Jitnarin et al., 2016)	Prevalence and correlates of late initiation of smokeless tobacco in US firefighters	Data are from a cross-sectional survey of firefighters from the International Association of Fire Chief's Missouri Valley Region and 20 career departments across 14 U.S. states and territories. Subjects (n = 207, mean age between 36 and 37 years) were male firefighters. Objective: To examine characteristics associated with late ST initiation in a sample comprising male career firefighters from two large cohort studies.	Age-standardized prevalence of ST use before and after joining the fire service was computed in the combined sample to facilitate comparison with the U.S. adult males in the general population and males in the U.S. military. The study also analyzed demographics and occupational history as well as physical and behavioral health.	"Fourteen percent of firefighters in the joint sample reported using [ST] and a surprisingly large percentage of [ST] using firefighters (15.9% unstandardized) reported initiating [ST] use after joining the fire service." Firefighters who used ST before joining the fire service initiated at a significantly younger age than those who started ST use after joining the fire service (mean age: 15.83 years vs. 28.06 years; p < 0.001). "The age-standardized [ST] initiation rate among firefighters after joining the fire service, using general adult male age distributions, was 38.2%, which is higher than the national prevalence rate of 0.8% for adult males who were late [ST] initiators (aged 18-25)." The authors speculate that the high prevalence of ST use among firefighters may be due to occupational factors, disease presumption laws disallowing claims for smokers, and cigarette smoking prohibitions in fire stations.	Strengths: The study used standardized and validated health measures. Limitations: (1) Study was cross-sectional; and (2) because the two cohort studies were designed for other purposes, authors could only examine variables that were measured similarly in both studies and, therefore, important variables that might play a role in late initiation could not be explored.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Lynne-Landsman et al., 2016)	Early trajectories of alcohol and other substance use among youth from rural communities within the Cherokee Nation	This study is part of a larger, randomized, controlled trial. Subjects (n = 684) were adolescents (50% female, 51% American Indian) who provided longitudinal data across five assessments spanning 9th grade (3 waves) and 10th grade (2 waves). At the first assessment, 41% of subjects were aged 14 years or younger, 52% were aged 15 years, and 7% were aged 16 years. Objective: To examine sex and racial/ethnic differences in substance use trajectories during early adolescence among American Indian and non–American Indian adolescents	The study analyzed subjects' demographics (age, race, sex, parental education, and whether they received reduced-price lunch) and substance use (past-month frequency of alcohol use, heavy drinking, cigarette smoking, chewing tobacco use, marijuana use, prescription drug misuse, and other illicit drug use).	"At each of the five longitudinal assessments, males (10-16%) consistently reported significantly higher rates of chewing tobacco use compared with females (2%-5%)." The majority of youth followed a trajectory of no chewing tobacco use (87%). "Nine percent of the sample followed a trajectory of moderate/increasing chewing tobacco use. These youths had a .25-estimated probability of past-month chewing tobacco use at the first assessment in early 9th grade, increasing to 0.50 by the final assessment in 10th grade. The smallest user class (4% of the sample) consisted of youth with high estimated probability of past-month chewing tobacco use (0.97 or greater across waves). Significantly, more males followed trajectories of moderate/increasing or high chewing tobacco use (13% and 7%, respectively) than females (5% and 1%, respectively)."	Strength: Ability to evaluate longitudinal changes in the use of individual substances over a relatively short time frame, the transition from 9th to 10th grades. Limitations: (1) The data were restricted to a single year; (2) the research was conducted in a largely understudied population of rural youth with a high proportion of American Indians and, therefore, the results are not generalizable to youth in general or other American Indian youth from different tribal communities; and (3) data are self-reported.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Morean et al., 2016)	Latent class analysis of current e-cigarette and other substance use in high school students	The study was cross-sectional, and subjects (n = 2,241; mean age: 15.6 years; 45.6% male; 65.1% white) were adolescents attending four high schools in southeastern Connecticut. Objective: To examine high school students' current use of EC, cigarettes, cigars, ST, hookah, blunts, marijuana, and alcohol.	The study analyzed demographic information (age, sex, and race/ethnicity), EC, cigar, ST, hookah, and blunt use, cigarette use, and alcohol and marijuana use.	Current ST use was reported for 2.8% of the subjects.	Limitations: (1) Adolescent self-study report; (2) data were collected from high schools in Connecticut only; (3) the study was cross-sectional; and (4) the study placed a premium on having complete past-month substance use data from subjects rather than imputing missing past-month substance use data.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Parent et al., 2016)	Racial disparities in substance use by sport participation among high school students	Data are from the cross-sectional YRBS. Subjects (n = 13,482, 49.9% male) were 9th to 12th grade students. Objective: To evaluate differences in substance use patterns among adolescents who did or did not participate in team sports; to evaluate differences in use of smoked tobacco, chew/dip, steroids, alcohol, marijuana, cocaine, inhalants, methamphetamine, diet pills, and prescription drugs; and to conduct exploratory analyses with other substances and examine racial/ethnic disparities.	The study analyzed tobacco and other substances use, demographic (sex and race/ethnicity); and activity in sport.	Among males, 15% used chew/dip; among females, 3% used chew/dip. Chew/dip prevalence by race/ethnicity was as follows: Asian (4%) Black or African American (3%) White (12%) Hispanic/Latino (4%) Multiracial Hispanic (7%) Multiracial non-Hispanic (9%)	Strengths: Data were from nationally representative survey with large sample size. Limitations: (1) Substance use was assessed using single items, which did not allow for detailed analysis of frequency and intensity use of the substances; (2) it was not a longitudinal study, and causality could not be inferred; (3) although it is unlikely that substance use precipitates sport participation, other variables might affect the relationship between sport participation and substance use; (4) sport participation was assessed broadly in the survey, and differences by type of and commitment to a sport were not detailed; and (5) the YRBS relied on students who were enrolled in schools and did not include those in nontraditional education systems.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Reichenberger et al., 2016)	Associations between sleep and health-risk behaviors in a rural adolescent population	Data are from a cross-sectional study. Subjects (n = 322) were 9th to 12th grade students (44.4% female, age: 14-19 years) in four frontier counties not adjacent to a metro area. Objective: To compare rates of various HRBs among adolescents in a rural setting who get at least the minimum recommended amount of sleep and those who get less than the recommended amount of sleep; to assess behaviors that have been shown to have a bidirectional association with sleep and those that are less likely to have a bidirectional association; to study whether the modes of substance use (i.e., smoking vs. chewing tobacco) differed in their associations with sleep.	Data derived from the Rural Adolescent Health Survey. The study assessed rural adolescents' health and HRBs, including reports of the time subjects usually went to bed and woke up, the number of days they used specific drugs or alcohol in the last month, and the number of different sexual partners they had during the past 12 months.	Of the 312 subjects with ST use data, 57 (18.3%) reported past–30-day ST use. "Sleep appeared to be unrelated to chewing tobacco use [p = 0.29]."	Limitations: The measure of sleep was based on reports of time spent in bed, and thus the amounts of sleep reported may not accurately reflect the actual amount of sleep.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Rhew et al., 2016)	Evaluation of community-level effects of communities that care on adolescent drug use and delinquency using a repeated cross-sectional design	Data were collected during CYDS, a repeated cross-sectional study (every 2 years from 2000 to 2008). Subjects (age: 11-18 years) were 6th graders (n = 10,127, mean age: 11.6 years), 8th graders (n = 9,601; mean age: 13.6 years), and 10th graders (n = 9,147; mean age 15.6 years) in Colorado, Illinois, Kansas, Maine, Oregon, Utah, and Washington. Data were stratified by communities that implemented the CTC prevention system. Objective: To examine effects of CTC on prevalence of youth problem behaviors using repeated cross-sectional data from the CYDS.	The study analyzed subjects' drug use, delinquency, risk and protective factors, and demographic characteristics.	There was no significant difference in community-level prevalence or mean of outcomes between CTC and control communities for 6th, 8th, and 10th grade students who were either lifetime ST users or past–30-day ST users. However, when adjusted for 6th grade outcomes and other covariates, the prevalence of lifetime ST use among 10th grade students was significantly lower in CTC than in control communities (p = 0.017). High-exposure CTC tended to have a lower prevalence than control communities for all other outcomes except past–30-day ST use. In contrast, low-exposure CTC tended to be more similar to control communities across outcomes, with the exception of lifetime ST use, where there was a significantly lower community-level prevalence in low-exposure CTC than in control communities (p = 0.037). Mean past–30-day prevalence of ST use in CTC was 1.9% (6th grade), 4.7% (8th grade), and 8.2% (10th grade); mean past–30-day prevalence of ST use in control communities was 1.4% (6th grade), 5.0% (8th grade), and 9.1% (10th grade).	Strength: Study used a large sample size. Limitations: Data were (1) from a cross-sectional study and were (2) self-reported.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Sutter et al., 2016)	Associations between unhealthy dieting behaviors and tobacco use among adolescents	Data are from a cross-sectional study. Subjects were students in 2013 (n = 6,903 [3,501 were female and 3,402 were male], age: 12-18 years, approximately 55% non-Hispanic white). Objective: To examine UDB prevalence in an adolescent sample from a specific U.S. geographic region and associations with a variety of tobacco-use behaviors and perceptions.	The study utilized publically available, deidentified, secondary data from the 2013 Virginia Youth Survey. The study analyzed demographics, tobacco product use, weight and UDB, psychosocial factors, and physical activity.	Past–30-day ST use was reported by 2% of females and 12% of males.	Strength: Study had a large sample size. Limitations: (1) Due to the cross-sectional nature of the data, any causality of relationships could not be determined; (2) social desirability bias might have led to underestimation of tobacco use behaviors as well as UDBs among adolescents; (3) the study was limited to adolescents living in a specific geographic region of the U.S.; and (4) the study was limited to the variables available in the database.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Tam, Day, Rostron, & Apelberg, 2015)	A systematic review of transitions between cigarette and smokeless tobacco product use in the United States	A systematic review of published literature on transitions between ST and cigarette use was performed. Search was performed through PubMed, Web of Science and EbscoHost databases from January 2000 to March 2014. Information were extracted on the proportion of the sample population transitioning from baseline to follow-up. Objective: To identify systematic information on transitions between ST and cigarette use in the U.S.	Information on the study characteristics including study population, follow-up, definitions for each tobacco use categories, and how transitions were calculated were extracted.	Six articles met all selection criteria. The following are findings from the selected articles: Among adults who used neither ST nor cigarettes at baseline, 1.7% of male former smokers (quit ≤ 1 y), 0.3% of male former smokers (quit >1 y), 0.7% of male never smokers, 0% of female former smokers (quit ≤ 1 y), 0.3% of female former smokers (quit > 1 y), and 0% of female never smokers were exclusive ST users after 1 year. Among adolescents who used neither ST nor cigarettes at baseline, 4.6% of males were ST users after 2 years, and 3.1% of males were ST users after 4 years.	Limitations: (1) Estimates from some studies are not generalizable to the U.S. population; (2) there was variability in tobacco use definitions and follow-up time; (3) there is a potential bias in estimates from some studies due to tobacco use prevention or ban; (4) there are an absence of confidence intervals; and (5) estimates for females are missing, with the exception of one article.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Timberlake, 2016)	Advertising receptivity and youth initiation of smokeless tobacco	Data are from a longitudinal study. Subjects (n = 1,388 from 1993-1996 to examine ever-use of ST; n = 1,014 from 1993-1999 to examine ST use on 20 or more occasions) were males, primarily young adolescents between the ages of 12 and 18 years who had never tried ST as of 1993. ST type included chewing tobacco/snuff. ST brands includes Redman®, Levi Garett®, Beechnut®, Skoal®, Skoal Bandits, Copenhagen®, Kodiak, and other. Objective: To test for the association between advertising receptivity and subsequent initiation of ST among adolescent males.	Data derived from The California Tobacco Survey completed in 1993 by subjects who had never used ST. Two separate longitudinal analysis were conducted: 1993-1996 and 1993-1999. The data analyzed the use of ST, ST brand identification, and predictors of ST initiation/use.	Among the never users at the 1993 baseline survey, 16.8% had tried ST by the 1996 survey and 5.8% had used ST 20 or more times by the 1999 survey. Hispanics were less likely than non-Hispanic white to initiate or use ST regularly. The risk factors risk taking/rebelliousness and intention to use ST were significantly associated with ever-use of ST by 1996, but not with regular use by 1999. Cigarette smoking and advertising receptivity were significantly associated with both ST outcomes. In the adjusted model, subjects who identified with an ST brand were 2.0 and 3.7 times more likely to ever use ST and to use on 20 or more occasions, respectively, than subjects who did not identify with an ST brand.	Strength: Data are from a longitudinal study. Limitations: (1) The use of rudimentary measure for advertising receptivity, and (2) analysis of older data.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Anand et al., 2015)	E-cigarette use and beliefs among urban public high school students in North Carolina	Data are from a cross-sectional and nonexperimental study. Subjects (n = 2,769; mean age: 16.4 years) were 51% males and 38% white. Most subjects were in 9th grade (31%), followed by decreasing numbers in the 10th grade (25.6%), 11th grade (22.8%), and 12th grade (20.6%). Type of ST included snuff, plug, dip, chew, and snus. Objective: To examine the prevalence, attitudes, and risk factors associated with EC use among high school students in a tobacco-growing state.	Data were derived from a questionnaire completed by high school students (9th-12th grades) in three high schools in an urban county in North Caroline. The study analyzed subjects' tobacco products use; frequency of use; tobacco products use by parents, family, and friends; perceptions, knowledge, and accessibility of EC; and demographics (age, sex, and race).	Ever use of ST was reported by 10.9%, 11%, 16%, and 15.9% of subjects in 9th, 10th, 11th, and 12th grade, respectively. Past–30-day use of ST was reported by 8.8%, 7.9%, 11.9%, and 13.3% of subjects in 9th, 10th, 11th, and 12th grade.	Limitations: Data from one county in a tobacco-growing state might not accurately reflect adolescent tobacco usage patterns of other states or the U.S.

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(Corey et al., 2015)	Flavored tobacco product use among middle and high school students - United States, 2014	A cross-sectional study. Subjects (n = 22,007) were U.S. middle school (Grades 6-8) and high school (Grades 9-12) students. ST was defined as chewing tobacco, snuff, or dip. Objective: To determine the prevalence of past–30-day use (current use) of flavored EC, hookah tobacco, cigar, pipe tobacco or ST products, and menthol cigarettes among middle school and high school students, and the proportion of current tobacco product users who have used flavored products.	Data derived from the 2014 NYTS. Demographic data (sex and race) were assessed. Subjects were asked about past 30-day use of different tobacco products. They were also asked about any current use of flavored tobacco products.	36.1% of middle school and 64.7% of high school ST users reported use of a flavored ST product. With respect to sex and race/ethnicity, the proportions who reported use of a flavored ST product were 40.7% among female; 63.3% among male; 67.6% among White, non-Hispanic; 32.5% among Hispanic; and 60% among other race, non-Hispanic ST users. Among high school students, ECs (8.8%) were the most commonly used flavored tobacco product, followed by hookah (6%), cigars (5.3%), menthol cigarettes (5%), any ST (4.1%), and tobacco in pipes (0.7%). The prevalence of flavored ST use among middle school and high school students was 2.6% (95% CI: 2.2, 3.1). Based on the findings of this study, the authors estimated that 690,000 middle and high school students in the U.S. used flavored ST in 2014.	Strengths: The study (1) had a large sample population and (2) was nationally representative. Limitations: (1) Data were collected only from students who attended either public or private schools and might not be generalizable to all middle- and high school–aged youths; (2) flavored tobacco product use was ascertained from a check-all-that-apply response, which might yield lower estimates than forced-choice response options; and (3) NYTS was a paper-and-pencil–based survey, and, therefore, students might report conflicting information: current use of a flavored product but also that they did not use any form of that product in past 30 days.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Creamer et al., 2015)	Trends in multiple tobacco product use among high school students	Data were collected during a repeated, cross-sectional study. Subjects were high school students, Grades 9-12, in public and private schools. Between 1999 and 2013, the overall response rate varied between 67% and 71%, and the number of usable questionnaires ranged from 13,601 to 16,460. Objective: To identify trends in tobacco use among all students and current tobacco users in a nationally representative sample of high school students from 1999 to 2013.	Data derived from 8 national YRBSs conducted between 1999 and 2013. The primary tobacco variables related to self-reported use of cigarettes, cigars, little cigars, cigarillos, and ST (past–30-day use). Sociodemographic variables of interest include race/ethnicity and sex.	ST use did not significantly change among boys (p = 0.76), but there was a significant increase in ST use among girls (p = 0.01). There was a significant increase of ST use among non-Hispanic black students (p = 0.01), but not among non-Hispanic white (p = 0.32) and Hispanic students (p = 0.67). ST use increased in boys and girls (p < 0.001) who used tobacco.	Strengths: (1) The study used YRBS data to examine trends in multiple tobacco product use among all students and high school tobacco users; (2) a nationally representative survey from a widely used surveillance system was used; (3) the measures of tobacco use behaviors are standard in the tobacco literature. Limitations: (1) Repeated cross-sections limit causal implications and some analytic capabilities; (2) data were self-reported measures; and (3) there were no data on ETPs.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Charak, Koot, Dvorak, Elklit, & Elhai, 2015)	Unique versus cumulative effects of physical and sexual assault on patterns of adolescent substance use	Data are from a cross-sectional study. Subjects (n = 918) were in the age range of 12-17 years (mean = 14.92 y); 49.6%, female; 68.6%, Caucasian; 19.3%. African American; 9.9%, Latino; 2.5%, American Indian; 1%, Asian; 0.2%, Pacific Islanders; and 7.7%, "other." Objective: To assess the unique versus cumulative effects of physical and sexual assault on patterns of substance use in adolescents.	The study assessed subjects from the National Survey of Adolescents who reported physical and/or sexual assault. Measures include physical and sexual assault and substance use (categorized subjects into three latent classes), including the use of chewed/snuffed tobacco in the past month.	There were 6.3% of all subjects (n = 918) that used chew/snuff in the past month. 2.6% of Class 1 (experimental use), 5.2% of Class 2 (light polysubstance use), and 12.2% of Class 3 (polysubstance use) subjects used chew/snuff tobacco in the past month.	Limitations: (1) This was a cross-sectional study; (2) the study was based on self-report, which introduced the possibility of recall and reporting bias; and (3) the study did not perform latent class analyses of substance use separately for boys and girls.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Elfassy et al., 2015)	Trends in cigarette, cigar, and smokeless tobacco use among New York City public high school youth smokers, 2001-2013	A cross-sectional study. Subjects (n = 59,122) were NYC public high school youth aged 14-17 years; about half were female; 62% were 9th and 10th graders; and 14% were white, 34% were black, 36% were Hispanic, and 13% were Asian. ST use was defined as using chewing tobacco, snuff, or dip. Objective: (1) To assess current trends in NYC youth smoking behaviors, and (2) to characterize trends in cigar and ST use among NYC youth by smoking status.	Data came from NYC YRBS from 2001 until 2013, a biannual study. The study analyzed tobacco (cigarette, cigars, and ST) past–30-day use. Demographic characteristics (age, sex, grade, and race/ethnicity) were assessed.	ST use increased between 2001 and 2013 overall (1.1% to 4.4%, p < 0.001), among nonsmokers of cigarettes (0.2% to 1.9%, p < 0.001) and among cigarette smokers (4.2% to 21.2%, p < 0.001).	Strength: Study used a large sample population. Limitations: (1) White adolescents were more likely to smoke and were proportionately underrepresented in this study. (2) The current analysis did not characterize use of other products like ECs because the data were not available.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Kaufman et al., 2015)	Tobacco use transitions in the United States: The National Longitudinal Study of Adolescent Health	Four waves of the National Longitudinal Study of Adolescent Health provided data on patterns of cigarette and ST use (within 30 days of survey) for 7th to 12th graders in the U.S. Initially, 20,774 adolescents participated in Wave I (Apr-Dec 1995); 14,738 in Wave II 1 year later (Apr-Aug 1996); 15,197 in Wave III 6 years later (Aug 2001-Apr 2002); and 15,701 in Wave IV 13 years later (Jan 2008-Feb 2009). Objective: To evaluate and describe transitions in cigarette and ST use, including dual use, prospectively from adolescence to young adulthood.	ST use and cigarette smoking were assessed in each wave. Markov modeling was used to estimate the probabilities of transitioning between tobacco use states.	Among respondents, 12.9% were ever-ST users, with 21.4% males and 4.5% females reported using ST within 30 days during at least one wave. Females, Asian subjects, and younger subjects who had reported neither cigarette nor ST use were significantly less likely to have transitioned to ST-only use 1 year later than were male, white, and older subjects. Northeastern subjects were less likely than westerners to transition to ST only.	Strengths: The study had a (1) large sample size and (2) was longitudinal. Limitations: (1) The study relied on self-reports of use without biochemical validation; (2) the sample size of potentially important minority groups was small; (3) the data were not weighted to provide nationally representative estimates; (4) the effect of attrition on estimates of cigarette and ST use was unclear; and (5) subjects who were surveyed at multiple waves were more likely to be white, from the Midwest, and female than subjects surveyed only once.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Lee et al., 2015)	Youth tobacco product use in the United States	Data are from a cross-sectional study. Subjects (n = 24,658; ages 9-18+) were middle school and high school students in the U.S. in 2012. Tobacco product use included cigarettes, roll-your-own cigarettes, cigars, ST, hookah, EC, other combustible (pipes, bidis, or kreteks) and other noncombustible (snus or dissolvables). Objective: To examine multiple tobacco product use and associated risk factors among U.S. youth.	Data derived from the 2012 NYTS collected in spring 2012. The study analyzed subjects' current tobacco product use, demographics (age, sex, and race/ethnicity), tobacco use factors, and attitudinal characteristics.	Overall, 0.6% (95% CI: 0.4, 0.7) of the sample population reported current ST use, and the prevalence rate increased with age: 0.2% (95% CI: 0.1, 0.3) among those aged 9 to 14 years; 0.7% (95% CI: 0.5, 1.0) among those aged 15 to 17 years; and 1.9% (95% CI: 1.1, 3.1) among those aged 18+ years. The reported prevalence of snus or dissolvables use was lower (0.1% of the sample population; 95% CI: 0.0, 0.1).	Strengths: Data are from a (1) large sample size and (2) nationally representative data set. Limitations: (1) The NYTS was cross-sectional and did not collect data on the use history of subjects; (2) the items used to measure OTP use in the NYTS might not capture the full extent of OTP use; and (3) the NYTS was a school-based sample of youth and might not adequately represent all youth.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Liu et al., 2015)	Risk perceptions of smokeless tobacco among adolescent and adult users and nonusers	Data are from a cross-sectional study. Subjects were adolescents (n = 53, mean age: 17 years; 66% male; 84.9% white) and adults (n = 63; mean age: 33.6 years; 79.4% male; 98.4% white) from four Ohio Appalachian counties. ST use was defined as daily, or almost daily, use of chew or snuff or as use on most days. Objective: To examine risk perceptions of ST products among adolescent and adult users and nonusers in the Appalachian region of Ohio.	Subjects were asked about their current use of ST and the frequency of ST use. Demographics analyzed include age, sex, race/ethnicity, marital status, level of education, employment status, and household income.	In the study, 43.4% of adolescents and 60.3% of adults reported ST use (chew and/or snuff) on every or most days. Nearly half of adolescent ST users (47.8%) used both snuff and chew products, whereas 60.5% of adult ST users used only snuff products. On average, adolescents in the study initiated tobacco use at an earlier age (11.7 years) than adults did in the study (15.0 years).	Limitations: (1) Subjects were recruited using flyers posted in a variety of agencies in four Ohio Appalachian counties and, therefore, findings might not be generalizable; and (2) no female ST users were recruited into the study.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Meier, Tackett, Miller, Grant, & Wagener, 2015)	Which nicotine products are gateways to regular use?	Data were from a voluntary online survey taken by psychology or speech undergraduate students (n = 1,304; mean age: 19.57 y; 65.2% female; 80.1% white) on past/current use of cigarettes, ST, hookah, ETPs, and NRT during 2012-2013 academic semesters. Objective: To examine use of various nicotine-containing products on a tobacco-free college campus and whether the first product tried predicts subsequent tobacco use.	Subjects were asked to identify the nicotine-containing product that they first tried. Descriptive statistics were used to explore first-tried tobacco products and variables potentially associated with current tobacco use. Multinomial logistic regression was used to evaluate whether first-used tobacco product predicted subsequent tobacco use.	Approximately 49.4% of subjects reported ever trying a tobacco product; specifically, 28.9% of them tried ETPs and 13.2% tried ST. Cigarettes were the most commonly first-tried product (50.6%), followed by hookah (24.2%), ST (15.1%) and ETPs (9.2%). Among the entire sample population, hookah use was the most common (11.9%), followed by conventional cigarettes (8.6%), ST (5.5%), ETPs (3.2%) and NRT (0.6%). Approximately 40% of individuals who first tried ST were current ST users and 52.5% were current users of any tobacco product (n = 51); 3.4% of individuals who first tried ETPs were current ETP users and 28.8% were tobacco users (n = 17).	Limitations: (1) The study design is cross-sectional; (2) all data were self-reported; (3) although a large sample of youth participated in the study, the demographic characteristics of the sample were not nationally representative of all youth, but rather were representative of just college students; (4) the study did not assess cigar use; and (5) the study, along with previous studies investigating the gateway potential of various tobacco products, only investigated the construct of first product tried as the mechanism for potential gateways.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Neff et al., 2015)	Frequency of tobacco use among middle and high school students – United States, 2014	Data are from a cross-sectional study. Subjects (n = 22,007) were middle school (Grades 6-8) and high school (Grades 9-12) students. ST was defined as chewing tobacco, snuff, or dip. Objective: To analyze data from the 2014 NYTS to determine how frequently U.S. middle school and high school students used cigarettes, EC, cigars, and ST products.	Data were derived from 2014 NYTS. Subjects were asked for their frequency of use for four products: cigarettes, cigars, ST, and EC.	Among current tobacco users in high school, frequent use (on more than 20 of the preceding 30 days) was most prevalent among ST users (42.0%).Among current tobacco users in middle school, frequent use was greatest among ST users (29.2%). By days of use in the last 30 days, the proportions of ST users were: High School 1-2 days: 26.6% 3-5 days: 11.1% 6-9 days: 8.2% 10-19 days: 12.2% 20-29 days: 11.2% All 30 days: 30.8% Middle School 1-2 days: 38.4% 3-5 days: 13.2% 6-9 days: 13.0% 10-19 days: 6.2% 20-29 days:11.3% All 30 days: 17.9%	Limitations: (1) All data were self-reported; (2) the data were collected from students who attended either public or private schools and might not be generalizable to all U.S. middle- and high school–aged youths; and (3) the pattern of use, primary product used, or which products were used on specific days could not be obtained from the data.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Sutfin et al., 2015)	First tobacco product tried: Associations with smoking status and demographics among college students	Data are from a cross-sectional study. Subjects (n = 1,656, 56% female, 89% white) were first-year college students in North Carolina and Virginia in fall 2010. ST category included chewing tobacco, moist or dry snuff (dip), snus, and dissolvables. Objective: To identify product choice for initial tobacco trial, correlates associated with product choice, and the relationship between first product and current cigarette smoking among college students.	Subjects' initiation ages were divided into three categories: 13 years or younger, 14-17 years, and 18 years or older. The study analyzed demographics (race, sex, and maternal education level), lifetime tobacco use, tobacco product age of initiation, first tobacco product, current cigarette smoker status, and parental cigarette smoking.	Prevalence of ever using any tobacco product was 48.6%. Cigarettes were the most common first product (37.9%), followed by cigars (29.3%), hookahs (24.6%), ST (6.1%), and bidis/kreteks (2.2%). About 65% and 5.7% of current smokers initiated with cigarettes and ST, respectively. Females were more likely to report cigarettes and hookahs as their first product, whereas males were more likely to report cigars and ST as their first product ($p < 0.05$). Of subjects whose first tobacco product tried was ST, 15% initiated use at age 13 years or younger, 73% initiated between the ages of 14 and 17 years, and 12% initiated at age 18 years or older. Initiation of tobacco use at age ≤17 years was associated with cigarettes and ST as first products, whereas initiation at age ≥18 years was associated with hookahs and cigars as first products ($p < 0.05$).	Limitations: (1) The study was a cross-sectional study that relied on subject recall of the first tobacco product used; (2) the study focused on college students only; and (3) the study was limited to students from colleges in two states.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Initiation of ST	Comments[1]
(Warren, Smalley, & Barefoot, 2015)	Perceived ease of access to alcohol, tobacco, and other substances in rural and urban US students	Data are from a cross-sectional study. Subjects (N = 513,909) were middle school (n = 252,403, Grades 6-8) and high school (n = 261,506, Grades 9-12) students in Georgia. About 18.2% of subjects attended school in a rural county, and 80.2% attended school in an urban county. Objective: To examine rural-urban differences in perceived ease of access to alcohol, smoking and chewing tobacco, marijuana, and seven other substances in order to better inform and promote future substance use prevention and programming efforts in rural areas.	The study analyzed access to 11 substances: alcohol, smoking tobacco, chewing tobacco, marijuana, cocaine, steroids, inhalants, "ecstasy", methamphetamines, hallucinogens, and prescription medications that were not prescribed to subjects.	Both middle school and high school students who lived in a rural area reported greater access to chewing tobacco (p < 0.001).	Limitations: (1) Generalization of the findings is limited by the study's focus on a single state in the U.S.; (2) study relied on self-reported perceptions of ease of access; (3) it is unclear if students had ever actually attempted to access the substances; (4) study was cross-sectional; (5) because of the very large sample size, there were some differences that, although statistically significant, may not reflect relevant urban-rural differences; and (6) information on sex and race/ethnicity was withheld in the data set, which precluded analyses that incorporated these factors.

7.5.3-2.3. The Likelihood that Nonusers Who Adopt the Tobacco Product Will Switch to Other Tobacco Products That Present Higher Levels of Individual Health Risk

Researchers examined the role of ST products as gateways to use of other tobacco products, particularly cigarettes, for both adolescents and adults in cross-sectional and longitudinal studies. Snus is a recent entry into the United States market, and several reports focused on its use. Noteworthy articles found in this literature review that inform the gateway potential of ST products are highlighted in the following subsections, and all nine articles are summarized in Table 7.5.3-2-2.

7.5.3-2.3.1. Effects of Smokeless Tobacco Products on Initiating Use of a Different Tobacco Product

Two observational studies, both prospective, found that current snus users have significantly increased odds for subsequently initiating cigarette use when compared with nonusers. In one of the studies (Taylor, Choi, & Forster, 2015), preliminary data analyzed from the Minnesota Adolescent Community Cohort Study in 2010-2011 and 2011-2012 indicated that young adult nonsmokers who had tried snus at baseline (19 females and 126 males) were subsequently more likely than those who had not tried snus (928 females and 623 males) to become current smokers (n = 1,696; adjusted odds ratio [AOR] = 1.79; 95% confidence interval [CI] = 1.01–3.14). In the other prospective study, Soneji et al. (Soneji, Sargent, Tanski, & Primack, 2015) investigated whether prior use of water pipe tobacco or snus among never-smokers were risk factors for subsequent cigarette smoking. After analyzing data from a two-wave longitudinal study (n = 2,541; aged 15-23 years), the authors concluded that baseline snus use was associated with subsequent cigarette smoking initiation (AOR = 3.73, 95% CI = 1.43–9.76), cigarette smoking at the second assessment (AOR = 6.19, 95% CI = 1.86–20.56), and higher intensity of subsequent cigarette smoking (AOR = 4.45, 95% CI = 1.75–11.27).

Shepardson and Hustad (Shepardson & Hustad, 2016) reported on observational data on hookah use collected longitudinally during a randomized, controlled trial of an Internet-delivered alcohol education intervention. The trial was conducted in male and female incoming first-year college students (n = 817). Baseline data were collected before the start of the fall semester, and subjects completed the follow-up survey administered 30 days after the start of the semester. The authors did not find that ST use at baseline predicted hookah initiation (AOR = 1.12, 95% CI = 0.79–1.59).

Wang et al. (Wang, Sung, Yao, Max, & Lightwood, 2016) pooled data from three waves of the Tobacco Use Supplement of the Current Population Survey (n = 13,673 nondaily smokers at baseline) and reported that current ST users were significantly less likely to transition from nondaily to daily cigarette smoking over 12 months than were noncurrent ST users (AOR = 0.60, 95% CI = 0.43–0.84).

During the 2012-2013 academic year, Meier et al. (Meier et al., 2015) investigated whether the first product tried predicts subsequent tobacco use by analyzing data from a cross-sectional survey of 1,304 undergraduate college students from a large, tobacco-free,

public university in Oklahoma. Subjects self-reported the nicotine-containing product that they tried first, and the authors concluded that individuals who initiated tobacco use with ST were more likely than those who first tried hookah (odds ratio [OR] = 6.15, 95% CI = 2.11-17.95, p = 0.001) or emerging tobacco products (i.e., dissolvables, snus, and electronic cigarettes) (OR = 4.05, 95% CI = 1.08–15.10, p = 0.04) to be current users of multiple tobacco products.

7.5.3-2.3.2.   Probabilities of Transitioning from Smokeless Tobacco Use to Cigarette Smoking

To estimate transitions between ST and cigarette product use, Kaufman et al. (Kaufman et al., 2015) analyzed data from the National Longitudinal Study of Adolescent Health. The data are representative of United States high schools in region, urbanicity, school size, school types, and ethnic distribution and included 20,774 male and female adolescents in Grades 7 through 12. Four survey waves of the same participants (n = 20,774) spanned approximately 13 years: Wave 1 in April to December 1995; Wave II (n = 14,738) in April to August 1996; Wave III (n = 15,197) in August 2001 to April 2002; and Wave IV (n = 15,701) in January 2008 to February 2009. The estimated 1-year transition rates from exclusive ST use to exclusive cigarette use and to dual ST and cigarette use were 1.6% and 3.0%, respectively. Among white males, the estimated rates were 1.3% and 5.2%, respectively. For comparison, the estimated 1-year transition rates from use of neither ST nor cigarettes to exclusive cigarette use and dual ST and cigarette use were 5.4% and 0.25%, respectively. Among white males, the estimated rates were 7.3% and 0.54%, respectively.

Soneji et al. (Soneji et al., 2015) estimated probabilities for subsequent cigarette smoking initiation, cigarette smoking at follow-up, and high-intensity cigarette smoking and found that the probabilities were 29.9, 27.2, and 22.2 percentage points higher, respectively, for subjects who used snus at baseline than for subjects who did not use snus.

Finally, Tam et al. (2015) conducted a systematic review of literature published from 2000 to 2014 on transitions between ST and cigarette use. While there were considerable differences between the six studies identified, the authors noted that "the existing data indicate that switching behaviors from exclusive smoking to exclusive [ST] use are limited (adults: 0%-1.4%, adolescents: 0.8%-3.8%) but may be more common from exclusive [ST] use to exclusive smoking (adults: 0.9%-26.6%, adolescents: 16.6%-25.5%).

7.5.3-2.3.3.   Updated Findings

As seen in the initial literature review, the updated literature review yielded conflicting results on whether initial ST use is associated with an increased likelihood of cigarette smoking initiation. The conclusions from the initial literature review have not changed based on the updated literature review.

A tabular summary of the literature informing the gateway effects of ST is presented in Table Table 7.5.3-2-2.

Table 7.5.3-2-2: Literature Review for Smokeless Tobacco - Gateway

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Carpenter et al., 2016)	Snus undermines quit attempts but not abstinence: a randomized clinical trial among US smokers	Subjects (n = 1,236; age ≥19 y; daily smoker of ≥10 CPD; nonuse of ST or other reduced exposure products in prior 6 months) were adult smokers with no plans to quit and were randomized to receive free samples of snus (n = 626; mean age: 48.7 y; 70% female; 89% Caucasian) or not (n = 610; mean age: 48.7 y; 65% female; 87% Caucasian) for 6 weeks and then advised to quit all tobacco products. Subjects were assessed for 1 year. Objective: To examine the effect of snus use within a naturalistic, noncessation context.	Primary outcome: Incidence and duration of quit attempts. Secondary outcomes: Point-prevalence abstinence from cigarette smoking at 6 and 12 months, smoking reduction, and associated measures of quitting (motivation and confidence to quit were assessed via standard 0-10 ladders, with 0 being "very definitely no" and 10 being "very definitely yes").	"Participants in both groups reduced the number of cigarettes smoked per day by 23% from baseline to the 1-year follow-up (p<0.0001). There were no between-group differences: 22.4% and 22.9% of snus and control participants, respectively, achieved a 50% reduction in smoking level." "[T]here were significant increases over time in both motivation and confidence to quit smoking in the next 30 days (both p<0.0001), but no significant between-group differences and motivation to quit remained low both at the end of the sampling period (mean snus group: 2.0 vs control: 1.9) and at final follow-up (mean snus group: 3.0 vs control: 3.3)."	Strengths: At the time of publication, this study was the largest and longest trial of snus usage among U.S. smokers. Limitations: (1) The study enrolled primarily Caucasian women, which could have influenced the results; (2) the focus was on smokers who did not want to quit, which decreases the generalizability of the findings; and (3) there was no biochemical verification of abstinence.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Wang et al., 2016)	Factors associated with short-term transitions of non-daily smokers: socio-demographic characteristics and other tobacco product use	Pooled data were analyzed from three waves of the TUS-CPS: Feb, Jun, and Nov 2003; May and Aug 2006 and Jan 2007; and May and Aug 2010 and Jan 2011. The pooled data included self-respondents aged ≥18 years (n = 527,198), with response rates of 63.6% for 2003, 62% for 2006/07, and 62.3% for 2010/11. The final sample population for this study included only established nondaily smokers (n = 13,673; 54.8% male; 61.5% non-Hispanic white; 3.3% current ST users). Objective: To examine the transitions in smoking status among nondaily smokers who transitioned to daily or former smokers or remained as nondaily smokers during a 12-month period.	Multinomial logistic regression model to determine the correlates of nondaily to daily, stable nondaily and nondaily to former smoking transitions among nondaily smokers at baseline. The model controlled for sociodemographic factors and the use of cigars and ST.	Current ST users were significantly less likely to transition from nondaily to daily cigarette smoking over 12 months than noncurrent ST users (AOR = 0.60; 95% CI: 0.43, 0.84; p = 0.003). Current ST users were nonsignificantly more likely to transition from nondaily to former cigarette smoking than noncurrent ST users (AOR = 1.21; 95% CI: 0.85, 1.72; p = 0.285).	Limitations: (1) Study was not conducted as a true longitudinal study: some measures only at baseline and some over 12-month period that limited ability to predict longer-term trends in smoking transition status; (2) since data lacked frequency of life-time use for each OTP, no differentiation of experimental vs. established uses of OTP; (3) there was no differentiation between former smokers who just quit cigarette smoking in past 30 days from nondaily smokers who had smoked for a few days in past 30 days; (4) there were no questions on use of ETPs (e-cigarettes) or separate questions on cigars, cigarillos, and large cigars, or for dry snuff, moist snuff, and snus; (5) self-reported data without validation; (6) selection bias was a possibility because responders with missing values (1.7%) were removed.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Burris et al., 2016)	A longitudinal, naturalistic study of U.S. smokers' trial and adoption of snus	Subjects (n = 1,236; age ≥19 y; daily smoker of ≥10 CPD; nonuse of ST or other reduced exposure products in prior 6 months) were adult smokers with no plans to quit and were randomized to receive free samples of snus (n = 626; mean age: 48.7 y; 70% female; 85.5% non-Hispanic white) or not for 6 weeks and then advised to quit all tobacco products. Subjects were assessed for 1 year. Objective: To advance the current literature via a detailed description of snus uptake during a longitudinal study with adult U.S. smokers who denied intention to stop smoking in the near future.	Primary outcome: Incidence and duration of quit attempts. Secondary outcomes: Point-prevalence abstinence from cigarette smoking, at 6 and 12 months, smoking reduction and associated measures of quitting.	"This study found that when 'unmotivated' smokers are offered free snus for a finite period of time, most will try it, but only a fraction will become regular snus users, and most of these individuals will stop snus use altogether after a few months."	Limitations: (1) Only a single snus product was offered, which may have influenced the study results; (2) the study population consisted of smokers who reported little to no interest in smoking cessation.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Dunbar, Shadel, Tucker, & Edelen, 2016)	Use of and reasons for using multiple other tobacco products in daily and nondaily smokers: associations with cigarette consumption and nicotine dependence	Data are combined from two previous studies conducted through RAND Patient Reported Outcomes Measurement Information System Smoking Initiative. Subjects were adult smokers for at least 1 year and had no plans to quit within next 30 days. The first sample included smokers recruited through Harris Interactive's online panel, and the second sample included smokers recruited via community advertisements in several large U.S. cities. Nondaily (n = 203; mean age: 43.85 y; 55.67% male; 44.55% white) and daily (n = 656; mean age: 48.61 y; 46.25% male; 61.59% white) smokers differed in age, race, education, and CPD. Objective: To examine the ways in which cigarette consumption and nicotine dependence among current daily and nondaily smokers are associated with (1) likelihood of OTP use, (2) number of different types of tobacco products used, and (3) reasons for OTP use.	Information was collected on the use of different OTPs (hookah, e-cigarettes, chew/snuff, snus, cigars, dissolvables), and reasons for using OTPs (e.g., "to cut down on smoking"), as well as cigarette consumption and nicotine dependence. Logistic regression models assessed the association of smoking status with OTP use (ever-use and current use) and reasons for use.	In nondaily smokers, nicotine dependence was marginally positively associated with likelihood of ever OTP use (p = 0.05) and significantly associated with higher likelihood of current OTP use and a greater number of OTPs currently used. "In addition, greater nicotine dependence was associated with likelihood of current OTP use in nondaily smokers, suggesting that OTP use may help to maintain or promote nicotine dependence among nondaily smokers, despite low rates of smoking."	Limitations: (1) Although significant correlations were identified, relatively modest effects suggested role for other factors in explaining OTP use in daily and nondaily smokers; (2) data were unvalidated and self-reported; and (3) heaviness of smoking that was correlated with amount of OTP consumption was not determined and, therefore, the ability to draw inferences about how individuals may substitute OTPs for cigarettes is limited.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Shepardson & Hustad, 2016)	Hookah tobacco smoking during the transition to college: prevalence of other substance use and predictors of initiation	Data were from a randomized, controlled trial of Internet-delivered alcohol education intervention to first-year undergraduates at mid-Atlantic state universities with U.S. mailing addresses. Of 936 students enrolled at the start of semester and who completed baseline assessments, 817 completed the follow-up 30 days after start of semester. Subjects were 49.7% female; 94.7% were aged 18 years (mean age: 18.1 y); 85.2% were white. Subjects were asked to select how many times they used these substances during the past 30 days: cigarettes; tobacco from a water pipe (hookah); cigars, little cigars, or clove cigarettes; ST; marijuana; cocaine; methamphetamine; other amphetamines; sedatives; hallucinogens; opiates; inhalants; MDMA ("ecstasy"); other club drugs; and other illegal drugs. Objective: To assess the prevalence of hookah use and initiation, as well as other forms of substance use among hookah users, and to identify which forms of substance use predicted hookah initiation during the first 30 days of college.	Multivariate binary logistic regressions were used to examine predictors (assessed at baseline) of hookah initiation at 1-month follow-up among the subset of participants who reported no lifetime hookah use at baseline.	ST use at baseline was not a significant predictor of hookah initiation (AOR = 1.12; 95% CI: 0.79, 1.59).	Limitations (1) Study was conducted at a single university and omitted non–college-attending young adults, and a higher number of white females completed follow-up survey, thereby lowering baseline rates of hookah or ST use; (2) the survey primarily focused on alcohol use intervention, thereby potentially skewing the study population toward a particular subset of students; however, survey demographics were similar to overall campus demographics; (3) no biological or collateral verification of substance use behaviors.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Kaufman et al., 2015)	Tobacco use transitions in the United States: The National Longitudinal Study of Adolescent Health	Four waves of the National Longitudinal Study of Adolescent Health provided data on patterns of cigarette and ST use (within 30 days of survey) for 7th to 12th graders in the U.S. Initially, 20,774 adolescents participated in Wave I (Apr-Dec 1995); 14,738 in Wave II 1 year later (Apr-Aug 1996); 15,197 in Wave III 6 years later (Aug 2001-Apr 2002); and 15,701 in Wave IV 13 years later (Jan 2008-Feb 2009). Objective: To evaluate and describe transitions in cigarette and ST use, including dual use, prospectively from adolescence to young adulthood.	ST use and cigarette smoking were assessed in each wave. Markov modeling was used to estimate the probabilities of transitioning between tobacco use states.	"Among participants who had reported ST only as of a given time, those who were female or younger were less likely to later report cigarette smoking; whereas those who lived in the Midwest or were Native American were more likely than Westerners or Whites to later report cigarette smoking" The estimated 1-year transition rates from exclusive ST use to exclusive cigarette use and dual ST and cigarette use were 1.6% and 3.0%, respectively. Among white males, the estimated rates were 1.3% and 5.2%, respectively. For comparison, the estimated 1-year transition rates from use of neither ST nor cigarettes to exclusive cigarette use and dual ST and cigarette use were 5.4% and 0.25%, respectively. Among white males, the estimated rates were 7.3% and 0.54%, respectively.	Limitations: (1) Self reports without biochemical validation; (2) small sampling size of important minorities and, therefore, estimates of transitions in use for these minorities are less precise; (3) demographic variables omitted ethnicity or socioeconomic status; (4) control variables from baseline and may not persist; (5) results not weighted for nationally representative estimates; (6) effect of attrition on estimates of cigarette and ST use not clear; (7) participants surveyed at multiple waves were more likely to be white, from the Midwest, and female than those surveyed only once; (8) changes in tobacco control efforts, tobacco marketing, and product availability occurred from 1995-2009.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Meier et al., 2015)	Which nicotine products are gateways to regular use? First-tried tobacco and current use in college students	Data were from a voluntary online survey taken by psychology or speech undergraduate students (n = 1,304; mean age: 19.57 y; 65.2% female; 80.1% white) on past/current use of cigarettes, ST, hookah, ETPs, and NRT during 2012-2013 academic semesters. Objective: To examine use of various nicotine-containing products on a tobacco-free college campus and whether the first product tried predicts subsequent tobacco use.	Subjects were asked to identify the nicotine-containing product that they first tried. Descriptive statistics were used to explore first-tried tobacco products and variables potentially associated with current tobacco use. Multinomial logistic regression was used to evaluate whether first-used tobacco product predicted subsequent tobacco use.	"[T]he odds of those who first tried [ST] were approximately six times more likely than those who first tried hookah to be current users of multiple tobacco products (OR=6.15, 95% CI=2.11, 17.95, p=0.001), and they were four times more likely than those who first tried ETPs to be current users of multiple products (OR=4.05, 95% CI=1.08, 15.10, p=0.04). Thus, individuals who initiated tobacco use with [ST] were more likely than those who first tried hookah or ETPs to be current users of multiple tobacco products." "Using either first-tried cigarette or first-tried [ST] users as the comparison group, none of the examined predictors significantly discriminated current smokers, [ST] users, or users of cigarettes and [ST] from non-users."	Limitations: (1) Because the study was cross-sectional, how tobacco use evolved over time could only be assessed by recall, and age at first use was not asked; (2) data were from self-reports with no biochemical verification; (3) only psychology or speech undergraduate students were surveyed; (3) cigar use was not assessed; (4) the only potential gateway assessed was first product tried.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Soneji et al., 2015)	Associations between initial water pipe tobacco smoking and snus use and subsequent cigarette smoking: results from a longitudinal study of US adolescents and young adults	The data were from a two-wave national longitudinal study in the U.S. among 2,541 individuals (48.4% male; 69.9% non-Hispanic white) aged 15 to 23 years. At baseline, it was determined if participants had smoked cigarettes, water pipe tobacco, or used snus. At the 2-year follow-up (n = 1,596; 47.7% male; 73.5% non-Hispanic white), it was determined whether baseline non-cigarette smokers had tried cigarette smoking, were current cigarette smokers, or were high-intensity cigarette smokers. Objective: To assess whether prior WTS and snus use among never-smokers were risk factors for subsequent cigarette smoking.	Multivariable logistic regression models were used to determine whether WTS and baseline snus use were associated with subsequent cigarette smoking initiation and current cigarette smoking; and whether baseline WTS and baseline snus were associated with high-intensity cigarette smoking at follow-up.	At follow-up, baseline snus use was associated with cigarette smoking initiation (AOR = 3.73, 95% CI: 1.43, 9.76), current cigarette smoking (AOR = 6.19, 95% CI: 1.86, 20.56), and higher intensity of cigarette smoking (AOR = 4.45, 95% CI: 1.75, 11.27). The predicted probabilities of cigarette smoking initiation was 29.9 (95% CI: 8.3, 50.2) percentage points higher for respondents who had used snus at baseline than for those who had not. Likewise, the predicted probabilities for current cigarette smoking and high-intensity cigarette smoking were 27.2 (95% CI: 4.2, 61.2) and 22.2 (95% CI: 3.8, 47.3) percentage points higher for respondents who had used snus at baseline than for those who had not.	Limitations: (1) The study could not establish if snus use caused subsequent cigarette smoking; (2) secular trends in cigarette smoking initiation were not considered, which could differ between youth who did/did not smoke water pipe tobacco and use snus; (3) accidental inclusion of past cigarette smokers in baseline nonsmokers of cigarettes may have occurred if subjects failed to recall cigarette use; (4) socioeconomic status was based on maternal educational level only; (5) the authors observed differential attrition of racial/ethnic minorities, high sensation seekers, subjects with friends or parents who smoked, and subject who had smoked water pipe tobacco and used snus.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Tam et al., 2015)	A systematic review of transitions between cigarette and smokeless tobacco product use in the United States	A systematic review of published literature on transitions between ST and cigarette use was performed. Search was performed through PubMed, Web of Science and EbscoHost databases from January 2000 to March 2014. Information were extracted on the proportion of the sample population transitioning from baseline to follow-up. Objective: To identify systematic information on transitions between ST and cigarette use in the U.S.	Information on the study characteristics including study population, follow-up, definitions for each tobacco use categories, and how transitions were calculated were extracted.	Six articles met all selection criteria. The following are findings from the selected articles: Transitioned out of exclusive ST use: Adult Exclusive ST Users: After 1 year, 3.9%-26.6% of males and 3.2% of females were exclusive smokers; after 4 years, 0.9% of males were exclusive smokers. After 1 year, 1.8% of males and 0% of females were dual users; after 4 years, 2.5% of males were dual users. Adolescent Exclusive ST Users: After 2 years, 16.6% of males were exclusive smokers, and 40.7% of males were dual users. After 4 years, 25.5% of males were exclusive smokers, and 14.3% of males were dual users.	Limitations: (1) Estimates from some studies are not generalizable to the U.S. population; (2) there was variability in tobacco use definitions and follow-up time; (3) there is a potential bias in estimates from some studies due to tobacco use prevention or ban; (4) there are an absence of confidence intervals; and (5) estimates for females are missing, with the exception of one article.

Author	Title	Study Methods	Primary Study Measurements and Endpoints	Author's Findings Related to Gateway Effects of ST	Comments[1]
(Taylor et al., 2015)	Snus use and smoking behaviors: preliminary findings from a prospective cohort study among US Midwest young adults	Data were from the Minnesota Adolescent Community Cohort Study conducted in 2010-2011 and 2011-2012. At baseline, subjects (n = 2,184) were aged 20-28 years. Objective: To examine if snus use was associated with progression of smoking among young adult nonsmokers and smoking cessation and reduction among young adult current smokers.	Multiple logistic regression models were used to assess the associations between snus use at baseline and smoking behaviors at follow-up, stratified by baseline smoking status, while adjusting for covariates and controlling for clustering by design.	"[Y]oung adult nonsmokers who had tried snus were subsequently more likely than those who had not tried snus to become current smokers (n = 1,696; [AOR] = 1.79; 95% [CI] = 1.01, 3.14). Snus use was not associated with subsequent smoking cessation or reduction among young adult current smokers (n = 488; P > .46)."	Limitations: (1) Subjects were mainly non-Hispanic whites and from Midwest, which limits generalizability; (2) there was a low prevalence of snus use, which limited detection of association between snus use and smoking reduction and cessation; (3) there was no assessment of the effect of snus use on smoking cessation behaviors that took into account the motivation for using snus.

7.5.3-2.4. The Likelihood That Former Users of Tobacco Products Will Reinitiate Use with the Tobacco Product

No articles informing the relapse potential of ST were identified in the literature review.

7.5.3-2.5. Literature Cited

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