Scientific Assessment of the Impact of Flavors in Cigar Products

Center for Tobacco Products
Food and Drug Administration
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Abbreviations

aOR	Adjusted odds ratio
aPR	Adjusted prevalence ratio
aRR	Adjusted relative rate
CI	Confidence interval
ENDS	Electronic nicotine delivery systems
FDA	U.S. Food and Drug Administration
HR	Hazard ratio
IARC	International Agency for Research on Cancer
LGBT	Lesbian, gay, bisexual, or transgender
LGBTQ+	Lesbian, gay, bisexual, transgender, or queer
LGB	Lesbian, gay, or bisexual
MSS	Minnesota Student Survey
MTurk	Amazon Mechanical Turk
MYTS	Minnesota Youth Tobacco Survey
NATS	National Adult Tobacco Survey
NESARC-III	National Epidemiologic Survey on Alcohol and Related Conditions III
NHIS	National Health Interview Survey
NSDUH	National Survey on Drug Use and Health
NYTS	National Youth Tobacco Survey
OR	Odds ratio
PATH	Population Assessment of Tobacco and Health
RSE	Relative standard error
U.S.	United States
USDA	U.S. Department of Agriculture
YRBS	Youth Risk Behavior Survey

Purpose and Scope

Use of combusted tobacco products including cigars causes a tremendous burden of death and disease every year. Flavored cigars are commonly used, addictive, and harmful. This document presents a synthesis of scientific evidence regarding the role that characterizing flavors[1] play in increasing the appeal and use of tobacco products, particularly cigars, among youth, young adults, and adults in the U.S. The Food and Drug Administration (FDA) focused its review on the published literature from the past approximately 15 years, with earlier seminal work on abuse liability and health effects included for context. The specific research questions addressed in this assessment of the scientific literature are:

1. How does the addition of characterizing flavors to tobacco products, including cigars, impact product appeal and product use?
2. How do characterizing flavors impact youth and young adult experimentation with tobacco products, including cigars, and do they make progression to regular tobacco use more likely?
3. What impact do local policies restricting the sale of flavored cigars and other flavored tobacco products have on cigar sales and use?

Research articles published up to December 31, 2021 were included in this document. Pre-publication research articles were also reviewed when accessible. Searches were conducted quarterly in PubMed, Web of Science, EMBASE, EBSCOHost (PsychINFO, Academic Search Complete) to identify studies on the role of characterizing flavors in cigars. The methods and search terms used for this quarterly search strategy are summarized in **Appendix 1**. Additional studies were identified through hand-searching of select article reference sections, in publications citing the studies identified in prior searches, and through external peer reviewer suggestions.

Criteria that have been used to categorize flavors in tobacco products include the presence of ingredients, the multisensory experience of a user, and how the product is represented in labeling and advertising. The studies cited in this review varied in their definitions of flavored tobacco products. Also, while the focus of this assessment is on flavors and cigars, evidence from other tobacco products, including cigarettes and e-cigarettes, is included where relevant. Similarly, this Assessment focuses on the public health literature on cigar use over the past 10-15 years, but earlier evidence on abuse liability, health effects, and the history of tobacco marketing is also included. The cumulative scientific literature identified through recent and past literature searches is summarized below. For key studies, we expand on the study summary with a description of the study design, findings, and limitations that may impact the generalizability of the findings.

Prevalence of Cigar Use Among Youth

While evidence from national surveys including the National Youth Tobacco Survey (NYTS) has suggested that, similar to cigarettes, cigar use has been on the decline among U.S. youth in recent years (2011 to 2017), beginning in 2019, cigars were the most commonly reported combustible tobacco product used by youth (Wang et al. 2018; Wang et al. 2019). The most recent data from the NYTS found that nationwide, nearly one million youth in middle and high school had smoked a cigar on at least one

[1] We do not use a specific definition of 'characterizing flavor' for this synthesis of the scientific evidence. Throughout this document, we use the terms 'characterizing flavor,' 'explicit flavor,' and 'concept flavor' according to their use or definition provided in the referenced article.

day during the past 30 days in 2020 (Gentzke et al., 2020). The 2020 NYTS also found that an estimated 960,000 youth (3.5%), including 5.0% (770,000) of high school students and 1.5% (180,000) of middle school students, had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days (Gentzke et al. 2020). These data also found that, of those youth who use cigars, the largest proportion use cigarillos (44.1%), followed by traditional cigars (33.1%), and little cigars (22.6%) (Parms, Head, Sawdey, Rostron, Cullen, 2022).

While these data indicate a high burden of cigar smoking among youth, there are methodological considerations to keep in mind when considering cigar use estimates among youth. First, several studies have shown that youth tend to underreport cigar smoking if brand name identifiers are not provided (Nasim et al., 2012; Terchek et al., 2009; Trapl et al., 2011; Corey, Dube, Ambrose et al. 2014). In one study of Virginia high school students, for example, the reported prevalence of cigar use nearly doubled after accounting for students who reported smoking Black & Mild (a brand name of cigarillos); previously, the students had not acknowledged using cigars, cigarillos, or little cigars (Nasim et al., 2012). A recent analysis of 2020 NYTS data found that 21.8% of youth who were current cigar smokers reported not knowing which cigar type they use (Parms et al., 2022), suggesting cigar subtype-specific youth prevalence estimates might also lead to under-estimation of cigar use among youth. **Appendix 2** presents a summary of youth prevalence estimates across published studies.

Age of Initiation

A study of almost 10,000 young adult college students who had ever used cigars reported that the mean age of first cigar use was 13.6 years (Do et al., 2018). A longitudinal analysis of four waves of data from the Population Assessment of Tobacco and Health (PATH) Study (2013-2017) found an increasing probability of initiating cigar use (including cigarillo, filtered cigar, or traditional cigar use) between ages 15 and 20 years of age (Chen, Sterling, Bluestein et al., 2020). Whereas only 1.5% (95% CI: 1.3, 1.8) of 15-year-olds had ever used a cigar, by age 20, 31% (95% CI: 28.7, 33.3) had ever used a cigar, with the greatest increase in first use between 17 and 18 years of age. Similarly, Fishbein et al. (2021) harmonized data from five large national surveys and found individuals aged 17-19 were the most likely to initiate cigar use, suggesting the most likely age of initiation extends into young adulthood (Fishbein et al., 2021). Initiation of cigars after age 25 was less common. For example, a longitudinal analysis of Waves 1-3 of PATH Study data found that over one year, in Wave 2 (2014-2015) or Wave 3 (2015-2016), 3.6% to 4.6% of 12-17-year-olds and 5.8% to 7.3% of 18-24-year-olds started using cigars for the first time (Stanton et al. 2020). In comparison, 1.4% to 2.0% of adults over 25 years initiated any cigar use in the same time period (Stanton et al., 2020).

Historically, published analyses of survey data created age categories using approximately age 18 or completion of high school as the defining age separating youth from adulthood. Until 2020, age 18 was also the age at which tobacco products could be legally purchased in many places in the United States, creating consistency between the traditional definition of adulthood and the legal purchase age for studies with data collection that preceded 2020, including all studies cited in this review. Thus, the age used to categorize youth, young adults, and individuals of legal purchase age ought to be considered when interpreting prevalence estimates. Given that cigar initiation continues to be common into young adulthood, the Prevalence of Cigar use Among Adults section includes estimates specifically for young adults aged 18-24 when available.

Flavored Cigar Use Among Youth

Youth cigar smokers commonly smoke flavored cigars. A study that used Wave 1 of the PATH Study to examine flavor use across tobacco products found that 65.4% of youth ever users of cigars reported the first product they had used was flavored, compared to 50.1% for cigarettes, 88.7% for hookah, 81.0% for e-cigarettes (Ambrose et al., 2015). According to more recent data from the 2020 NYTS, more than half (58.3%; 95% CI: 53.2, 63.3) of current (i.e., use in the past 30 days) youth cigar smokers, or approximately 550,000 youth, reported using a flavored cigar during the past 30 days (Parms et al., 2022). Furthermore, data from Wave 5 (2018-2019; data collected December 2018 through November 2019) of the PATH Study indicate that among youth (aged 12-17 years) who have ever tried a cigar, 60.4% (95% CI: 54.9, 65.7) report that the first cigar they used was flavored (PATH Study Memo) and 44.0% (95% CI: 34.4, 53.7) of past 30-day cigar smokers reported using flavored cigars (PATH Study Data Tables and Figures). Among youth (12-17 years) who used any type of flavored cigar in the past 30 days, fruit flavors were the most commonly used flavor (51.4%[2]; 95% CI: 33.8, 68.7) (PATH Study Memo). By cigar type, flavored cigars were used by 33.9% (95% CI: 18.2, 49.6) of youth traditional cigar users, 46.0% (95% CI: 33.6, 58.5) of youth cigarillo users, and 50.2% (95% CI: 19.2, 81.2) of youth filtered cigar users (PATH Study Data Tables and Figures). Data from all Waves of the PATH Study also indicate that a greater proportion of youth and young adults aged 18-24 initiate with a flavored cigar relative to adults aged 25 and over (PATH Study Memo; Villanti et al., 2017; Villanti et al., 2021).

The proportion of middle and high school youth current cigar users reporting using flavored cigars in the past 30 days in NYTS data declined from 63% (95% CI: 59.3, 67.6) in 2014 to 49% (95% CI: 43.7, 54.2) in 2017 (Dai, 2019). The researcher notes that the primary limitation of the analysis is that flavored tobacco product use is self-reported in NYTS, noting ambiguous labeling of flavor in cigars as an example of a potential source of measurement bias (Dai, 2019). Concurrent with the decline in reported youth flavored cigar use as a proportion of youth cigar use, sales of concept flavors that include ambiguous labeling (e.g., sweet, jazz) increased from 2.2% of U.S. flavored cigar sales in 2009 to 21.4% of U.S. flavored cigar sales in 2020, a 33% average annual percentage change (Delnevo et al., 2021). The increasing availability of concept flavors may impact flavored cigar prevalence estimates in youth if cigar users do not report concept flavors as a flavored cigar product.

Disparities in Cigar Use Among Youth

Data indicate that patterns of cigar use differ by race and ethnicity[3], household income and educational attainment, education level, and among other vulnerable populations[4] such as individuals

[2] Estimate should be interpreted with caution because it has low statistical precision. It is based on relative standard error (RSE) value or its complement is larger than 30 percent and/or the total unweighted sample size is less than 50.

[3] Throughout this document, we use both the terms “Black” and “African American.” The term “African American” is used to describe or refer to a person of African ancestral origins or who identifies as African American. “Black” is used to broadly describe or refer to a person who identifies with that term. Though both of these terms may overlap, they are distinct concepts (e.g., a Black person may not identify as African American). As a result, we rely on the specific term used by researchers when citing to specific studies.

[4] Throughout this document, the term “vulnerable populations” refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved

who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+) and persons with disabilities. While there has been an overall downward trend in cigar use among youth as a whole over the past several years, cigars are the most commonly used combustible tobacco product among youth, and, cigar use remains disproportionately high among non-Hispanic Black youth (Gentzke et al. 2020). The 2020 NYTS data show that 6.5% (95% CI: 5.2, 8.2) of non-Hispanic Black middle and high school students reported past 30-day cigar use compared to 2.8% (95% CI: 2.1, 3.7) non-Hispanic White middle and high school students (Gentzke et al. 2020). Additionally, the findings show that cigar use was statistically significantly higher than cigarette use among non-Hispanic Black high school students in 2020, with 9.2% (95% CI: 7.0, 12.1) reporting having smoked cigars during the past 30 days, compared with 2.8% (95% CI: 1.7, 4.6) reporting having smoked cigarettes (Gentzke et al., 2020). Data also indicate that non-Hispanic Black youth have a higher risk than non-Hispanic White youth of initiating cigar use. An analysis of youth (aged 12-17) data from Waves 1-4 of the Population Assessment of Tobacco and Health (PATH) Study (2013-2017) indicated that when compared to non-Hispanic White youth, non-Hispanic Black youth were 47% (HR: 1.47, 95% CI: 1.17, 1.86) more likely to initiate past 30-day cigarillo or filtered cigar use and 111% (HR: 2.11, 95% CI: 1.36, 3.27) more likely to be "fairly regular" users of these products (Chen et al., 2020). Similarly, findings from the 2013 Cuyahoga County Youth Risk Behavior Survey indicate that non-Hispanic Black youth had significantly higher odds of past-30-day cigar use compared to non-Hispanic White youth (OR: 1.82; 95% CI: 1.50, 2.22) (Trapl & Koopman Gonzalez, 2018).

These observed disparities in cigar use initiation among youth are associated with higher levels of current cigar use and frequency of cigar use among Black youth and young adults. A study by Cantrell et al. (2022) found that once non-Hispanic African- American youth and young adults initiated cigar use, they had twice the odds of past-30-day cigar use within six months relative to non-Hispanic White youth (adjusted Odds Ratio (aOR): 2.03, 95% CI: 1.37, 3.01). Also, within six months of initiation, the average frequency of use among youth and young adults was higher by 2.21 days per month for non-Hispanic African American youth compared to non-Hispanic White youth (aOR: 0.63 SE, $p<0.001$) (Cantrell et al., 2022).

Disparities in cigar use among Black youth may also pose additional concerns due to risk associated with other combusted tobacco product use. In a nationally representative longitudinal study of youth, ever cigar use significantly increased the odds of subsequent past 30-day cigarette use among non-Hispanic Black youth (OR: 2.68; 95% CI: 1.21, 5.93). However, ever cigar use did not increase the odds of subsequent past 30-day cigarette use among non-Hispanic White youth (OR: 1.37; 95% CI: 0.69, 2.72). This study found that 9.1% of cigarette initiation among non-Hispanic Black youth was attributable to cigar use, compared with only 3.9% among non-Hispanic White youth (Stokes et al., 2021).

LGBTQ+ youth also face disparities when compared with heterosexual/ straight and cisgender youth, including higher prevalence of cigar use. An analysis of 2020 NYTS data found that past 30-day use of any tobacco product was higher among lesbian, gay, and bisexual (LGB) youth (25.5%; 95% CI: 21.8, 29.5) than their heterosexual peers (15.1%; 95% CI: 13.1, 17.3) (Gentzke et al., 2020). Past 30-day cigar use was nearly twice as prevalent among non-LGB youth (6.0%; 95% CI: 4.4, 8.3) than heterosexual youth (3.1%; 95% CI: 2.5, 3.7) (Gentzke et al., 2020). Findings from an analysis of Wave 3 PATH data (2015-2016) indicated that lesbian and bisexual female youth are more than twice as likely as their heterosexual peers to report ever using cigars (11.3%; 95% CI: 8.8, 14.3 vs. 5.2%; 95% CI: 4.4, 6.1) and to

rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with mental health conditions or substance use disorders.

have used cigars in the past 30 days (3.2%; 95% CI: 2.0, 5.0 vs. 1.0%; 95% CI: 0.7, 1.6) (Johnson et al. 2019). An analysis of the 2015 Youth Risk Behavior Survey data found that lesbian and bisexual females have significantly higher prevalence of current use of cigars than their heterosexual peers (16.4%; 95% CI: 6.7, 26.0 for lesbian females, 10.2%; 95% CI: 6.0, 14.5 for bisexual females, 5.4%; 95% CI: 4.6, 6.1 for heterosexual females, p<0.0001), as do gay and bisexual males (20.0%; 95% CI: 9.4, 30.6 for gay males, 16.9%; 95% CI: 9.2, 24.6 for bisexual males, and 13.5%; 95% CI: 12.3, 14.8 for heterosexual males; p=0.008) (Dai, 2019). Transgender youth are also significantly more likely than cisgender youth to report ever using any tobacco products (transgender: 53.6%; 95% CI: 40.2, 66.5, vs. non-transgender: 31.5%; 95% CI: 30.2, 32.8) including cigars (transgender: 16.1%; 95% CI: 8.4, 27.8 vs. non-transgender: 7.5%, 95% CI: 6.8, 8.2), and to be past 30-day users of more than one tobacco product, including cigars (transgender: 10.2%; 95% CI: 5.2, 19.1 vs. non-transgender 3.5%; 95% CI: 3.0, 4.1) (Johnson et al., 2019).

Prevalence of cigar use among youth with disabilities (defined as individuals with a visual, hearing, cognitive, mobility, self-care, and/or independent living disability) is also elevated compared to their non-disabled peers. In one study of more than 20,000 11th graders in Oregon that controlled for sociodemographic risk factors of tobacco use, the proportion of little cigar use among students with at least one reported disability (7.0%, 95% CI: 6.1, 8.1) was higher than among students without a disability (5.4%, 95% CI: 4.8, 6.1) (Senders & Horner-Johnson, 2020). In Senders and Horner-Johnson (2020), individuals with a disability were also more likely to report fair to poor mental health status. Poor mental health is independently associated with greater likelihood of cigar use among youth. In a study of Wave 1 PATH data, both severe internalizing and externalizing problems were associated with greater odds of ever using any cigars (internalizing: aOR: 1.4; 95% CI: 1.2, 1.7; externalizing: aOR: 1.4, 95% CI: 1.2, 1.7), and with ever using each type of cigar, including traditional cigars, filtered cigars, and cigarillos, $p < .05$ (Conway et al., 2018).

Prevalence of Cigar Use Among Adults

In the 2019 National Health Interview Survey (NHIS), 3.6% of adults 18 or older (including 3.8% of adults aged 18-24 and 4.4% of adults aged 25-44) reported currently using cigars some or every day, behind cigarettes (14%) and e-cigarettes (4.5%) (Cornelius et al., 2020). Comparing 2011 to 2019 National Survey on Drug Use and Health (NSDUH) data, while past month cigarette smoking and cigar use were both statistically significantly lower (p<0.05) in young adults (aged 18-25 years) over time, the absolute decline in cigar use was less than the decline in cigarette use (33.5% in 2011 to 17.5% in 2019 for cigarettes; 10.9% in 2011 to 7.7% in 2019 for cigars). For adults (aged 26 years or older), cigarette use in 2011 was statistically significantly higher (p<0.05) compared to in 2019; however, cigar use remained relatively stable and did not significantly change (21.9% in 2011 to 18.2% in 2019 for cigarettes; 4.2% in 2011 to 4.0% in 2019 for cigars) (SAMHSA, 2020).

Prevalence of cigar smoking varies by the type of cigar smoked. According to most recent data from the PATH study (Wave 5, collected in 2018-2019), 4.8% (95% CI: 4.3, 5.4) of young adults aged 18-24 used traditional cigars, 7.9% (95% CI: 7.3, 8.5) used cigarillos, and 2.4% (95% CI: 2.0, 2.8) used filtered cigars in the past 30 days. Among adults aged 25 and older, 3.5% (95% CI: 3.2, 3.7) used traditional cigars, 3.3% (95% CI: 3.0, 3.6) used cigarillos, and 1.5% (95% CI: 1.4, 1.7) used filtered cigars in the past 30 days (PATH Study Data Tables and Figures). See **Appendix 3** for a summary of adult prevalence estimates included in this document.

Flavored Cigar Use Among Adults

Both young adults and adults aged 25 years and older report considerable use of flavored cigars. Wave 5 data from the PATH Study (2018/2019) showed that 63.2% (95% CI: 60.6, 65.7) of young adults (aged 18-24 years) and 41.9% (95% CI: 40.7, 43.1) of adults (aged 25 years and older) who reported ever using cigars said that the first cigar they used was flavored (PATH Study Data Tables and Figures). Moreover, 38.3% (95% CI: 34.2, 42.4) of young adult cigar smokers and 36.0% (95% CI: 33.0, 39.1) of adult cigar smokers reported past 30-day use of flavored cigars from 2018-2019 (PATH Study Data Tables and Figures). A review of published studies suggests younger adults are more likely to use flavors than older adults. College students aged 18-24 were more likely to use flavored cigars compared to students aged 25-29 years (OR: 2.17; 95% CI: 1.13, 4.17) (Hinds et al., 2018). In a study using data from the 2016 National Adult Tobacco Survey (NATS), the use of flavored cigars was significantly more common among younger compared to older adults (Bonhomme et al., 2016). There are also gender differences in the use of flavored cigars; while males are significantly more likely than females to use cigars overall (e.g., Bonhomme et al., 2016; Corey et al., 2018; Cornelius et al., 2020; Hinds et al., 2018; PATH Study Data Tables and Figures), among cigar users, females are significantly more likely than males to use flavored products (Bonhomme et al., 2016; Hinds et al., 2018; PATH Study Data Tables and Figures). For example, a study of college students aged 18-29 years who had used cigars in the past 30 days found that 60.5% of cigar users were male, but, among cigar users, males were statistically significantly less likely to have used flavored cigars than females (OR: 0.28, 95% CI: 0.18, 0.45) (Hinds et al., 2018).

Use of flavors also varies by cigar type. Based on Wave 5 data from the PATH Study, flavored cigar smoking was less common among past-30-day traditional cigar smokers (young adults: 17.7%; 95% CI: 12.5, 24.0; adults: 19.7%; 95% CI: 16.4, 23.3) compared with users of cigarillos (young adults: 46.0%; 95% CI: 40.5, 51.4; adults: 46.5%; 95% CI: 42.3, 50.7) and filtered cigars (young adults: 41.0%; 95% CI: 29.8, 52.1; adults: 48.7%; 95% CI: 42.1, 55.4) (PATH Study Data Tables and Figures). This is consistent with another study in which the majority of flavored cigar users reported smoking cigarillos (68.3%), whereas most users (64.5%) of large cigars did not report using flavored products (Hinds et al., 2018). There was no statistically significant change in the proportion of adults using flavored cigars within each of the cigar types from PATH Waves 4 to 5 (2016-2019) (PATH Study Data Tables and Figures). Among young adults, use of flavored filtered cigars declined from 3.1% to 2.4% from Wave 4 to 5, reflecting the only recent significant change in young adults' use of flavored cigars.

Disparities in Cigar Use Among Adults

Race and ethnicity. A disproportionate burden of cigar smoking exists among vulnerable populations and has grown over the past two decades. In an analysis of 2002-2016 National Survey on Drug Use and Health (NSDUH) data, non-Hispanic Black individuals were significantly more likely than all other racial/ethnic groups to have used cigars in the past 30 days (Weinberger et al., 2020). Decreases in prevalence of cigar use have not been observed in non-Hispanic Black adults like they have for other racial/ethnic groups (Weinberger et al., 2020). There was no significant change in past 30-day use prevalence between 2002-2016 in the NSDUH data among non-Hispanic Black and non-Hispanic other/mixed race adults, whereas there were decreases among both non-Hispanic White and Hispanic adults. Further, over this same time period, cigar use decreased among non-Hispanic White men and stayed the same among non-Hispanic White women, but it increased among non-Hispanic Black women and remained the same among non-Hispanic Black men (Weinberger et al., 2020). When considering

more recent NSDUH data, this disparity has persisted, with the prevalence of past 30-day cigar smoking remaining significantly higher among non-Hispanic Black adults compared to non-Hispanic White adults through 2019 (SAMHSA, 2020).

A recent analysis of PATH Study data from Wave 3 (2015-2016) showed racial differences in daily cigar smoking (Chen-Sankey et al., 2021). Non-Hispanic Black individuals are significantly more likely to report that they have ever been a "fairly regular" cigar smoker (5.4%; 95% CI: 4.8, 6.1) than non-Hispanic White cigar smokers (2.5%; 95% CI: 2.3, 2.8) and to report that they smoke cigars daily (1.9%; 95% CI: 1.0, 2.0), as compared to non-Hispanic White cigar smokers (0.5%; 95% CI: 0.4, 0.6), with these differences being most pronounced for cigarillos (non-Hispanic Black: 3.7%; 95% CI: 3.3, 4.2 vs. non-Hispanic White: 0.9%, 95% CI: 0.8, 1.1) (Chen-Sankey et al., 2021). Non-Hispanic Black smokers were most likely to smoke cigars within 30 minutes of waking (30.7%; 95% CI: 25.4, 36.5), followed by Hispanic adults (29.5%; 95% CI: 24.0, 35.7), and Non-Hispanic White adults (21.8%; 95% CI: 14.4, 31.6) (Chen-Sankey et al., 2021). The authors found a consistently higher prevalence of cigar use for non-Hispanic Black adults compared with non-Hispanic White adults for three cigar-smoking outcomes (past 30–day use, daily use, and established use) across all the cigar types (Chen-Sankey et al., 2021).

Differences in prevalence across racial and ethnic populations have been observed for specific cigar types and in the use of flavored cigars as well. In the PATH Study, among adults aged 25 and older, past 30-day use of all types of cigars, including cigarillos, traditional cigars, and filtered cigars use was significantly higher among non-Hispanic Black adults compared with non-Hispanic White and Hispanic adults at all waves (2013-2019) (PATH Study Data Tables and Figures). Among young adults, this pattern was only observed for cigarillos, with racial/ethnic differences being small or in the reverse direction for traditional cigars and filtered cigars. Among past 30-day users of cigars, past 30-day use of flavored traditional cigars was significantly higher among non-Hispanic Black adults aged 25 years and older compared to non-Hispanic White adults at Waves 2-5 (2014-2019) and compared to Hispanic adults at Waves 2-3 (2014-2016) and 5 (2018-2019) (PATH Study Data Tables and Figures). An analysis of survey data on college students aged 18-29 indicated that non-Hispanic Black young adults who had smoked cigars in the past 30 days were three times more likely to have smoked flavored cigars than their White counterparts (OR: 3.24, 95% CI: 1.43, 7.37) (Hinds et al., 2018).

Some studies suggest Hispanic adults are less likely to use cigars compared to non-Hispanic White adults. For example, an analysis of the 2002–2016 National Survey on Drug Use and Health found statistically significantly lower cigar use prevalence among Hispanic participants compared to non-Hispanic White participants (Weinberger et al., 2020). However, data from Waves 1-5 of the PATH Study, as well as the 2019 NHIS survey suggest current cigar use is not statistically significantly different between Hispanic and non-Hispanic White adults (Cornelius et al., 2020; PATH Study Data Tables and Figures). Another study found that Hispanic adults who smoked cigarettes were significantly more likely to also use cigars (17.4%) compared to non-Hispanic White adults (8.4%) who smoked cigarettes (Sterling, Fryer, Pagano, & Fagan, 2017).

An analysis of National Health Interview Survey (NHIS) data from 2006 – 2018 found that Asian Indian, Chinese, and Filipino adults were statistically significantly less likely to have ever used cigars, cigarillos, or filtered little cigars compared to non-Hispanic White adults (Rao et al., 2021). This finding was replicated with 2019 NHIS data; non-Hispanic Asian adults were significantly less likely to use cigars, cigarillos, or filtered little cigars "every day" or "some days" compared to all other racial/ethnic groups (Cornelius et al., 2020). Likewise, an analysis of PATH Wave 1 data found lower prevalence of ever cigar use and past-30-day cigar use among Asian American and Native Hawaiian and Other Pacific Islander

(AANHOPI) adults compared to non-AANHOPI adults (Nguyen, 2019). However, when cigar use prevalence was examined by sex and AANHOPI subgroup, prevalence of ever cigar use was similar between Korean men (66.9%, 95% CI: 43.0, 84.5), the AANHOPI subgroup with the highest prevalence, and non-AANHOPI men (61.3%, 95% CI: 59.7, 62.8) (Nguyen, 2019). The lowest prevalence of ever cigar use among AANHOPI subgroups was among Vietnamese women (6.07%, 95% CI: 2.33, 14.90), demonstrating differences in cigar use when AANHOPI subgroups are disaggregated.

One study of young adults suggests that, among cigar users, both Hispanic and Asian young adults may be more likely to use flavored cigars compared to non-Hispanic White young adults (Hinds et al., 2018). Specifically, among college students aged 18-29 who had used cigars in the past 30 days, Hispanic and Asian participants were more likely to have used flavored cigars compared to non-Hispanic White participants (Hispanic: OR: 2.22, 95% CI: 1.36, 3.64; Asian: OR: 2.21, 95% CI: 1.05, 4.65) (Hinds et al., 2018).

Socioeconomic status. Research indicates income gradient effects (where higher levels of household income and educational attainment are linked to better health outcomes and lower levels of household income and educational attainment are linked to poorer health outcomes) for cigar use. Data from the 2012-2013 NATS show that higher educational levels and higher annual household income generally were associated with lower prevalence of usual use of cigarillos, other mass market cigars, and of little filtered cigars (Corey, King, Coleman et al., 2014). Data from the PATH Study in 2018-2019 show that 7.3% (95% CI: 6.3, 8.4) of adults 25 years and older with less than a high school diploma smoked cigars in the past 30 days, compared to 3.8% (95% CI: 3.2, 4.4) of adults (25 years and older) with a college degree or higher (PATH Study Data Tables and Figures). At every wave of the PATH Study, among adults aged 25 years and older who had smoked cigars in the past 30 days, individuals with a college degree were also statistically significantly less likely to use a flavored cigar (20.0%, 95% CI: 14.9, 26.0) than individuals categorized as having less than a high school diploma (44.9%, 95% CI: 35.7, 54.0), a high school diploma (37.4%, 95% CI: 31.3, 43.5), or some college (42.9%, 95% CI: 38.2, 47.5) (PATH Study Data Tables and Figures). In another study of 470 unhoused individuals, 74.0% of respondents had used cigars in the past 30 days, including 55% who had used flavored cigars (Alizaga, Hartman-Filson, Elser, Halpern-Felsher, & Vijayaraghavan, 2020).

Physical and mental health. Using data from 9 years (2005-2013) of the U.S. National Survey on Drug Use and Health (NSDUH), adults over 18 years with at least one chronic physical or mental health condition (e.g., asthma, heart disease, substance abuse, anxiety, depression) were more likely to use cigars (2005: 5.9%, 2013: 5.5%) than those without a chronic condition (2005: 3.8%, 2013: 3.6%) in all years of the survey (aOR: 1.57; 95% CI: 1.49, 1.65, $p < 0.01$) , with no significant changes over time (aOR: 0.99, 95% CI: 0.98, 1.00, $p = 0.07$) (Stanton, Keith, Gaalema, et al., 2016). Mental health conditions were associated with particularly high odds of cigar use. Adults with anxiety, depression, and substance abuse disorders exhibited significantly higher rates of cigar use (6.0% to 9.4%) than any other group, including compared to individuals without a chronic condition (anxiety: aOR: 1.69; 95% CI: 1.55, 1.85, $p < 0.01$; depression: aOR: 1.67; 95% CI: 1.53, 1.82, $p < 0.01$; substance abuse disorder: aOR: 2.52, 95% CI: 2.39, 2.65, $p < 0.01$) (Stanton et al., 2016). The association between mental health and tobacco use, including cigar use, is robust and has been replicated across several studies (Conway, Green, Kasza, et al., 2017; Cohn, Johnson, Ehlke, & Villanti, 2016; Ganz, Cohn, Goodwin, et al., 2022).

Use of flavored tobacco products is also more likely among individuals with poor mental health. Using seven waves (2011-2014) of data from a nationally representative survey of young adults aged 18-34 years, past-30-day use of menthol-flavored tobacco products was associated with significantly higher

odds of having anxiety and depression symptoms (aOR: 1.20, 95% CI: 1.02, 1.42) compared to those who did not report menthol-flavored tobacco product use (Cohn et al., 2016). Likewise, using Waves 1-4 of PATH data, adults who reported past-year severe internalizing problems (compared to those who did not) were more likely to have initiated use of flavored cigarillos since the prior wave ((adjusted prevalence ratio) aPR: 1.09; 95% CI: 1.03, 1.16), and were also more likely to be past-30-day users of flavored cigarillos (aPR: 1.15, 95% CI: 1.04, 1.28) (Ganz et al., 2022).

LGBTQ+. Adults who identify as LGBTQ+ are more likely to use tobacco products, including the experimental and current use of cigars, and to meet the criteria for nicotine dependence when compared to their heterosexual and cisgender peers (Agaku et al., 2014; Blosnich, Jarrett, & Horn, 2011; Cornelius et al., 2020; Emory et al., 2016; Freitag, Chen-Sankey, Duarte, Ramsey, & Choi, 2021; Ganz et al., 2018; Johnson et al., 2019; Rath, Villanti, Rubenstein, & Vallone, 2013; Schuler & Collins, 2020; Wheldon, Kaufman, Kasza, & Moser, 2018; Wheldon & Wiseman, 2019).[5] For example, an analysis of data collected in 2011 as part of a nationally representative cohort study indicated that young adults who identified as lesbian, gay, or bisexual (LGB) reported higher ever cigar use (46%) compared to young adults who identified as heterosexual or straight (31%), $p = .05$ (Rath et al., 2013). Bisexual young adults also reported significantly higher ever use of little cigars/cigarillos/bidis compared to heterosexual or straight adults (41% vs. 26%, $p = .03$). Results from a 2013 survey of adults aged 18 years and older also found LGB adults were significantly more likely to be current small cigar users (11.6%) compared to their non-LGB peers (6.2%), $p < .001$ (Emory et al., 2016). In data from Wave 10 (2016) of the Truth Initiative Young Adult Cohort Study, past-30-day use of little cigars/cigarillos/bidis was higher among those who identified as homosexual or gay/lesbian, bisexual, transgender, other, or not sure/don't know compared to those who did not (Ganz et al., 2018).

These disparities also exist for flavored cigar use, as LGBT adults have a higher prevalence of flavored cigar use (8.2%; 95% CI: 5.6, 11.9) than heterosexual/straight and cisgender adults (2.7%; 95% CI: 2.5, 3.0) and compared to the national prevalence of cigar use (2.8%; 95% CI: 2.6, 3.1) (King, Dube, & Tynan 2013). In Waves 2-8 (2011-2015) of the Truth Initiative Young Adult Cohort Study, past-30-day use of flavored large cigars and little cigars/cigarillos/bidis was also significantly higher among LGB adults compared to straight/heterosexual adults (OR: 3.81; 95% CI: 1.27, 11.40) (Glasser et al. 2017).

Lesbian/gay and bisexual women, in particular, have a significantly higher rate of cigar use when compared to heterosexual women. Using data collected in 2016, Delahanty et al. (2019) found that both cisgender lesbian/gay (aOR: 1.49, 95% CI: 1.24, 1.79) and bisexual females (aOR: 1.50, 95% CI: 1.22, 1.84) had higher odds of ever cigar use compared to cisgender gay males (Delahanty, Ganz, Hoffman, et al., 2019). Cisgender lesbian/gay females also had higher odds of past 30-day cigar use compared to cisgender gay males (aOR: 1.24, 95% CI: 1.01-1.53) (Delahanty et al., 2019). Using data from the 2015-2017 NSDUH, Schuler and Collins (2020) found that LGB women were more than twice as likely to use cigars relative to non-LGB women (aOR: 2.63, 95% CI: 2.25, 3.07). These findings were echoed by Emory et al. (2016) who found that LGB women were more than twice as likely as non-LGB women to use cigars.

Transgender adults are significantly more likely to use tobacco products, including cigars, than their cisgender peers. In a national cross-sectional online survey, a greater proportion of transgender adults reported past 30-day use of any cigar, cigarette, or e-cigarette product (39.7%; 95% CI: 29.5, 50.8) compared to cisgender adults (25.1%; 95% CI: 24.2, 26.0) (Buchting et al., 2017). This study also found

[5] Studies varied in how they categorized and grouped sexual and gender identities. The terminology reported here reflects what was used in each study, resulting in some variability across studies.

that a greater proportion of transgender adults were past 30-day users of cigars (26.8%; 95% CI: 19.0, 36.4), specifically, when compared with cisgender adults (9.3%; 95% CI: 8.8, 9.9) (Buchting et al., 2017). Transgender adults also had significantly higher odds of past 30–day use of any cigar, cigarette, or e-cigarette product (OR: 1.97; 95% CI: 1.25, 3.1) and of past 30-day use of cigars (OR: 3.56; 95% CI: 2.27, 5.59) compared to cisgender adults (Buchting et al., 2017).

Intersectionality. The intersection or interplay of multiple characteristics may influence the observed patterns of disparities in cigar use. For example, the relation between mental health and tobacco use may be stronger for females than males (Conway et al., 2017). There are also differences across race/ethnicity in the association between LGB identity and tobacco use, and differences across LGB identity in how other sociodemographic predictors are associated with tobacco use (Blosnich, Jarret, & Horn, 2011; Freitag et al., 2021; Johnson et al., 2019; Rath, et al., 2013). For example, using data from the National Epidemiological Survey on Alcohol and Related Conditions-III (2012-2013) gay/lesbian identity (compared to heterosexual identity) was significantly associated with greater odds of being a current tobacco user among Hispanic and non-Hispanic Black adults, but not among non-Hispanic White adults (Freitag et al., 2021). Similarly, bisexual identity was significantly associated with greater odds of being a current tobacco user among Hispanic, non-Hispanic Black, and non-Hispanic White adults, but the association was weaker for non-Hispanic White adults compared to Hispanic and non-Hispanic Black adults (Freitag et al., 2021). In a national sample of college students, Black LGB individuals also had a significantly higher prevalence of cigar/little cigar/clove cigarette use (17.9%; 95% CI: 13.1–22.8) compared to White (10.8%; 95% CI: 9.6–11.9) or Hispanic (9.5%; 95% CI: 6.3–12.7) LGBs individuals (Blosnich, Jarrett, & Horn, 2011). Finally, using nationally representative data from the Truth Initiative's Young Adult Cohort Study (2011), there were significant associations between age, race/ethnicity, and socioeconomic status, with any tobacco use in the heterosexual population, but not in the LGB population (Rath et al., 2013).

Methodological Considerations

Several methodological features should be considered when interpreting estimates of cigar use based on national surveys. First, there are multiple types of cigars, including cigarillos, filtered, and traditional cigars. Patterns of use of each type differ by age and demographic characteristics. Likelihood of use of flavored cigars can also differ by cigar sub-type. A full understanding of patterns of cigar use necessitates a consideration of how patterns differ across cigar types.

Next, criteria that have been used in published research to categorize flavors in tobacco products include the presence of ingredients, the multisensory experience of a user, and how the product is represented in labeling and advertising. Most national surveys rely on respondents' self-reported use of flavors, which may be influenced by any or all these criteria. For example, survey respondents may categorize concept flavors alongside explicitly flavored products, assigning them to the flavor response options provided on the survey (e.g., fruit, candy) or as part of the "other" flavor category. Concordance is moderate between the cigar flavor (non-flavored vs. any flavor) that participants self-report in surveys compared to experts' coding of flavor based on descriptors or marketing materials, suggesting adults can accurately self-report their flavor use, although factors beyond descriptors and marketing materials may influence their perceptions (Rose et al., 2020).

Finally, some individuals use cigars and cigar components, such as blunt wraps, including flavored cigars and components, as blunts by replacing the tobacco in the cigar with marijuana and retaining the tobacco leaf wrapper (Cohn et al., 2016). Some individuals who smoke blunts, especially

youth and young adults, may not consider themselves to be cigar users (Delnevo, Bover-Manderski, & Hrywna, 2011; Yerger, Pearson, & Malone, 2001). While some individuals may practice blunting exclusively, most individuals who use cigars as blunts also use cigars with the tobacco contents intact, often sequentially or as substitute products (Albert, Ishler, Perovsek, et al., 2020), suggesting there is considerable overlap between the two user groups. However, surveys likely vary in the extent to which blunt use is captured in estimates of cigar use prevalence depending on methodological features (Delnevo, Bover-Manderski, & Hrywna, 2011; Yerger, Pearson, & Malone, 2001). **Appendix 4**, which summarizes the methodological features of each national survey cited in this report, details whether cigar use estimates exclude blunt use.

Health Effects of Cigar Use

In 2010 in the United States, regular cigar smoking was responsible for approximately 9,000 premature deaths and more than 140,000 years of potential life lost (or 15 years of life per death) among adults aged 35 years or older (Nonnemaker et al., 2014). A detailed review of the health effects associated with cigar use can be found in **Appendix 5** of this document. In summary, cigar smoking presents many of the same health risks as cigarette smoking, including, but not limited to, cancers of the mouth and throat, lung cancer, and heart disease. The risks of cigar smoking can even exceed those related to cigarette use depending on the number of cigars smoked and the depth of smoke inhalation (Chang et al., 2015; Chen et al., 2014).

Additionally, the health risks of cigar use reveal a dose-response relationship, with greater cumulative exposure and earlier age of cigar initiation being associated with greater likelihood of adverse health risks (Boffetta et al., 1999; U.S. Department of Health and Human Services, 2010). For example, a large European case-control study found that cigar users who initiated before age 20 years were at a fivefold higher risk of developing lung cancer compared to those who started after age 26 years (Boffetta et al., 1999). Mortality estimates are generally also higher for men than women, reflecting differences in use pattern by sex (Nonnemaker et al., 2014).

Question 1: How Does the Addition of Characterizing Flavors to Tobacco Products, Including Cigars, Impact Product Appeal and Product Use?

Addition of Flavors in Tobacco Products

Tobacco product manufacturers add flavors to tobacco products, including cigars, to appeal to youth (Brown & Williamson, 1972; RJ Reynolds Tobacco Company, 1974); to ensure pleasant flavor and taste; to reduce the harshness, bitterness, and astringency of tobacco during inhalation; and to soothe irritation during product use (Carpenter et al., 2005; Cummings et al., 2002; Manning, Kelly, & Comello, 2009).

In the literature, a distinction is often made between flavored products that explicitly indicate a flavor, often termed "characterizing flavors" or "explicit flavors," and "concept flavors," which have ambiguous names that imply non-tobacco flavors in their labeling or packaging without explicitly indicating a flavor (Farley et al., 2020; Farley et al., 2018; Gammon et al., 2019). In this document, the terms 'characterizing flavor' and 'explicit flavor' are used according to their use in the referenced article. Concept flavors raise unique considerations related to compliance and enforcement, and, thus, are described in Question 3 as part of the effects of local policies restricting the sale of flavored cigars.

As documented by the United States Surgeon General, tobacco product manufacturers have historically added characterizing flavors to products with lower levels of free nicotine (i.e., products that have lower amounts of nicotine in a form that is easily absorbed by the user) that are intended for use as "starter products" for new tobacco users (U.S. Department of Health and Human Services, 2012). Internal tobacco manufacturer documents illustrate cigar manufacturers' historical practices of adding characterizing flavors to diminish the harshness of tobacco products' taste with specific intent to appeal to young consumers (Kostygina, Glantz, & Ling, 2016). A review of the Truth Tobacco Industry Documents Library, an archive of tobacco manufacturer documents, showed that some flavors in cigars (e.g., vanilla beans, peach, apricot, licorice, cocoa) may mask the bitterness of tobacco leaves, throat burn, and heavy taste, thereby facilitating inhalation, making smoking more tolerable for current users and increasing palatability for new users. These documents similarly suggest that tobacco manufacturers added flavors and changed some design characteristics of little cigars and cigarillos to facilitate inhalation and make smoke more tolerable for current smokers, as well as more palatable for new users (Kostygina et al., 2016).

Flavors can activate the brain's reward circuit, producing rewarding effects that, when added to tobacco products, can reinforce the effects of nicotine (Palmatier et al., 2013; Touzani, Bodnar, & Sclafani, 2010). The use of sweet/candy and other characterizing flavors popular among youth produces a robust reinforcing effect in young populations (Palmatier et al., 2013; Touzani et al., 2010). The reinforcing properties of flavors are discussed in greater detail in Question 2.

Appeal of Flavors in Tobacco Products

Research on perceptions and use of flavored cigars finds that flavored cigar products are appealing to potential users of all ages and may be particularly attractive to youth and young adults (Ambrose et al., 2015; Cornacchione et al., 2016; Corey et al., 2018; Nyman et al., 2016; Schneller, Li, Tavárez, et al., 2020; Sterling, Fryer, Nix, & Fagan, 2015; Villanti et al., 2017). Youth report in survey and qualitative research that flavors are a common reason for use. Flavors play an important role in

attracting youth to initiate with and use tobacco products. The scientific literature indicates that youth find new and existing flavored tobacco products appealing, based on continued reporting of flavor as a reason for tobacco use, use of a flavored product over an unflavored one during first tobacco use, and the sustained higher prevalence of youth use of flavored tobacco products relative to unflavored products (Delnevo et al., 2015; Harrell et al., 2017; Cullen et al., 2019).

Qualitative Literature on Appeal of Flavored Cigars

In one qualitative study with youth and young adult cigar users, nearly half of all participants identified flavor information on the packaging (e.g., a flavor name or image) as the most appealing component of cigar packaging (Kong et al., 2017). Participants also indicated that words describing the flavor (e.g., "sweet") were a reason to buy the product (Kong et al., 2017). Survey research supports the importance and appeal of information about flavors on tobacco product packaging (e.g., Huang et al., 2017; Meernik et al., 2019; Shang, Nonnemaker, Sterling, et al., 2021)

In a qualitative study of adolescents (Liu, Ramamurthi, & Halpern-Felsher, 2021), both users of tobacco products (including users of cigars/cigarillos) and non-users indicated flavors make tobacco products appealing and are a reason to use tobacco products. Participants indicated that both the taste and smell of flavored products were appealing, specifically mentioning minty, sweet, and fruit flavors, and noting that the smell of flavors could obscure the smell of tobacco. Qualitative studies with adult participants have revealed similarly high appeal of flavors in cigars, especially sweet and fruity flavors, describing them as appealing (i.e., evoking positive affect) and contributing to their own initiation and continued use of cigars (Giovenco, Miller Lo, et al., 2017; Sterling et al., 2015).

Reasons for Use of Cigars

In 2018-2019, 50.4% (95% CI: 40.5, 60.3) of youth participants (aged 12 to 17) in the Population Assessment of Tobacco and Health (PATH) Study Wave 5 who reported past 30-day cigar smoking identified flavors as a reason for use (PATH Study Memo). Although the proportion of youth reporting flavors as a reason for use of cigars overall declined from 2013 to 2019 (73.8%; 95% CI: 68.2, 79.4 compared to 50.4%; 95% CI: 40.5, 60.3), a majority of youth reporting use of cigarillos (51.7%; 95% CI: 39.3, 63.8), and filtered cigars (69.2%[6]; 95% CI: 44.5, 86.3) still indicated flavors were a reason for use (Ambrose et al., 2015; PATH Study Memo).

An analysis of Wave 5 (2018-2019) PATH Study data indicated that among young adults (aged 18-24 years) who used cigars some or every day, 54.1% of traditional cigar users (95% CI: 42.1, 65.6), 66.5% of cigarillo users (95% CI: 60.0, 72.4), and 65.1% of filtered cigar users (95% CI: 51.7, 76.6) reported flavoring as a reason for cigar use (PATH Study Memo). Among adults over 25 years old who used cigars some or every day, 54.8% of traditional cigar users (95% CI: 48.2, 61.4), 69.6% of cigarillo users (95% CI: 64.8, 73.9), and 71.4% of filtered cigar users (95% CI: 65.9, 76.4) reported flavoring as a reason for cigar use (PATH Study Memo). Overall, such data from this large national observational study shows that flavors are a leading reason for use of cigars among all age groups.

[6] Estimate should be interpreted with caution because it has low statistical precision. It is based on relative standard error (RSE) value or its complement is larger than 30 percent and/or the total unweighted sample size is less than 50.

Perceived Harm of Flavored Cigars

Several studies suggest that lower perceived harm of cigars is associated with greater likelihood of cigar initiation and use (Nyman, 2015; Sterling et al., 2019). The appeal of cigars, such as the positive affect or feelings people associate with their use (e.g., enjoying the taste or feeling relaxed), can be associated with the likelihood of use directly, and also indirectly because flavored products are often perceived as less harmful (Huang et al., 2017; Sterling et al., 2019). Several studies suggest flavored cigar products are both more appealing and perceived as less harmful than both unflavored cigars (Evans et al., 2020; Gonzalez, Quisenberry, Pike Moore, et al., 2021) and cigarettes (Sterling, Fryer, & Fagan, 2016). For example, in a qualitative study, young adults perceived fruit and mint flavors of cigarillos as having the fewest additives and being the least harmful compared to other flavors (Gonzalez et al., 2021). In two other qualitative studies, participants perceived flavored little cigars and cigarillos to be less harmful, less addictive, and less likely to cause cancer compared to cigarettes (Liu et al., 2021; Sterling, Fryer, & Fagan, 2016). Participants provided a variety of reasons to explain their lower harm perceptions, including the belief that flavored cigars had fewer toxic ingredients than cigarettes (Sterling, Fryer, & Fagan, 2016). Sterling et al. (2015) found similar results, with comments from participants conveying the perception that the flavorings contributed to the "naturalness" and safety of products, as well as reduced risk of cigars relative to cigarettes. For example, one participant stated, "When I think of like little cigars, I think of the most natural tobacco used because most of the stuff I see has like byproducts on it and everything, especially the regular cigarettes, but you don't see it as much on the little cigars" (Sterling et al., 2015).

Moreover, in another study with a national sample of adults aged 18-44 who smoked cigarettes, non-Hispanic Black and Hispanic adults were significantly more likely than non-Hispanic White adults to perceive flavored little cigars and cigarillos to be less addictive than cigarettes (Sterling et al., 2017). In another study conducted in 2018-2019, a significantly greater percentage of Black adults than White adults reported the perception that cigars may be less harmful than cigarettes as a reason for their cigar use (Dunn, Johnson, Sterling, & Cohn, 2021). Thus, evidence suggests there are racial/ethnic differences in the perceived harm of flavored cigars, which may contribute to the observed disparities in cigar use.

Systematic Literature Reviews on Appeal, Use, and Progression to Regular Use of Flavored Tobacco Products

While the focus of this scientific assessment is on the role of flavors in the use of cigars, research across tobacco products, including e-cigarettes, is relevant to the role of flavors in the appeal, use, and progression to regular use of flavored cigars. Research consistently illustrates that flavors increase youth appeal of tobacco products (Feirman et al., 2016; Huang et al., 2017; Meernik et al., 2019; Zare et al., 2018). Four systematic reviews of the scientific literature have found that flavored tobacco products attract youth to the tobacco product (Feirman et al., 2016; Huang et al., 2017; Meernik et al., 2019; Zare et al., 2018). Two systematic reviews (Feirman et al., 2016; Huang et al., 2017) assessed the literature on perceptions, use, and attitudes of flavored tobacco products including cigars. Both reviews concluded that flavors in tobacco products were an appealing feature of tobacco products and that flavors influence perceptions and initiation and progression to use tobacco products, particularly among youth.

One systematic review summarized studies conducted in the United States published up to 2013 that examined use or attitudes toward flavored tobacco products (Feirman et al., 2016). The review was comprised of 32 studies, including experimental, observational, and qualitative studies. Results from

nationally representative cross sectional studies included showed that flavored tobacco use was more common at younger ages and that flavoring in tobacco products may be associated with more positive perceptions of the product. The review included six qualitative studies and found that both users and nonusers of tobacco products across all qualitative studies perceived flavors as an attractive feature of these products. Overall, the heterogeneity of the study designs and measures examined in this review limited its ability to draw conclusions about any one type of tobacco product, including cigars (Feirman et al., 2016). Also, given when the review was published, the studies included may not reflect the current tobacco marketplace. However, this review, alongside more recently published reviews, illustrates consistent findings of the general appeal and attractiveness of flavored tobacco products relative to unflavored products, especially for youth.

A more recent systematic review included 40 studies published through 2016 that examined attitudes, intentions, use, and cessation of non-menthol flavored tobacco products in the United States and globally (Huang et al., 2017). The review concluded that flavors in most tobacco products contribute to how users and non-users of tobacco products, particularly youth, perceive, initiate, and progress to regular use of the product. Twelve studies assessed intention to try or initiation of flavored tobacco products and found that the variety and availability of flavors in tobacco products is strongly appealing to youth and young adults interested in initiating tobacco use or experimenting with different products. Two studies that examined the impact of flavors on the progression from initiation to regular use of tobacco products concluded that flavors play an important role in use, including in use of little cigars and cigarillos among younger people (Leatherdale et al., 2011; Oliver et al., 2013). This review also included 17 studies conducted outside of the United States and Huang et al. (2017) concluded results from those studies did not meaningfully differ from studies conducted in the United States. Overall, Huang et al.'s (2017) conclusions about the appeal of flavors in tobacco products, particularly among youth, are consistent with and expand upon the Feirman et al. (2016) review. Of note, since all included articles were published in or before 2016, results may not fully generalize to the current tobacco product marketplace. Other limitations are that only 3 studies examined cigars specifically and several outcome measures lacked established validity and reliability measures (Huang et al., 2017).

Evidence of the appeal of flavors is consistent across tobacco products. In particular, the rise in popularity of flavored electronic nicotine delivery systems (ENDS) provides an example of the appeal of flavors in tobacco products that is relevant to cigars. Extensive evidence suggests flavors, especially flavors not found in traditional tobacco products, such as combusted cigarettes, are particularly appealing to youth, affecting initiation, product preferences, and harm perceptions (Chen et al., 2019; Cooper et al., 2016; Goldenson et al., 2019; McKelvey et al., 2018; Meernik et al., 2019; Morean et al., 2018; Pepper et al., 2016; Wagoner et al., 2021). Indeed, several studies have reported that flavor is among the most important factors in determining whether youth will try ENDS (Bold et al., 2018; Groom et al., 2020; Kong et al., 2015; Landry et al., 2019). These results are supported by conclusions from systematic reviews, including a 2018 review that found that youth were more likely to initiate ENDS use through flavored ENDS (especially fruit and sweet flavors among non-smokers) than non-flavored or tobacco-flavored ENDS (Zare et al., 2018). Another systematic review (Meernik et al., 2019) found that, relative to unflavored or tobacco-flavored products, other flavors (e.g., sweet flavors) were associated with greater appeal of ENDS and willingness to try ENDS among both youth and adults, as well as greater likelihood of initiation and lower harm perceptions among youth. Furthermore, several regional studies have found that flavors in ENDS are associated with increased risk of progressing to more frequent or regular use among youth (Audrain-McGovern et al., 2019; Leventhal et al., 2019; Morean et al., 2018).

The consistency between these findings for ENDS and the findings described above specific to cigars provide evidence of broad consistency across tobacco products.

Marketing of flavored cigars

Tobacco marketing influences the appeal of flavored cigars by shaping social norms around tobacco use, which spread through social networks and make tobacco use more socially acceptable, thereby increasing the likelihood of tobacco use, especially among youth (Berg et al., 2020; Christakis & Fowler, 2008; Etcheverry & Agnew, 2008; Gunther, Bolt, Borzekowski, Liebhart, & Dillard, 2006; Hinds, Loukas, & Perry, 2019; Portnoy, Wu, Tworek, Chen, & Borek, 2014; Wakefield, Flay, Nichter, & Giovino, 2003). For decades, tobacco manufacturers disproportionately marketed their tobacco products, including flavored cigars, to members of underserved communities and vulnerable populations, such as youth and young adults, racial and ethnic populations, those with lower household income and educational attainment, individuals who identify as LGBTQ+, and individuals with mental health disorders (Harlow, 1972; Jackson, 1975; Kostygina, Glantz, & Ling, 2016). Evidence suggests tobacco manufacturers continue to target underserved communities with cigar marketing, including flavored cigar marketing, across diverse marketing platforms, ranging from traditional print media to online platforms (see, e.g., Emory, Buchting, Trinidad, et al., 2019; Henriksen et al., 2017; Kong, Queen, Golden, & Ribisl, 2020; Moran et al., 2019; Ribisl et al., 2017; Smiley et al., 2020; Tan et al., 2021).

Brick-and-mortar tobacco retailers, as well as storefront, outdoor, and point-of-sale tobacco marketing are all disproportionately present in Black, Hispanic, and low-income communities (Cruz et al., 2019; Fakunle, Curriero, Leaf, et al., 2019; Lee, Henriksen, Rose, et al., 2015; Lee et al., 2017; Primack, Bost, Land, & Fine, 2007; Rodriguez, Carlos, Adachi-Mejia, et al., 2013; Rose et al., 2021; Seidenberg, Henriksen, & Ribisl, 2021). Two systematic reviews and several studies found that tobacco retailers in predominately Black neighborhoods were significantly more likely to sell cigars and cigarillos, were significantly more likely to have exterior advertisements for cigars and cigarillos, and sold cigars and cigarillos at a lower price, as compared to tobacco retailers in other neighborhoods (Cantrell et al., 2014; Cruz et al., 2019; Giovenco, Spillane, & Merizier, 2019; Lee et al., 2015; Roberts et al., 2015; Smiley et al., 2020).

For decades, flavored tobacco products, in particular, have been disproportionately marketed to youth and young adults, racial and ethnic minority populations, and women. A 1972 report on the findings of an industry consumer research study concluded that adding menthol and mint flavor to little cigars was appealing to young study participants, and recommended marketing this flavored cigar product at a lower price point than cigarettes in order to attract young users (Harlow, 1972; Kostygina et al., 2016). A 1975 memorandum also highlighted tobacco companies' desire to purposefully publish promotions for flavored little cigars in Black-only newspapers (Jackson, 1975; Kostygina et al., 2016). Industry market research also studied how to increase cigar use among young women, including the addition of flavors to improve palatability and mildness to promote product trial (Harlow, 1972; Kostygina et al., 2016). More recently, an analysis of the extent to which local bans on flavored tobacco products include communities with vulnerable groups (i.e., the reach equity of the policy) found that the policies rated as strongest had unfavorable reach equity for women, youth, Hispanic, American Indian/Alaskan Natives, and African American populations (Rose, Amato, Anesetti-Rothermel, et al., 2020). Unfavorable reach equity of strong policies restricting flavored tobacco may contribute to

continued disparities in exposure to flavored cigars and cigar marketing (Garrett, Dube, Babb, & McAfee, 2015; Lieberman, Golden, & Earp, 2013). In summary, evidence suggests that exposure to flavored cigar marketing increases product appeal and likelihood of use, and that disproportionate marketing and product exposure among vulnerable populations contributes to the ongoing disparities in cigar use noted in the Prevalence section of this scientific assessment.

Appeal of Flavors in Food Science Literature

The appeal of flavors in tobacco products, including cigars, is not only consistent across the literature on tobacco products, but is also consistent with the food literature. Physiologically, research has shown that youth have a heightened preference for sweet food tastes and greater rejection of bitter food tastes, preferences that diminish with age (De Graaf et al., 1999; Desor et al., 1987; International Agency for Research on Cancer, 2004; Mennella et al., 2005).

The choice of sweet flavored tobacco products over non-flavored products may reflect greater rewarding and reinforcing values (Bickel & Vuchinich, 2000). Sweet flavoring may activate similar reward pathways in the brain as sweet food (Freeman et al., 2018; Rolls, 2016; Touzani, Bodnar, & Sclafani, 2010). A recent analysis identified high-intensity sweeteners in cigarillo wrappers and mouth-tips, where they would come in contact with saliva upon use, potentially creating a sweet taste (Erythropel et al., 2018).

An FDA-funded review of 474 articles published between 1931 and 2015 conducted to understand how youth and adults differ with respect to their preferences for characterizing flavors, primarily in food, concluded that preference for sweetness and saltiness is generally higher for children than it is for adults; and the level of sugar selected as most preferred in clinical experiments decreased between adolescence and adulthood (Hoffman et al., 2016). The researchers hypothesized that the higher caloric needs of children to sustain growth likely account for the more pronounced preference for sweetness in youth.

Laboratory research analyzing the chemical composition of food and tobacco products has confirmed that the fruit flavors in tobacco products are often the same as those found in popular candies (Brown et al., 2014; Chen et al., 2010). Researchers reviewed the levels of flavor chemicals in several brands of candy (e.g., Life Savers) and one drink mix (Kool-Aid) and concluded in laboratory analyses that the chemical amounts and combinations largely overlapped with similarly labeled “cherry,” “grape,” “apple,” “peach,” and “berry” cigar and other tobacco products (Brown et al., 2014; Chen et al., 2010).

Summary and Conclusion

Overall, we conclude that the addition of characterizing flavors to tobacco products, including cigars, increases product appeal and makes tobacco products easier to use, particularly among youth. According to tobacco manufacturer documents, manufacturers have historically added characterizing flavors to tobacco products to make them more appealing to new users. Numerous qualitative and population-based quantitative studies underscore the appeal of flavors in participants’ own words and in studies showing that flavors are a leading reason for cigar use. Additionally, laboratory studies suggest that cigars have similar flavor chemical profiles to popular candies and drink mixes commonly marketed to youth. This finding is consistent with research from the food science literature that has identified high preferences for sweet flavors among youth.

As outlined in the Prevalence section, cigars are the most commonly used combustible tobacco product among youth, with the majority of youth users reporting use of flavored cigars. The literature on the appeal and ease of use of flavored cigars relative to non-flavored cigars is consistent with and helps explain these patterns of use. The literature on the appeal of flavors and cigars also helps explain the observed disparities in cigar use and flavored cigar use, including the disproportionately high rates of cigar use among non-Hispanic Black youth and adults and among LGB youth. For example, non-Hispanic Black communities are disproportionately exposed to tobacco retailers and marketing, and non-Hispanic Black adults also express lower perceived harm of flavored products compared to non-Hispanic White adults. The evaluation of this research leads FDA to conclude that characterizing flavors added to cigars increases their appeal and makes them easier to use, particularly among youth. Given the health risks associated with cigar smoking discussed previously and in **Appendix 5**, flavored cigars contribute to the public health burden of tobacco use, particularly the disproportionate burden among vulnerable populations in the United States.

Question 2: How Do Characterizing Flavors Impact Youth and Young Adult Experimentation with Tobacco Products, Including Cigars, and Do They Make Progression to Regular Tobacco Use More Likely?

First Use of Flavored Tobacco and Progression to Regular Use

Qualitative studies

Qualitative studies of youth and young adults indicate that most cigar users start with flavored products and perceive that flavors contributed to their progression to regular use. For example, in Sterling et al. (2015), some young adult participants found the flavors of little cigars and cigarillos particularly appealing and acknowledged that flavorings impacted their cigar use. The qualitative studies that were included in a systematic review on the appeal and use of flavored tobacco products found that participants perceived that the flavors in tobacco products impacted their rate of consumption (Feirman et al., 2016). In a qualitative study of youth and young adults who used little cigars and cigarillos, half of whom also smoked cigarettes (Antognoli et al., 2018), many cigarette smokers indicated that they started using little cigars and cigarillos because of perceived taste and/or smell. For example, one young adult participant stated, "I didn't like the cigarettes, but the Black & Mild tasted better, so it didn't make me cough as bad when I smoked it. So I just liked the taste better." An adolescent participant stated, "Milds always smelled amazing, so I'm like 'Wait. If I can get my hands on some. That would be great.'" (Antognoli et al., 2018). These respondents did not specify whether the little cigar or cigarillo, including Black & Milds, they described was flavored (Antognoli et al., 2018). Overall, the authors concluded based on this qualitative analysis that respondents found little cigars and cigarillos more attractive in terms of smell and taste relative to cigarettes (Antognoli et al., 2018).

Quantitative studies

Quantitative studies suggest that for youth, young adults, and adults, first use of a flavored tobacco product, including cigars, is associated with greater likelihood of continued use over time and increased progression to regular use, compared to first use of non-flavored products. As discussed previously, when using a cigar for the first time, most youth and young adults report using a flavored cigar, and youth and young adults are more likely to initiate with a flavored cigar than adults are (e.g., PATH Study Memo).

Villanti et al. (2019) conducted a longitudinal data analysis of Waves 1 (2013-2014) and 2 (2014-2015) of the PATH Study to assess whether there is a prospective association between the first flavor of cigar used and subsequent use of cigars. Survey items assessed whether participants' first cigar was "flavored to taste like menthol, mint, clove, spice, candy, fruit, chocolate, alcohol (such as wine or cognac), or other sweets," and responses were categorized as flavored or nonflavored (e.g., tobacco-flavored). The authors estimated the association between first flavored tobacco use among ever users at Wave 1 and both current tobacco use and progression to greater frequency of use (adult sample only) at Wave 2 (Villanti et al., 2019).

Among youth, there were no significant associations observed in the adjusted models for the association between first use of flavored cigars (versus nonflavored) at Wave 1 and subsequent current

use of cigars at Wave 2. Among young adults (18-24 years), compared to first use of nonflavored cigars, first use of any flavored cigar at Wave 1 was associated with greater likelihood of past 12-month any cigar use (aPR, 1.19; 95% CI: 1.10, 1.29), past 30-day use (aPR, 1.13; 95% CI: 1.01, 1.27), and current regular use (aPR, 1.60; 95% CI: 1.26, 2.02) at Wave 2. Examining cigar types separately, first use of flavored cigarillos (aPR, 1.49; 95% CI: 1.08, 2.05) and flavored filtered cigars (aPR, 3.69; 95% CI: 2.08, 6.57) were associated with greater likelihood of current regular use (some/every day use) of those products at Wave 2 compared to first use with nonflavored products.

An even stronger pattern of associations emerged for adults aged 25 years and older. First use of flavored any cigars (aPR, 1.56; 95% CI; 1.29, 1.87), cigarillos (aPR, 1.29; 95% CI: 1.01, 1.64), and filtered cigars (aPR, 1.79; 95% CI: 1.24-2.54) at Wave 1 were prospectively associated with greater likelihood of current regular use (some or every day use) of those products at Wave 2 compared to first use with nonflavored products. Moreover, first use of any flavored cigar product was positively associated with all measures of subsequent cigar use at Wave 2, including past 12-month use; past 30-day use; use on 6 or more days in the past 30 days; use on 20 or more days in the past 30 days; daily use; and current regular use. Adults who initiated with a flavored cigar were 56% more likely than those who initiated with a nonflavored cigar to be a current regular cigar user one year later, after controlling for demographics, education, income, age at first tobacco use, substance use (including alcohol and marijuana use), and mental health indicators (Villanti et al., 2019). Keeping in mind that most first tobacco use occurs during youth or young adulthood, this nationally representative estimate suggests that if flavored cigar smokers had initiated with nonflavored cigars instead, they would have been 35.9% (1 – 1/1.56) less likely to progress to regular use of cigars as adults. One limitation of this study is the one-year time frame for progression to regular use to occur, as such progression may occur over a longer time period (U.S. Department of Health and Human Services, 2012). In addition, tobacco product use, and particularly first flavored used, is based on the respondent's ability to recall whether past or current products were flavored, introducing the possibility for recall bias and errors (Villanti et al., 2019).

In a separate study using Waves 1-4 (2013-2017) of PATH Study data, Villanti et al. (2021) examined whether new users of cigars who first used a flavored cigar were more likely to use cigars one or more years later (i.e., in later PATH Waves) compared to new users who first used a nonflavored cigar. The authors defined new users of cigars as youth, young adults, and adults who reported trying the product for the first time between any adjacent wave (e.g., never use at Wave 1 and new use at Wave 2). Following new use at either Wave 2 or 3, current use was assessed in multiple ways at either Wave 3 or 4, respectively (i.e., past 30-day use, moderate use, frequent use, daily use, and current regular use). The authors assessed whether the first use of a cigar was flavored by asking if the cigar was "flavored to taste like menthol, mint, clove, spice, candy, fruit, chocolate, alcohol (such as wine or cognac), or other sweets." Respondents were then asked to respond "yes/no/I don't know" to the following flavor options: "Menthol or mint," "Clover or spice," "Fruit," "Chocolate," "An alcoholic drink (such as wine, cognac, margarita or other cocktails)," "Candy or other sweets," or "Some other flavor." Cigar smokers that reported using "Menthol or mint" were categorized as menthol or mint cigar smokers. Cigar smokers reporting one or more of the flavor options, other than "menthol or mint," were categorized as "other flavored" cigar smokers. The authors used modified Poisson regression models to estimate the association between first flavored cigar use at Waves 2 or 3 and current cigar use at the subsequent wave (Villanti et al., 2021).

Among youth, the first use of a menthol or mint or other flavored cigar at Wave 2 or Wave 3 was associated with a significantly higher prevalence of past 30-day any cigar use at a subsequent wave compared to first use of a nonflavored cigar (menthol or mint: aPR 1.72; 95% CI: 1.13, 2.62; other flavor: aPR 1.47; 95% CI: 1.09, 1.99). Examining cigar types separately, youth who first used a menthol or mint-flavored cigarillo had more than double the prevalence of subsequent past 30-day cigarillo use compared with those who first used a nonflavored cigarillo (aPR 2.25; 95% CI: 1.31, 3.85). Youth who first used a cigarillo flavor other than menthol or mint also had a significantly higher prevalence of past 30-day cigarillo use compared to those who first used a nonflavored cigarillo (aPR 1.58; 95% CI: 1.02, 2.43). The sample sizes for the other types of cigars were too small to generate precise and reliable estimates. Neither the first use of a menthol or mint or other flavored cigar was associated with the likelihood of past 12-month cigar use at a subsequent wave (Villanti et al., 2021).

Among young adults, those who first used a menthol or mint or other flavored cigar had a significantly higher prevalence of past 30-day cigar use at a subsequent wave compared to first use of a nonflavored cigar (menthol or mint: aPR 1.71; 95% CI: 1.10, 2.67; other flavor: aPR 1.52; 95% CI: 1.13, 2.06). Those who first used an other flavored cigar also had a significantly higher prevalence of past 12-month cigar use (aPR 1.45; 95% CI: 1.19, 1.77). Examining cigar subtypes separately, first use of a menthol or mint-flavored cigarillo and first use of a cigarillo in another flavor were associated with greater likelihood of past 12-month cigarillo use compared with first use of a nonflavored cigarillo (menthol or mint: aPR 1.78; 95% CI: 1.11, 2.85; other flavor: aPR 1.47; 95% CI: 1.01, 2.14). The first flavor used for traditional and filtered cigars was not associated with the likelihood of cigar use at subsequent waves. Sample sizes for past-30-day use of each cigar subtype were too small to generate estimates (Villanti et al., 2021).

Among adults, the first use of a flavored cigar other than menthol or mint was associated with greater likelihood of both past 30-day and past 12-month cigar use at subsequent waves compared to first use of a nonflavored cigar (past 30 days: aPR 1.78; 95% CI: 1.35, 2.33; past 12 months: aPR 1.55; 95% CI: 1.28, 1.87). First use of a menthol or mint cigar was not associated with subsequent cigar use. Examining cigar subtypes separately, first use of a traditional cigar flavored other than menthol or mint was associated with subsequent past 30-day use (aPR 2.03; 95% CI: 1.31, 3.14) and past 12-month use (aPR 1.74; 95% CI: 1.27, 2.39). For cigarillos and filtered cigars, the first flavor used was not associated with the likelihood of cigar use at subsequent waves (Villanti et al., 2021).

This study extends findings from the previous study (Villanti et al., 2019) showing that, among youth and young adults, first use of any menthol or mint-flavored or other (e.g., fruit, alcohol, chocolate, candy, and other flavor) flavored cigar is associated with greater likelihood of past 30-day use of these products at a subsequent wave compared with individuals who first used a nonflavored cigar, even after controlling for sociodemographic variables (Villanti et al., 2021).

Of note, youth had the highest proportion of “I don’t know” responses regarding first flavored used, potentially suggesting that youth may have difficulty recalling the flavored product they recently used or may be less able to distinguish concept flavors from explicit flavor names. Further, the study relied on self-reported recall of flavor use over the past year. Although such methods may introduce recall bias, in contrast to the authors’ Wave 1-Wave 2 analysis of first flavored use (Villanti et al., 2019), this analysis relied on more recent flavored product recall and found similar associations between young adult and adult first flavored use and subsequent use, as well as a new association among youth first menthol or mint-flavored cigar use, as well as other flavored cigar use and subsequent cigar use.

Abuse Liability of Flavored Tobacco Products

Clinical studies have found that cigar flavors can influence product abuse liability[7] which may contribute to the associations observed in the population studies described above between first use of a flavored cigar and subsequent progression to regular use. A recent study used several behavioral economics purchase and choice tasks to examine and compare the abuse liability of four different flavors of Black & Mild cigars (original, cream, wine, and apple) and participants' usual brand cigarettes (Bono et al., 2020). Participants included 25 adults aged 18 to 24 who currently smoked cigarettes and were relatively cigar-naïve (≤10 cigars in the last month or ≤50 lifetime cigars). In a drug purchase task that was intended to measure abuse liability of the different tobacco products, participants chose between receiving ten puffs of each product or varying amounts of money. In these relatively cigar-naïve participants, usual brand cigarettes had higher relative abuse liability compared to the cigars tested. However, in a cross-purchase task, all four tested cigar flavors were selected as a substitute for usual brand cigarettes, suggesting young adult cigarette smokers are willing to use flavored cigars. They also found that abuse liability can differ with cigar flavor, with cream-flavored cigars having higher abuse liability than the other flavors (Bono et al., 2020).

Research on the abuse liability associated with specific characterizing flavors in tobacco products relative to others is limited. However, one study reported that exhaled carbon monoxide after smoking cherry flavored little cigars was higher than after smoking combusted cigarettes (Cunningham et al., 2019). Cherry flavored little cigars were also associated with higher subjective effects ratings, such as reported liking and satisfaction, compared to the ratings for the unflavored or menthol flavored little cigars (Cunningham et al., 2019). These data indicate that characterizing flavors may be associated with increased abuse liability and subsequent toxicant exposure from little cigars, though characterizing flavor was not the only characteristic different between the tested little cigars (e.g., different cigar brands were used), which may have influenced findings.

A mechanism that may be involved in increased reward and susceptibility with flavored tobacco products is elucidated through animal studies. In one study, the authors found that nicotine can acquire additional reinforcing properties through associations with other rewards, such as flavors. This ability to acquire additional reinforcing properties through associative learning may contribute to the development and perpetuation of tobacco use disorder (Charntikov et al., 2020). These recent findings extend those by Palmatier and colleagues (2013), who used a different animal model to show that nicotine can also increase the rewarding and reinforcing effects of flavors. The authors suggest "the addition of taste incentives to tobacco may increase the attractiveness of these products and the probability of continued use" (Palmatier et al., 2013). Palmatier and colleagues (2020) also found that flavors can enhance the reinforcing effects of low nicotine doses in rodents; the authors suggest this effect may influence nicotine dependence. While flavors can activate the brain's reward circuit and produce rewarding effects on their own (Touzani et al., 2010), these finding suggest that flavors and

[7] See FDA Guidance: "Assessment of Abuse Potential of Drugs Guidance for Industry" accessible at https://www.fda.gov/media/116739/download. Drug abuse is defined as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect. Therefore, abuse potential refers to the likelihood that abuse will occur with a particular drug product or substance with central nervous system activity. Desired psychological effects can include euphoria, hallucinations and other perceptual distortions, alterations in cognition, and changes in mood.

nicotine can interact to enhance the reinforcing effects of nicotine (Charntikov et al., 2020; Palmatier et al., 2013; Palmatier et al., 2020).

Population-based studies provide additional evidence of the abuse liability of flavored cigars. An analysis from the 2014-2015 Tobacco Use Supplement to the Current Population Study (TUS-CPS), a large (n=163,920) household-based cross-sectional survey of United States adults aged ≥18 years found that among current cigar users, use of flavored cigars was associated with higher levels of nicotine dependence than use of unflavored cigars (Odani, Armour, & Agaku, 2020). Flavored cigar use among adults was associated with greater odds of daily cigar smoking (aOR: 1.42; 95% CI: 1.07, 2.42) and greater odds of smoking cigars within 30 minutes upon waking (aOR: 1.80; 95% CI: 1.39, 2.76) compared to the use of non-flavored cigars, after adjusting for age, sex, race/ethnicity and multiple tobacco product use (Odani et al., 2020). In a similar analysis using 2019-2020 NYTS data, use of one or more flavored tobacco products, including menthol, during the past 30 days was associated with higher odds of reporting strong cravings (OR: 1.8; 95% CI: 1.4, 2.2) and desire to use tobacco within 30 minutes of waking (OR: 1.6; 95% CI: 1.2, 2.1) compared to use of an unflavored tobacco product (NYTS Dependence Memo).

Evidence on Developing Nicotine Dependence During Tobacco Product Experimentation

Experimentation with cigars can lead to regular use and nicotine dependence. The process of becoming a regular cigar smoker includes stages of experimentation, development of symptoms of tobacco-use dependence, and progression to regular use (Leventhal & Cleary, 1980; Flay, 1993). Cantrell et al. (2022) examined the progression from experimentation to regular cigar use in a recent study. Using recent data from the nationally representative Truth Longitudinal Cohort over a five year period (2014-2019), the authors examined cigar use progression among youth and young adults (15-25 years) who had newly initiated cigars. The analysis found that the youth and young adults had a 42% probability of becoming a current past 30-day user of cigars within six months of first reporting ever cigar use (Cantrell et al. 2022). The youth and young adults who were current past 30-day cigar users six months after initiation engaged in a higher frequency of cigar use during the 6-month period than those who were not past 30-day users at 6 months. The likelihood of transition to current past 30-day cigar use declined after six months had passed since initiation, suggesting a period of experimentation during which longer term use patterns solidify. After the decline six months past initiation, the analysis found a stabilization of use, suggesting continued risk of transitioning to regular, more frequent cigar use among some current users. Individuals who were younger, non-Hispanic Black, and who currently used other tobacco products were at highest risk of being a past-30-day cigar user within 6 months of cigar initiation (Cantrell et al., 2022).

Studies illustrate the potential to develop nicotine dependence symptoms while experimenting with cigars. The U.S. Surgeon General has noted that symptoms of nicotine dependence in cigar smokers could result from even a limited exposure to nicotine during adolescence (U.S. Department of Health and Human Services, 2010). Researchers analyzing NYTS data found that, although the percentage of middle and high school students reporting various measures of dependence was lower for cigars than for cigarettes or smokeless tobacco, youth cigar smokers demonstrated indicators of nicotine dependence (Apelberg et al., 2014). For example, 6.7% of middle and high school students who only smoked cigars reported strong cravings for a tobacco product during the past 30 days, and 7.8% reported “sometimes/ often/ always” feeling irritable or restless when not using tobacco for a while (Apelberg et al., 2014). More recently, researchers analyzing NYTS data from 2017-2018 found that

43.1% of middle and high school students using cigars in the past 30 days reported nicotine dependence symptoms, including feeling a strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Gomez et al., 2020). Current and frequent cigar use (use on 20 days or more), as well as exclusive and polyuse use of cigars were all associated with increased odds of reporting indicators of nicotine dependence (Gomez et al., 2020). However, the use of cigars exclusively was associated with lower odds of reporting dependence symptoms compared to exclusive use of another product (Gomez et al., 2020).

The use of cigars alongside other tobacco products is common (e.g., Cohn, Cobb, Niaura, & Richardson, 2015; Sterling, Masyn, Pike Moore, et al., 2021) and may further increase levels of tobacco dependence. In adults, an analysis of tobacco dependence symptoms among daily cigarette, cigar, and e-cigarette users in the United States, using data from the 2012-2013 NATS, found that compared to cigarette-only smokers, dual cigarette and cigar smokers exhibited greater dependence symptoms, with a higher average number of cigarettes smoked per day (17.3, 95% CI: 16.1, 18.6 vs. 15.8, 95% CI: 15.4, 16.2), shorter times to first tobacco use after waking (21.4 minutes, 95% CI: 16.6, 24.9 vs. 25.9 minutes, 95% CI: 25.3, 26.5), and more frequent reporting of withdrawal and craving symptoms compared to exclusive cigarette smokers (Rostron, Schroeder, & Ambrose, 2016). In addition, data from Wave 1 of the PATH Study demonstrates that high nicotine dependence is two to three times more likely among poly users compared to dual and single product users (Strong et al., 2017).

Data from the 2012 and 2019-2020 NYTS also noted that reports of dependence symptoms were consistently associated with polyuse (Apelberg et al., 2014; NYTS Dependence Memo). In the analysis of 2017-2018 NYTS data, use of cigars in combination with other tobacco products was common, with 76.1% of youth past 30-day cigar users reporting use of cigars in combination with one or two additional tobacco products (Gomez et al., 2020). Cigarettes and e-cigarettes were the most common products used alongside cigars (Gomez et al., 2020). When youth cigar use included multiple product use, current cigar use was associated with twice the odds of nicotine dependence (Gomez et al. 2020). Given the role of frequent use and polyuse in the relationship between cigar use among youth and dependence, as well as the finding that multiple product use among youth cigar users is common, the authors note "… the importance of examining behaviors related to use, as they can affect and/or exacerbate the risk of nicotine dependence" (Gomez et al., 2020).

In regard to dependence, several studies found that cigars reduce craving and the urge to smoke to a similar magnitude as cigarettes (Koszowski et al., 2015; Pickworth et al., 2017; Rosenberry et al., 2018). Cigars have also been shown to decrease acute nicotine withdrawal symptoms (e.g., craving, anxiousness; Blank et al., 2016). Available scientific data on nicotine's addictiveness demonstrate that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain (U.S. Department of Health and Human Services, 2012). Exposure to nicotine can disrupt brain development and may lead to long-term consequences for cognitive function (Chamberlain et al., 2012; Chen et al., 2013). Exposure to nicotine from cigarette smoking in adolescence, even light use, is associated with changes in the brain that could increase the likelihood for addiction and dependence as adults (England et al., 2017). Furthermore, nicotine exposure in adolescence may have lasting implications and has been associated with decreased attention, increased impulsivity, and various lasting mental health issues in adult smokers (England et al., 2017). Currently available research methods preclude fully disentangling whether the association of nicotine with changes in attention and impulsivity are primarily a result of nicotine exposure or partially due to pre-existing vulnerabilities (England et al., 2017; i.e., confounding by unmeasured co-occurring factors, as has been observed in the relation between prenatal cigarette

smoking and ADHD in offspring; Skoglund, Chen, D' Onofrio, Lichtenstein, & Larsson, 2014). However, considerable research does show that exposure to nicotine in adolescence causes long-term changes in the brain, with implications for nicotine dependence, attention, and impulsivity, as well as other areas of cognitive function and substance use (England et al., 2017; U.S. Department of Health and Human Services, 2012).

Hypothetical Scenario studies

Several studies have assessed participants' self-reported reactions to hypothetical scenarios, such as hypothetical policies that restricted flavored tobacco products. In one non-peer-reviewed study, 40 Black young adults (aged 21-29) who were current cigar users reported what they would do if the sale of flavored cigars was restricted (Pakdaman et al., 2021). Approximately half of regular premium cigar and cigarillo users said they would stop or cut down on using them, citing flavors as a key reason for use. The other half predicted they would either smoke unflavored cigars or transition to other tobacco products (Pakdaman et al., 2021). In another non-peer-reviewed study, young adults aged 21-28 who were current cigarillo users were asked whether they would substitute with menthol cigarettes if flavored cigarillos were not available. Whereas 14.3% of cigarillo users who were also current menthol cigarette users said they would switch to menthol cigarettes, only 3.3% of non-current menthol cigarette users would (Trapl et al., 2021). Another study identified the reverse substitution pattern; as the price of menthol cigarettes increased in a series of experimental purchase tasks, demand for menthol little cigars and cigarillos among participants increased (Denlinger-Apte et al., 2021), suggesting participants are willing to switch between menthol cigars and cigarettes when necessary. Finally, one survey asked youth and young adults who had used flavored tobacco products in the past 30 days whether they would continue using their product if it was not flavored (Harrell, Loukas, Jackson, et al., 2017). Among youth (aged 12-17) cigar users, 80.5% said they would no longer use them, and 54.9% of young adult (aged 18-29) cigar users reported they would no longer use cigars if they were not flavored (Harrell et al., 2017).

Together, these results reinforce other evidence that flavors are a leading reason for the use of cigars, and if flavors were removed, many cigar users would either stop using tobacco products or switch to a different flavored product. However, results from studies that examine the effects of hypothetical scenarios and/or assess participants predictions about their future behavioral intentions have limited external validity and should be interpreted with caution. People tend to be inaccurate in their predictions about their future behavior, as evidenced in Canada following their national ban on menthol cigarettes where only 39% of menthol cigarette users who had predicted they would switch to another flavored tobacco product had actually switched one year later (Chaiton et al., 2020). Thus, the epidemiological evidence of real-world patterns of cigar use and responses to flavored tobacco restrictions in local jurisdictions that is reported elsewhere in this Scientific Assessment are considered stronger and more generalizable sources of evidence.

Summary and Conclusion

We conclude that characterizing flavors in cigars are associated with increased likelihood of youth and young adult experimentation, as well as progression to more regular patterns of use. Qualitative studies indicate that young people themselves acknowledge that flavor impacts their cigar use, particularly first cigar use. An analysis using nationally representative longitudinal data found that youth and young adults that first used a flavored cigar were more likely to progress to regular cigar use

compared to youth and young adults that first used a non-flavored cigar. This association was consistent with a previous study of earlier data from the same cohort that found young adults and adults first using a flavored cigar were more likely to be using a cigar one year later.

Clinical and population studies consistently find that flavors in cigars are associated with increased measures of abuse liability and dependence, potentially through a mechanism examined in animal studies where flavors activate the brain's reward circuit and produce rewarding effects on their own and by enhancing the reinforcing effects of nicotine. They also illustrate that experimentation with cigars can lead to regular use and nicotine dependence.

Adolescence is a critical developmental period for tobacco use experimentation. Studies indicate this is both the age period when most tobacco initiation occurs and also a vulnerable developmental period during which nicotine exposure can disrupt brain development and lead to longer-term health consequences. Given that nicotine is highly addictive and present in all cigars, as youth experiment with these products, there is a risk of developing nicotine dependence and progressing to regular use, especially when frequency of use and polyuse are considered. These trajectories result in an increased risk of developing the many negative health consequences associated with regular cigar use.

Question 3: What Impact Do Local Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products Have on Cigar Sales and Use?

Local and National Policy Evaluation Studies

Jurisdictions across the United States have implemented policies to restrict the sale of flavored tobacco products. These sales restriction policies vary in many ways, in terms of which tobacco products are covered by the policy, which flavors are covered by the policy, where the sales restriction applies and does not apply, and the extent of education and enforcement. See Table in **Appendix 6** for a summary of local policy evaluation studies of sales restrictions including flavored cigars and a description of the policy (i.e., restricted tobacco products, excluded products, excluded flavors, retailer exemptions, effective and/or enforcement date). Examination of the impact of these policies on tobacco use behavior can inform an assessment of the potential impact of a national prohibition of characterizing flavors in cigars. The evaluations of each of these localities are discussed in more detail below.

New York, New York

In 2009, New York City enacted a policy prohibiting the sale of all flavored non-cigarette tobacco products (e.g., cigars, cigarillos, little cigars, chew, snuff, snus, tobacco, pipe tobacco, roll-your-own (RYO) tobacco, and dissolvables), except in legally permitted tobacco bars. Products with the taste or aroma of menthol, mint, or wintergreen including menthol cigarettes were excluded from the policy. E-cigarettes were also excluded from the policy. The policy was effective July 2010 and enforcement began in November 2010.

Farley and Johns (2017) conducted an evaluation of New York City's tobacco sales restriction of flavored non-cigarette tobacco products using (1) an interrupted time series analysis of changes in flavored and non-flavored cigars, smokeless tobacco, and pipe and RYO sales, adjusted for inflation, before and after the sales restriction, and (2) a cross-sectional analysis of changes in youth (13-17 years) ever use of flavored tobacco products, any tobacco product use, and smoking prevalence before and after the sales restriction. The authors used a pre- post-design without a comparison jurisdiction. The authors categorized flavored tobacco products based on the product description listed with the Universal Product Code (UPC). All flavored descriptors except menthol, wintergreen, or mint-flavored were categorized as flavored tobacco products (e.g., fruit, candy, alcohol). All other descriptors were categorized as non-flavored tobacco products, including menthol, wintergreen, and mint-flavored products. Sales data came from a non-random sample of 922 unique stores (range of 736 stores in 2008 to 868 stores in 2012) with annual sales of over U.S. $2 million. Following policy enforcement, sales of flavored tobacco products declined overall (87%; $p<0.001$), and for flavored cigars (86%; $p<0.001$) and flavored pipe and RYO (91%; $p<0.001$). Sales of non-flavored tobacco products overall showed a non-significant increase following enforcement of the New York City policy (18%, $p=0.066$). Sales of non-flavored, including menthol, wintergreen, and mint cigars, as well as pipe and RYO both demonstrated significant increases of 5% ($p=0.003$) and 4% ($p=0.030$), respectively.

Data from the 2010 and 2013 Youth Risk Behavior Survey (YRBS), a probability-based cross-sectional self-administered survey representative of New York City public high school students, were used to examine changes in youth tobacco use. Students that used cigars/cigarillos in the past 30 days were asked about ever flavored tobacco product use in 2010 with the following item: "'Have you ever

tried any flavoured tobacco products, such as chocolate, candy, fruit, cinnamon, or alcohol-flavoured cigarettes, cigars, blunts, chewing tobacco, snus, snuff, dip, or dissolvable tobacco pellets?" The item was modified in 2013 to the following" "Have you ever tried any flavoured tobacco products such as chocolate, candy, fruit, cinnamon, or alcohol-flavoured cigarettes or cigars?" In adjusted models, youth in 2013, which was after policy enforcement, had 37% lower odds of ever trying flavored tobacco products compared to youth in 2010, which was before policy enforcement ($p<0.001$). Youth in 2013 also had 28% lower odds of using any type of tobacco product ($p=0.025$) compared with youth in 2010. Limitations of the evaluation include: the non-random store sample for sales data, which did not include small, independent stores – the predominant tobacco retailers in New York City; the inability to capture Native American reservation and black market sales; challenges in correctly classifying flavored vs. non-flavored tobacco products using available product name descriptors; the inability to draw causal conclusions from cross-sectional YRBS data; and wording changes in the YRBS between 2010 and 2013, and possible misinterpretation of flavored tobacco questions. Additionally, the observed declines in sales and youth tobacco use attributed to the policy may be limited if declines are also occurring in other non-policy jurisdictions (Farley & Johns, 2017).

Rogers et al. (2017) examined the impact of New York City's policy restricting the sale of non-cigarette flavored tobacco products on tobacco product sales. The authors used Nielsen retail scanner four-week data from January 2010 to January 2014 to assess changes in sales of flavored cigars, flavored smokeless tobacco, and flavored loose tobacco (roll-your-own, RYO), in New York City and in a proximal comparison area before and after policy implementation. Changes in total cigars (both flavored and non-flavored) before and after policy implementation were also assessed. The proximal comparison area consisted of ten non-New York City counties surrounding the city, where retailers were not subject to the New York City sales restriction. The authors categorized flavored tobacco products based on the Universal Product Code (UPC) product description. They coded tobacco products as flavored consistent with the NYC policy's definition of a flavored tobacco product, including concept flavors (e.g., "Blue Haze") and including mint, menthol, or wintergreen flavored tobacco products in the non-flavored tobacco product category. In New York City, sales of all flavored tobacco products combined (-27.1%), and sales of flavored cigars (-22.3%), flavored smokeless tobacco (-97.6%), and flavored RYO (-42.5%) declined at policy implementation. Policy implementation was associated with an immediate significant 11.6% decrease in total cigar sales in New York City ($p<0.05$); a non-significant 6.4% decrease was observed in the comparison area and a non-significant 2.1% increase in sales was observed nationally. Average sales of all cigars in New York City decreased by 7.4% ($p<0.01$) from pre- to post-policy while average sales of all cigars increased 9.8% ($p<0.01$) in the comparison area and 12% ($p\geq0.05$) nationally from pre- to post-policy. These data suggest that New York City consumers did not appear to substitute non-flavored cigars for flavored cigars. The authors conclude that there was little evidence of cross-border sales; a significant increase in unit sales of flavored products was not observed. Generalizability of these study findings is limited by the types of retailers included in Nielsen sales data. Nielsen uses proprietary methods to project sales from certain types of retail outlets. Therefore, these data do not include specialty stores such as vape stores, online sales, or retailers making less than $2 million in yearly sales.

The analyses by Farley and Johns (2017) and Rogers et al. (2017) illustrate consistent decreases in flavored cigar sales following the New York City restriction, but considerations should be noted. First, similar to other sales data studies, the use of sales data may serve as a reliable proxy for consumption, though it may not reflect sales from outside of the policy catchment area. The Farley and Johns (2017)

analyses of sales and youth cross-sectional prevalence data used a pre-and post-design without a comparison jurisdiction. Therefore, attributing observed declines in sales and youth use to the policy is limited if declines were also happening elsewhere. In contrast, the Rogers et al. (2017) study include use of comparison groups, which increases the internal validity of the study. Rogers et al. (2017) also included retail scanner data from a large sample of various retail outlets, including convenience stores, compared to the Farley and Johns (2017) analysis.

Unlike other products included in the ordinance that reached near-zero levels of sales around policy implementation, such as flavored smokeless tobacco products, Rogers et al. (2017) observed that flavored cigars declined, then trended upward during 2013. The authors note that flavored cigars specifically continued to be sold at persistently high levels in New York City in violation of the restriction. Therefore, similar to studies in other jurisdictions (e.g., Providence, below) an observed decline in sales following flavored cigar restrictions may underestimate the potential decline in cigar sales if the incomplete compliance attenuated the potential impact of the restriction. Challenges with compliance with the New York City policy have been reported. A study examining flavored tobacco product availability in New York City nearly 7 years after policy implementation found that 70.9% of retailers had policy-restricted explicit-named flavored tobacco products available for sale, and 69.3% of retailers had concept-named flavored products available for sale, highlighting the need for additional retailer education and enforcement efforts (Farley et al. 2020). Concept-flavored large cigars and cigarillos were available in 62.5% of establishments (58.4% sold explicit-flavored large cigars and cigarillos), and concept-flavored little cigars were available in 2.8% of establishments (3.5% sold explicit-flavored little cigars) (Farley et al., 2020). Additionally, a discarded cigar package survey conducted in New York City about 6 years after policy implementation found that 28.6% of all collected products had explicit or concept flavor names (Kurti et al., 2020). The availability of concept-flavored large cigars, cigarillos, and little cigars was greater in neighborhoods with higher proportions of Black residents and residents under age 18, and was also more likely when a high school was located nearby (Farley et al., 2020).

Lastly, despite utilizing a pre-post comparison of data from the large, cross-sectional school-based New York City Youth Risk Behavior Survey (YRBS), Farley and Johns (2017) youth analysis examined ever use of flavored tobacco and any tobacco use as outcomes and not cigar use specifically. Therefore, generalizability of these findings to changes in youth cigar use may be limited.

Providence, Rhode Island

In January 2013, Providence, Rhode Island implemented a restriction on the sale of all flavored non-cigarette tobacco products (cigars, smokeless tobacco, loose tobacco, and e-cigarettes with nicotine). Menthol, mint, and wintergreen flavors were exempt from this policy. Tobacco price discounting and multipack offers were also restricted.

Rogers et al. (2020) examined the effects of Providence, Rhode Island's flavored tobacco sales restriction using interrupted time series regression and Nielsen retail scanner data from January 2012 to December 2016 to assess weekly changes in unit sales of all flavored non-cigarette tobacco products and flavored cigars in Providence, Rhode Island and a comparison area consisting of all localities in the rest of the state of Rhode Island. The regression models provided estimates of the sales level at the point of implementation and rate of week-to-week change in the number of unit sales for each of the pre-policy and post-policy periods (2012 vs 2013 to 2016). The authors also assessed changes in unit sales of all non-cigarette tobacco products and all cigars (Rogers et al. 2020). The authors sub-categorized products with explicit flavor label names (e.g., Cherry, Wine) and with those labelled with

concept flavor names (e.g., “Jazz,” “Wild Rush”) using the descriptors provided for each Universal Product Code (UPC). The authors did not include menthol, mint, or wintergreen within the flavored tobacco product category for consistency with the Providence sales restriction.

The study found that in Providence, average weekly unit sales declined significantly from pre- to post-policy for all flavored non-cigarette products and for flavored cigars (both -51%, $p < 0.01$); in the rest of the state, average weekly unit sales of these increased (both by 10%, $p<0.01$) (Rogers et al., 2020). The decrease in sales of all flavored tobacco products from pre- to post-policy in Providence was driven by a decrease in sales of explicit flavored cigars; no change in sales of explicit flavored cigars was observed in rest of the state. However, average weekly unit sales of cigars labelled with concept flavor names increased significantly in both Providence and the rest of the state from pre- to post-policy (74% and 119%, respectively). Despite the increase in concept flavor-named cigar sales, overall flavored cigar sales still decreased from pre- to post-policy in Providence. The authors report some evidence of product substitution of tobacco-flavored cigars for flavored cigars following policy implementation; unit sales of tobacco-flavored cigars increased in Providence, while sales of tobacco-flavored cigars decreased in the rest of the state (11.3%, -19.5% respectively). The authors also note that the increase in share sales of flavored cigars (explicit and concept combined) from pre-policy to post-policy in the rest of state could suggest cross-border purchasing of flavored cigars by Providence consumers following policy implementation. Generalizability of these study findings is limited by the types of retailers included in Nielsen sales data; for example, these data do not include sales from tobacco specialty shops, groceries with small sales volume, vape shops, and online sources. The flavor categorization approach used in this study relied on interpretation of Nielsen provided product descriptors, manufacturer information, and online consumer comments, which may have resulted in misclassification of flavors. Furthermore, this study did not control for the effect of a Providence policy implemented in 2013 that prohibits price discounting and redemption of coupons for tobacco products.

Pearlman et al. (2019) evaluated the impact of Providence, Rhode Island’s flavored tobacco sales restriction using a cross sectional, pre-post study design with no comparison group. Self-reported data on adolescents’ current use of tobacco products were obtained from the 2012 (pre-policy) (N=2,150), 2016 (post-policy) (N=2,062), and 2018 (post-policy) (N=2,223) Annie E. Casey Evidence2Success Providence Youth Experience Survey (YES), which collects information in classrooms from all 10th and 12th grade students. The paper neither describes participation rates nor demographic composition of the sample, within or across years. In 2012, 3.2% (95% CI: 2.4, 4.0) of high school students reported having tried smoking cigarettes in the past 30 days. By 2016, that percentage had increased to 7.6% (95% CI: 6.3, 9.0), however, by 2018, it decreased to 3.0% (95% CI: 2.1, 3.8), only 0.2% less than pre-policy level. Between 2016 and 2018, the percentage of high school students who tried any tobacco product in the past 30 days declined significantly, from 22.2% (95% CI: 20.0, 24.3) to 12.1% (95% CI: 10.5, 13.7); cigars and cigarillos use decreased from 7.1% (95% CI: 5.7, 8.5) to 1.9% (95% CI: 1.2, 2.6); e-cigarettes use declined from 13.3% (95% CI: 11.4, 15.1) to 6.6% (95% CI: 5.3, 7.8); and hookah use decreased from 13.5% (95% CI: 11.6, 15.3) to 7.7% (95% CI: 6.4, 9.2). Retail availability and enforcement data also analyzed as part of this study suggest that rigorous retail education and compliance monitoring contributed to changes in tobacco use among youth, and despite this, concept-flavored tobacco products remained an issue post-policy. The proportion of stores having policy-restricted clearly labeled flavored tobacco products available for sale decreased from 41% in October 2017 to 17% in January 2018.

Limitations for the population health survey include that questions about tobacco products other than cigarettes were only asked in post-policy years (i.e., 2016 and 2018); and flavor-related data were not captured for any year. Additionally, post-policy data were for 3 and 5 years after the policy was implemented, thereby introducing possibility that contextual factors beyond the policy itself could have impacted behavior change. Furthermore, the flavor policy was implemented concurrently with restrictions on price promotions that could have impacted the findings. However, the findings of decreased youth use of cigars following the policy is consistent with findings of declining cigar sales data in Providence following policy implementation.

Lowell, Massachusetts

Kingsley et al. (2019) assessed the short-term impact of a flavored tobacco restriction in Lowell, Massachusetts (effective October 1, 2016), on flavored tobacco availability and youth perceptions/behaviors related to flavored tobacco use. Menthol, mint, and wintergreen flavors were exempt from the restriction. The authors used a pre-post design with a comparison community (Malden, MA) with no policy matched on demographics, retailer characteristics, and point-of-sale policies. Youth surveys were administered to public high school students in randomly selected classrooms in both communities at baseline (November 2016-January 2017 in Lowell, September 2016 in Malden) and follow-up (May 2017 in Lowell, April 2017 in Malden). Youth were asked in the survey to report each "non-flavored" (e.g., plain, tobacco, regular, menthol and mint) tobacco product (e.g., cigarettes, cigars, e-cigarettes) they ever used and each type they used at least once in the last 30 days, termed current use. Youth also reported their ever use and current use of "flavored" (e.g., grape, cherry, rum) types of each tobacco product.

Current youth use of any flavored tobacco products decreased 2.4% in Lowell from baseline to follow-up and increased 3.3% in the comparison community, resulting in a significant difference of -5.7% between the communities ($p=0.03$). Current youth use of any non-flavored, mint, wintergreen, or menthol flavored tobacco products decreased 1.9% in Lowell from baseline to follow-up and increased significantly in the comparison community by 4.3%, resulting in a significant difference of -6.2% between the communities ($p=0.01$). When considering the change in specific product use, ever use of flavored cigars and current use of flavored cigars decreased in Lowell and increased in the comparison community, though the changes were not statistically significant. In general, there were no statistically significant changes in youth use by specific tobacco products in Lowell, in the comparison community of Malden, or in the difference estimate between the communities when the models were adjusted for age, gender, and race/ethnicity. This study also found that the proportion of retailers with one or more flavored tobacco products available for sale decreased from 77.3% to 7.3% in Lowell and remained similar (76% to 78%) in the comparison community, suggesting a high degree of retailer compliance in Lowell. The authors concluded this was likely supported by the Massachusetts Tobacco Control Program's rigorous compliance and enforcement infrastructure that included multiple education visits and educational materials. Study limitations include the inability to draw causal relationships from cross-sectional survey data; the implementation of baseline surveys in Lowell 1-3 months after policy implementation, which may underestimate the effect of the policy on change in tobacco product use from baseline to follow-up in Lowell; difference in baseline data collection periods between the two communities, and limited sample sizes for some survey questions. Although limitations in the study design may limit attribution of youth use changes to the policy, this evaluation illustrates consistent

findings with other localities, including Providence and New York City, that found similar declines in flavored and non-flavored tobacco use after implementation of a flavor restriction.

Attleboro and Salem, Massachusetts

Kingsley et al. (2021) assessed the impact of flavored tobacco restrictions in Attleboro, MA (effective January 2016) and Salem, MA (effective March 2017) on access to, awareness, and use of tobacco among high school students, compared to the matched community of Gloucester (with no policy). Menthol, mint, and wintergreen flavors were exempt from the restrictions in Attleboro, MA and Salem, MA. Surveys were administered at baseline (December 2015) to students in randomly selected classrooms in the sole public high school in each municipality; and at follow-up (January/February 2018) to a census of students in each school (n=2000+ at both time periods). Youth that had used any tobacco product in a flavor other than mint or menthol in the past 30 days were classified as current users of flavored tobacco products. Three focus groups (one in each municipality) were also conducted in March and May 2019 with (purposely sampled) high school-aged students. Difference-in-difference multivariate linear probability models were used to analyze survey data. Increases in current use of flavored and non-flavored or menthol tobacco were observed from baseline to follow-up in all three municipalities, although increases from baseline to follow-up were significantly smaller in the municipalities with flavored tobacco restrictions than in the comparison (flavored tobacco use: −9.4%, 95% CI: −14.2%, −4.6%; non-flavored or mint- or menthol- tobacco product use: −6.3%, 95% CI: −10.8%, −1.8%). There were significantly smaller increases in current use of flavored e-cigarettes and flavored smokeless tobacco in both municipalities with flavored tobacco restrictions compared to the comparison. Based on focus group data, students in Attleboro reported visiting other localities outside their municipality more often than students in Salem and the comparison municipality. Students in municipalities with flavored tobacco restrictions agreed that it would be harder for a younger sibling or friend to get a flavored tobacco product in their municipality now compared to when they were that age. Study limitations include: awareness outcomes were collected only at follow-up; analyses did not control for multiple comparisons, so some significant outcomes may have emerged by chance alone; only one focus group was conducted in each municipality, so it is not clear whether thematic saturation was reached. A study examining the impact of flavored tobacco sales restrictions on flavored product availability in 38 Massachusetts communities, including Attleboro, found high compliance with flavored tobacco sales restrictions among tobacco retailers throughout Massachusetts (Kingsley et al. 2020). Kingsley et al. (2020) found reductions in the prevalence of policy affected retail outlets with flavored product availability ranging from 27.2% to 50.9%, adjusting for community-level characteristics. About 6 months to 1-year post-implementation, approximately 90% of retailers surveyed no longer carried flavored tobacco products. Additionally, a study examining local tobacco control policies in 42 municipalities in Massachusetts found that nearly 95% of stores with flavored tobacco advertisements were in municipalities without a flavored tobacco product sales restriction (Usidame et al., 2019).

Minneapolis and St. Paul, Minnesota

In 2016, the cities of Minneapolis and St. Paul, Minnesota implemented sales restrictions on flavored tobacco products (excluding mint, wintergreen, and menthol products). In 2018, both localities expanded the restrictions to include mint-, wintergreen- and menthol-flavored tobacco products (including e-cigarettes and menthol cigarettes). Olson et al. (2021) conducted an analysis of weekly retail

tobacco product sales at food/grocery, pharmacy, mass merchandiser, warehouse, and convenience stores from the Nielsen Company for Minneapolis and St. Paul compared to the rest of state between January 2015 – December 2019. The analysis used a single-group interrupted time series model and assessed the percent change before compared to after implementation of the sales restrictions on flavored tobacco products and menthol tobacco products compared to the rest of the state of Minnesota. The authors found significant decreases in sales of cigars overall and flavored cigars in Minneapolis and St. Paul after the flavor restrictions in 2018, including mint-, wintergreen- and menthol-flavored tobacco products compared to before the policies were in place in 2015. The authors did not see the relative magnitude of change in flavored cigar sales in the rest of the state during the same period. The analysis used retail scanner data that was limited to mainstream brick and mortar stores, and therefore, did not capture sales from tobacco product shops, vape shops, or internet stores.

Olson et al. (accepted publication), analyzed youth tobacco use prevalence in Minneapolis and St. Paul and compared it to the rest of the state of Minnesota using data from two cross-sectional surveys: the Minnesota Youth Tobacco Survey (MYTS) and the Minnesota Student Survey (MSS). The authors used MYTS data from students in grades 6-12 to estimate tobacco use before (2014) and after (2017) Minneapolis and St. Paul implemented flavor policies in 2016 that included all tobacco products, including ENDS but excluded menthol, mint, and wintergreen flavors. The authors used MSS data from students in grades 8, 9, and 11 to assess changes in tobacco use before (2016) and after (2019) the menthol policies were implemented in 2018. Using the MYTS data, the authors found that between 2014 and 2017 when the flavor restriction, excluding menthol, was implemented in 2016 on all tobacco products, the prevalence of tobacco product use overall and cigar use did not change in the Twin Cities among 6-12th graders; however, e-cigarette use increased 34.1%. In contrast, tobacco use prevalence, cigar use, and e-cigarette use increased in the rest of the state (+26.6%, +71.3%, and +114%, respectively). Using the MSS data, the authors found that between 2016 and 2019 when the flavor restriction also included menthol, tobacco use and e-cigarette use among students in grades 8, 9, and 11 increased in the Twin Cities; however, the increase was smaller than the rest of the state (34.6% vs. 44.6% tobacco use increase; 49.5% vs. 88.9% e-cigarette increase). Cigar use declined more in the Twin Cities compared to the rest of the state (-42.4% and -23.7%, respectively). Cigarette use decreased more in the Twin Cities relative to the rest of the state (-40.5% and -22.6%, respectively). Use of any menthol or mint tobacco product decreased in both areas (-5.9% Twin Cities and -15.7% rest of state), and flavored (non-menthol) use of non-cigarette tobacco products increased in both areas (+5% Twin Cities and +10.2% rest of state). Given the differences in survey items, timing of data collection, and inclusion of some counties not implementing flavor restrictions in the Twin City analyses, attributing observed prevalence changes to the polices may be limited. However, the observed stable and decreasing cigar use among youth across the surveys in the Twin Cities relative to the rest of the state is consistent with declining sales in cigars in Minnesota (Olson et al. 2021) and declining use of cigars in youth in Providence, Rhode Island (Pearlman et al. 2019), as well as in young adults in San Francisco (Yang et al. 2020) following their implementation of their flavor restrictions.

Findings from Olson et al. (2021) and Olson (accepted publication) are generally consistent with studies examining the availability of flavored tobacco products in Minnesotan cities, including Minneapolis and St. Paul, reporting high rates of retailer compliance with the policies (D'Silva et al., 2021; Brock et al., 2019; Bosma et al., 2021). For example, Brock et al. (2019) conducted observational retail assessments at a random sample of stores with tobacco licenses in Minneapolis and Saint Paul before and after policy implementation. The study found a reduction from 80.5% to 61.5% of stores in

Minneapolis that sold tobacco products with ambiguous flavor names. However, there was no substantial change in the availability of products with ambiguous flavor names in Saint Paul, nor notable differences between Minneapolis and Saint Paul compared to a nearby city used for comparison (Brock et al., 2019). Additionally, studies from Minnesotan cities including Minneapolis and St. Paul suggest that tobacco retailers in localities with flavored tobacco product sales restrictions are less likely to feature flavored marketing materials compared to localities with no flavored tobacco product sales restrictions (D'Silva et al., 2021; Brock et al., 2019).

San Francisco, California

In July 2018, San Francisco, California implemented a restriction on the sale of all flavored e-cigarettes (other than tobacco flavor), menthol cigarettes, and other non-tobacco flavored tobacco products with no retailer exemptions. The San Francisco Department of Public Health announced that enforcement would begin January 2019 and enforcement with routine retailer compliance inspections began April 2019 (Vyas et al., 2021).

Gammon et al. (2021) used an interrupted time series analysis to assess changes in unit sales of tobacco products in San Francisco and in two Californian cities without flavored tobacco sales restrictions (San Jose and San Diego). The authors used Nielsen retail scanner sales data from June 2015 through December 2019 and an interrupted time-series analysis to estimate within-city changes in average weekly unit sales of tobacco by comparing three time periods: prior to policy enactment (June 2015-July 2018), during policy enactment (July 2018-January 2019), and during policy enforcement (January 2019-December 2019). Using Nielsen's provided flavor descriptor, the authors categorized flavors as tobacco or unflavored, menthol or mint, other explicit flavor (e.g., cherry) or concept-named flavor (e.g., "magic puff"). The authors graphed trends in sales by tobacco product and flavor category for San Francisco and comparison cities using models that estimated a regression line for the three time periods. Average weekly sales of flavored tobacco products overall decreased 96% from pre-policy to enforcement period in San Francisco ($p<0.05$). Sales of menthol cigarettes, flavored cigars, flavored smokeless tobacco, and flavored ENDS all significantly decreased to low levels from pre-policy to enforcement period ($p<0.05$). In the comparison cities, average weekly sales of flavored tobacco products either decreased more modestly, yet still statistically significantly (e.g., 10% for all flavored products and 13% for flavored cigars in San Diego), or did not significantly change from pre-policy to enforcement period with the exception of ENDS, which increased in both comparison cities (by 195% in San Jose and 118% in San Diego) and for smokeless tobacco which increased by 3% in San Diego. Furthermore, average weekly total tobacco sales in San Francisco decreased 25% from pre-policy to enforcement ($p<0.05$), suggesting that there was not complete substitution of tobacco or unflavored products for flavored products. Additionally, the proportion of explicit flavored products and menthol or mint sales significantly decreased in San Francisco (from 6.9% to 0.3% and from 26.5% to 1.1%, respectively) but significantly increased in San Jose and San Diego. The proportion of concept-named flavored product sales decreased for San Francisco and San Jose from the pre-policy to enforcement periods and did not change for San Diego; this result differed from the evaluations of New York City and Providence, where increases in sales of concept-flavored cigars were found. Similar to other sales data analyses, generalizability of these findings is limited by the types of retailers included in Nielsen sales data. These data do not include online retailers or small stores, including small local retailers and specialty tobacco shops. If sales of flavored cigars in these venues differed from larger retailers captured in the Nielsen data, the findings may not reflect San Francisco as a whole.

Yang et al. (2020) evaluated the impact of San Francisco's flavored tobacco sales restriction on young adults' tobacco use behaviors. This was a retrospective study that collected data at only one point in time. Self-report data were collected from participants recruited via Amazon Mechanical Turk (MTurk) in November 2019, after the policy was implemented in January 2019. Inclusion criteria for participants (N=247, ages 18-24 n=62, ages 25-34 n=185) were: age 18–34 years; lived, worked or studied in the city of San Francisco from one month before the policy went into effect (December 2018) until the time of the survey (November 2019) without interruption; ever used any tobacco product including cigarettes, e-cigarettes, cigars, hookah/waterpipe, pipes, smokeless/dissolvable tobaccos from December 2018 until the time of the survey; and ≥90% approval rating from previous MTurk tasks.

Participants self-reported whether they had used a tobacco product at least once both before the policy (during December 2018) and currently (during the past 30 days) (in November 2019 at time of data collection), including any of the following products: cigarettes; e-cigarettes; cigars (including cigars, cigarillos, and little cigars); hookah/waterpipe; and/or smokeless/dissolvable tobacco. Participants were also asked whether each of the tobacco products that they previously or currently used were flavored or non-flavored. The specific flavors used other than menthol cigarettes were not captured by the survey. Participants were also asked how/where they typically obtained their tobacco products, and about their subjective reaction to the flavor policy (e.g., try to quit/reduce the use of tobacco product, was able/unable to quit/reduce use, stock up flavored products before the policy, buy flavored products from illegal sellers after the policy).

The prevalence of using any tobacco products decreased by 17.7% (95% CI: -27.5, -8.0; $p<0.01$) among the 18-24 age group and by 7.6% (95% CI: -11.4, -3.7; $p<0.01$) among the 25-34 age group. Overall cigar prevalence decreased among the 18-24 age group, but the change was not statistically significant. Flavored cigar use decreased by 12.9% (from 19.4% to 6.5%) (95% CI: 23.7, −2.1; $p<0.05$) among the 18-24 age group. No significant changes were detected for use prevalence of overall cigar or flavored cigar use among the 25-34 age group. The overall ENDS use prevalence decreased by 9.2% (from 60.0% to 50.7%) (95% CI: -15.4, -3.0; $p<0.01$) among 25-34-year-olds, whereas no significant change was seen among those aged 18-24. The prevalence of using flavored (including menthol; it is not clear from the article whether this includes tobacco-flavored) e-cigarettes decreased by 11.3% (from 56.2% to 48.1%) (95% CI: -22.7, 0.07; $p<0.1$) among those 18-24 years and by 8.1% (95% CI: -14.7, -5.0; $p< 0.05$) among those 25-34 years. Use of flavored (other than menthol and tobacco) e-cigarettes decreased among the 25-34 age group by 8.1% (95% CI: -13.5, -2.7; $p<0.01$), however, no significant change was observed among those 18-24 years old. Use prevalence of tobacco-flavored e-cigarettes decreased by 8.1% (95% CI: -16.4, 0.3; $p< 0.1$) among the 18-24 age group, and flavored (other than menthol and tobacco) e-cigarette use decreased by 8.1% (95% CI: -13.5, -2.7; $p<0.01$) among the 25-34 age group, and there was also a statistically significant decrease in dual use of e-cigarettes with cigars from 14.1% to 9.7% ($p<0.05$).

Overall, 19.8% of respondents reported that they quit using tobacco and another 14.2% reported that they reduced their tobacco use post-policy. However, participants were not asked which specific products they quit or reduced using post-policy. The study found some lapses in policy compliance and cross-border purchasing. For example, a small percentage of respondents reported purchasing flavored tobacco products in San Francisco (5.3%), purchasing flavored tobacco products online (15.4%), and purchasing flavored products outside of San Francisco (12.2%) post-policy. The proportions of e-cigarettes, cigarettes, and cigars obtained over the Internet or through the mail increased post-policy, and the proportions obtained from retailers outside of San Francisco increased

overall. However, the overall distribution was only significantly different for e-cigarettes (<0.001), not for cigarettes or cigars. Limitations include use of a relatively small convenience sample, and that the survey was conducted in November 2019 and required that participants recall behaviors from December 2018, thus participants may not have been able to precisely recall their past tobacco use patterns. Lastly, it is possible that contextual factors beyond the policy (e.g., 2019 E-cigarette or vaping use-associated lung injury outbreak) could have affected tobacco use behaviors. Despite these limitations, the San Francisco evaluation findings were consistent with other evaluation studies in Providence, Rhode Island; New York, New York; Lowell, Massachusetts; and Canada in regard to observed decreases in overall tobacco use after the policies took effect among young people.

Friedman (2021) estimated the association between San Francisco's sales restriction on flavored tobacco product sales and cigarette smoking among high school students younger than 18 years using data from the 2011-2019 Youth Risk Behavior Surveillance System (YRBSS) biennial school district surveys. Friedman (2021) used a pre-post design[8] with comparison to other school districts both within and beyond California, with consideration towards districts with response rates ≥60%. The data set yielded an analytic sample of 95,843 high school students with non-missing data on recent smoking. Difference-in-differences analyses found a significant increase in cigarette use among high school students after the policy was observed in the San Francisco school district relative to other school districts. Specifically, San Francisco's flavor ban was associated with two times the odds of recent smoking among high school students relative to concurrent changes in other districts (aOR: 2.24; 95% CI: 1.42, 3.53; p=.001). However, another study reported a methodological mistake with these findings: data collection for the 2019 YRBS in San Francisco occurred in Fall 2018, prior to when the San Francisco flavor restriction was enforced in April 2019 (Liu et al., 2022). Since data collection occurred before formal enforcement of the policy, findings from Friedman (2021) do not reflect the impact of the San Francisco flavored tobacco sales restriction on youth cigarette use.

Canada

Evaluations of a federal flavored tobacco policy in Canada reinforce trends observed in the U.S. with local flavored tobacco policies resulting in decreased cigar sales and use of cigars among young people. Chaiton et al. (2019) examined the association of the federal Canadian flavored tobacco regulation restricting the sale of flavor additives (except menthol) in cigarettes and all cigars under 1.4g (or in any cigar that had a filter or non-spiral wrap) with changes in cigar sales. The federal regulation was enacted on October 8, 2009. The authors used interrupted time series to examine trends in sales of flavored cigars during the 2004–2016 period, using equal periods of six years before and six years after enactment of the 2009 policy. The authors used seasonally corrected cigar wholesale data that is required to be reported by manufacturers to Health Canada under section 13 of the Government of Canada's Tobacco Reporting Regulations. This analysis also examined trends in flavor descriptors over this time period. Explicit flavor descriptors provided in the brand name were used to categorize the flavor status of cigar products into one of the following five categories: fruit, alcohol, cocktail, mint or menthol, or no flavor descriptor. Cigars with implicit or ambiguous flavor descriptors, such as colors, were categorized as not having flavor descriptors. The authors note that classifying flavored products

[8] While the author describes a pre-post design, Liu et al., 2022 found that the 2019 YRBS was conducted in Fall 2018 prior to when the flavor policy was enforced in April 2019 signifying it was a pre-only design.

based on the flavor descriptor and not based on the presence of flavorings or aromas means that the term "flavored" in this study refers to the descriptor on the product and not the additives.

The authors found that overall cigar sales decreased 49.6 million units (95 percent CI: -73.5, -25.8) and sales of flavored cigars decreased 59 million units (95% CI: -86.0, -32.4) in the quarter immediately following policy enactment (i.e., first quarter of 2010). Sales of cigars with no flavor descriptors increased 9.6 million units (95% CI: -1.3, 20.5) in the quarter immediately after policy implementation (i.e., first quarter of 2010). Sales of mint or menthol cigars, which were not included in the restriction, increased in the quarter immediately after policy enactment. Additionally, the study found an increase in sales of cigars with no flavor descriptors in the quarter immediately after policy enactment, although this increase was not significant. The level of increase in sales of unflavored cigars with no flavor descriptors (9.6 million units) in the quarter immediately after policy enactment did not offset the decrease in sales of cigars with flavor descriptors (59 million units), suggesting that complete substitution with cigars with no flavor descriptors did not occur after the policy was passed. It is important to note that the Ontario province enacted additional tobacco control legislation in 2010, which could have been driving overall changes observed. However, the authors conducted sensitivity analyses and found that the findings did not change, suggesting that the decreased sales can be attributed to the federal flavored tobacco policy rather than provincial initiatives. Lastly, sales of cigars that had color descriptors, but no flavor descriptors, increased after the policy. It is possible that some of the increases in sales of cigars with color descriptors were concept flavored products. The authors note that the wholesale data may not accurately represent total consumption in smaller provinces such as Prince Edward Island and other territories as wholesalers and retailers in small territories may receive their products from wholesalers in larger provinces.

Nguyen and Grootendorst (2015) analyzed data from the Canadian Tobacco Use Monitoring Survey (CTUMS) to study the effect of a 2010 Canadian ban on the sale of flavored cigarillos and implementation of a minimum pack size of 20 units of unflavored cigarillos. The study focused on self-reported use of cigarillos and overall use of cigars among Canadian youth. The analysis used annual CTUMS cycles from 2007 to 2011 and regression models to compare cigar use during the pre-policy period (January 2007–June 2010) to the post-policy period (July 2010–December 2011). The authors found that the ban on flavored cigarillos and implementation of the minimum pack size on unflavored cigarillos was associated with a statistically significant 2.3 percentage point decrease in past 30-day cigarillo use and a statistically significant 4.3 percentage point increase in past 30-day abstinence, defined as no cigar use in the prior 30 days among previous cigarillo users among young people aged 15 to 24 years. Cigarillo use declined in the older age group, 25 to 65 years, but the decline was not statistically significant. The study noted that there was some evidence of a small increase in use of cigars other than cigarillos or little cigars that were not included in the policy and the analysis did not distinguish flavored cigarillo from unflavored cigarillos (Nguyen & Grootendorst, 2015). Therefore, the findings may not apply to flavored cigarillo use specifically. Further, the analysis was not able to separate the effect of the minimum 20-unit restriction on unflavored cigarillos from the effect of the ban on flavored cigarillos.

Chaiton et al. (2020) examined product substitution following Ontario's sales restriction (effective January 1, 2017) on menthol in all tobacco products except cigars over 6 grams and electronic cigarettes (which are not classified as tobacco products in Canada). The authors used a pre-post study design without a control group. From September through December 2016, a convenience sample of smokers was recruited via email (n=772) using an existing registry, and by telephone (n=1026) through a

commercial list (total n=1798). Eligible participants were Ontario residents age 16+ who were current (past 30-day) cigarette smokers. Participants were contacted for follow-up from January 2018 (one year after the implementation of the policy) through August 30, 2018. Of the 1738 approached, 913 participants completed the follow-up survey. At baseline, participants were asked about menthol cigarette use and categorized as "daily menthol", "occasional menthol", or "non-menthol" smokers. At follow up, participants reported their use of menthol cigarettes as well as use of each type of other flavored or unflavored tobacco products, including cigars, pipes, smokeless (pinch, snuff, chew, snus), bidis, kreteks, hookah, e-cigarettes, or electronic vaping devices. The authors also assessed cigarette smoking quit attempts and continued abstinence at follow up. At follow up, 27% of follow up participants reported using menthol cigarettes since the beginning of the policy, with 0.3% among non-menthol users at baseline, 5% among occasional menthol users at baseline, and 22% among daily menthol users at baseline (p<.001). Daily and occasional menthol users at baseline were more likely to report a quit attempt (63% and 62% vs. 43%, p<.001) or not smoking (24% and 20% vs 14%; p = .014) than non-menthol users at baseline. Adjusted models showed that daily and occasional menthol cigarette smokers at baseline (vs. non-menthol smokers) were more likely to use flavored cigar products after the policy (adjusted relative risk (aRR): 1.53, 95% CI: 1.01, 2.31; aRR: 1.57, 95% CI: 1.06, 2.30). Occasional menthol cigarette smokers at baseline were more likely to use other tobacco products (aRR: 1.25, 95% CI: 1.02, 1.53) or flavored other tobacco products (aRR: 1.56, 95% CI: 1.09, 2.24) following the sales restriction. There was no significant difference in the post-policy use of flavored e-cigarettes among occasional menthol smokers at baseline. Study limitations include the use of a convenience sample limiting the generalizability of the findings; a lengthy follow-up period, which could affect temporal precedence; and the continued availability of untaxed tobacco from First Nations reserves in most areas in Ontario.

Chaiton et al. (2021) conducted a follow-up study in which they surveyed participants again two years after the ban. Results suggest people who had smoked menthol cigarettes at baseline and had not quit by the 1-year follow-up were less likely to have quit at the 2-year follow-up if they also reported having used another flavored tobacco product (e-cigarettes, cigars, smokeless, hookah, bidis, kreteks). This suggests use of flavored products may have influenced participants' ability to quit smoking, but the authors assessed all flavored products together, so it is not possible to examine the role of flavored cigars specifically (Chaiton et al., 2021).

Local and National Policy Evaluation Study Summary and Limitations

A recent scoping review by Rogers et al. (2021) identified studies of flavored tobacco sales policies implemented in the U.S. between 2010-2019. The authors included evaluation studies published up to May 2020, including most of the studies summarized in the current evidence synthesis. Based on the included studies, Rogers et al. (2021) concluded that there was moderate to high quality evidence on the impact of flavored tobacco policy restrictions on decreased tobacco product consumption and moderate quality evidence on the impact of restrictions on decreased tobacco use prevalence among youth. In assessing study quality, the authors noted that the large magnitude of effect sizes across the studies increased study quality while the inconsistent use of study designs with control groups, as well as imprecise and inconsistent outcome measurement were factors that reduced study quality. Rogers et al. (2021) did not include several studies published after they completed their search in May 2020 including studies included in this document that examined policy implementation and youth use (e.g., Hawkins et al., 2021; Kingsley et al., 2021; Olson et al., accepted publication). Rogers et al. (2021) also

did not include conference presentations or studies of policy in other countries (e.g., Chaiton et al., 2020; Nguyen & Grootendorst, 2015; Olson et al., 2021). Rogers et al. (2021) noted that including studies published after May 2020 or studies from other countries, such as Canada, may further strengthen the quality of evidence particularly on tobacco use prevalence among youth.

Limitations

Taken in totality, these studies of the impact of real-world restrictions on flavored tobacco products provide insight into the likely responses of youth, as well as current cigar smokers to flavored tobacco restrictions; however, we acknowledge there are limitations to the application of these findings. One limitation includes the timing of data collection on cigar use. Some of the evaluation studies rely on data collection only after the policy with retrospective recall of cigar use prior to policy implementation. Limitations also include a reliance on aggregate tobacco sales information as a proxy for consumption, rather than data concerning individual-level tobacco use behaviors. Study authors used cigar sales as a proxy for consumption, given that sales and consumption tend to be highly correlated. However, with sales data, there is a potential that smokers may obtain flavored products through alternate means (e.g., internet sales) that are captured in sales data from an affected jurisdiction. Alternatively, a number of noted studies utilized state or nationally representative surveys of youth and young adults to assess differences in tobacco use before and after policy implementation. Some of these studies were able to assess changes in cigar use specifically, while others assessed changes in overall tobacco use or flavored tobacco use more broadly.

Furthermore, the impact of flavored tobacco product sales restrictions depends on the level of enforcement and compliance with these policies. Several studies provide evidence of high rates of retailer compliance after policy implementation resulting in reduced availability of flavored tobacco products in policy affected stores in U.S. jurisdictions and in Canada (Andersen-Rodgers et al., 2021; Borland et al., 2017; Bosma et al., 2021; Brock et al., 2019; Brown, Rogers, Eggers, et al., 2019; D'Silva et al., 2021; Kephart et al., 2020; Kingsley et al., 2019; Kingsley et al., 2020; Pearlman et al., 2019; Timberlake, Rhee, Silver, Padon, Vos, Under, & Andersen-Rogers, 2021; Vyas et al., 2020). However, studies have also reported continued availability of flavored tobacco products after flavored tobacco product sales restriction. For example, Jo et al. (2015) found that 28.6% of U.S. internet cigarette vendors continued to sell flavored cigarettes after the 2009 U.S. federal ban on flavored cigarettes (excluding menthol). These findings support the need for additional and continued compliance and enforcement activities (Kurti et al., 2020; Farley et al., 2020; Czaplicki et al., 2019; Schroth et al., 2021).

Lastly, evaluations of local flavored tobacco product sales restriction policies likely under-estimate the potential effects of federal policies that would apply throughout the U.S. A flavored tobacco product standard, like the U.S. 2009 flavored cigarette ban, would apply to tobacco product manufacturers, importers, distributors, and retailers and be accompanied with strong enforcement at the federal level. This differs from local flavored tobacco product sales restrictions that have applied only to retailers and often included exemptions for specific types of retailers, such as adult-only establishments, liquor stores, retail stores for which most revenue is derived from tobacco sales, smoking/tobacco bars, and retail tobacco stores. Furthermore, federal policies as compared to state/local policies would minimize the potential for cross-border purchasing of restricted tobacco products from nearby jurisdictions where the products are not restricted.

Concept Flavors in Cigars

Following the implementation of the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009 that prohibited flavored cigarettes excluding menthol, several United States jurisdictions (e.g., New York City, New York; Chicago, Illinois; Providence, Rhode Island) further prohibited the sale of nonmenthol flavored tobacco products, including cigars (Public health Law Center, 2017). Subsequently, tobacco manufacturers introduced a variety of concept-flavored products – those with ambiguous names (e.g., "Jazz," "ba-boom," "purple," "tropical sunset") or characteristics, such as colors, that imply flavor but do not explicitly indicate any particular flavor in its labeling or packaging (Farley et al. 2020; Farley et al. 2018; Gammon et al. 2019). For example, people associate certain colors with certain flavors and flavor attributes, so package coloring is often used to convey flavor information implicitly (e.g., Delnevo, Jeong, Ganz, et al., 2021; Evans, Wilhelm, Abudayyeh, et al., 2020; Meernik, Ranney, Lazard, et al., 2018).

Chemical testing of non-cigarette concept-flavored tobacco products revealed flavor profiles similar to explicitly-flavored tobacco products. In most cases, the concept-flavored products contained more total flavor chemical levels than the lowest total levels found in explicitly-flavored products (Farley et al. 2018). Moreover, the descriptions manufacturers use for concept flavors are often explicitly focused on flavors. For example, "Jazz" is described as a "unique fruity" taste, "Golden" as "vanilla and nutty," "Royale" as "creamy, vanilla and mild flavored," "Tropical Fusion" as "pineapple and coconut flavored," "Spicy Hot" as "cinnamon-like," "Summer Blend" and "Dark Blend" as "citrus/raspberry," "Tropical Storm" and "Island Bash" as "watermelon/fruit punch," "Arctic Ice" as "icy mint," "Calypso" as "orange/cream/blueberry," and "Summer Twist" as "lemon/mango" (Viola et al. 2016). Combined with the trends in the tobacco retail market described below, these findings suggest that concept flavors are part of tobacco manufacturers' response to sales restrictions on flavored products. A retail marketing surveillance study conducted in 2015-2016 that examined cigar advertising in stores located near middle and high schools in California found that 34.2% of retail cigar advertisements contained ambiguous flavor descriptors, and 49.6% contained explicit flavor descriptors, suggesting ambiguous flavor descriptors are common in point-of-sale marketing, including near schools (ambiguous and explicit flavor descriptors were not mutually exclusive; an ad could have both types; Sterling, Vishwakarma, Ababseh, & Henriksen, 2021).

Sales data suggest that concept-flavored cigars have become an increasing share of the cigar market since the implementation of the Tobacco Control Act (Delnevo et al., 2017; Delnevo et al., 2021; Viola et al., 2016). Researchers analyzing Nielsen data trends found that the flavored cigar sales—including, for example, those the researchers defined as characterizing flavors such as chocolate, mint, or rum—increased substantially between 2009 and 2020 while non-flavored cigar sales did not change (Delnevo et al., 2021). In particular, sales of concept flavors (e.g., sweet, jazz) increased from 2.2 percent of U.S. flavored cigar sales in 2009 to 21.4 percent of U.S. flavored cigar sales in 2020, a 33 percent average annual percentage change (Delnevo et al., 2021).

Sales data suggest that a relatively large share of concept flavored cigar sales come from a small number of flavors and brands. In 2016, the top three selling brands for concept-flavored cigarillos accounted for 85% of all sales (Gammon et al., 2019). From 2012-2016, 9 flavors made up 94.7% of sales of concept flavored cigarillos: "Sweet," "Green Sweet," "Tropical," "Tropical Twist," "Wild Rush," "Tropical Fusion," "Island Bash," and "Topical Storm" (Gammon et al., 2019). There is also wide variability in the use of concept flavors across brands. Sterling et al. (2021) examined the content of retail cigar ads located near schools in California (observations conducted in 2015-2016). They found

that 15.9% of ads for Imperial Brands cigars included an ambiguous flavor descriptor, compared to 29.4% of ads for Swisher International cigars and 55.6% of ads for Altria cigars. In addition, whereas explicit flavor descriptors were more common than ambiguous descriptors for Swisher International and Imperial Brands, ambiguous descriptors were more common than explicit descriptors for Altria cigars (Sterling et al., 2021).

Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products and the Potential for Tobacco Product Substitution

As illustrated by evaluations of policies restricting flavored tobacco products, flavored cigar users may move to other tobacco products or available flavored products when one type of product or flavor is no longer available. One study in San Francisco (Friedman (2021)) reported an increase in cigarette smoking among high school students after the policy. However, another study reported a methodological mistake with this finding because the reported increase was based on data collected only prior to when the San Francisco flavor restriction was enforced in April 2019 (Liu et al., 2022). Furthermore, other evaluations of San Francisco's policy, sales data showed a decline in overall tobacco product and cigarette sales (Gammon et al., 2021) and a convenience sample of young adult tobacco users did not find a significant change in cigarette use following the policy (Yang et al. 2020). In addition, in other U.S. jurisdictions with similar flavor restrictions, studies found contrasting findings in youth use of cigarettes. For example, Olson et al. (accepted publication) found decreased cigarette smoking among youth in Minnesota following a similar policy prohibiting flavors in all tobacco products (including e-cigarettes). Furthermore, a study of local level restrictions across Massachusetts from 2011-2017 found that counties with greater proportions of county residents covered by local coverage of policies that limit the sale of flavored tobacco products (excluding menthol) were associated with a decrease in the number of days high school students smoked in the past 30 days and a decrease in the likelihood of their e-cigarette use (Hawkins et al., 2021).

In addition, there is possible evidence of substitution of tobacco products to retain flavored tobacco product use in Ontario, Canada following a 2017 menthol sales restriction (Chaiton et al., 2020) and in the U.S. following the 2009 U.S. federal ban on flavored cigarettes (excluding menthol) (Courtemanche et al., 2017; Rossheim et al., 2020) and following 2018 to 2020 changes in sales and enforcement prioritization of certain ENDS (Hammond et al., 2021; Morean et al., 2020; Wagoner et al., 2021).

There is also evidence from the United Kingdom and United States that tobacco manufacturers responded to bans on flavors, including menthol, in cigarettes by creating new flavored cigars that were not subject to the flavor restrictions (Branston, Hiscock, Silver, et al., 2021; Delnevo & Hrywna, 2015; Ganz, Hrywna, Schroth, & Delnevo, 2021; Silver & Hiscock, 2020). In the United States, Kretek International, a company that sold clove-flavored cigarettes, responded to the 2009 flavored cigarette ban by developing a clove cigar product that had a filler identical to their clove cigarettes (Delnevo & Hrywna, 2015). An analysis of data from the USDA Foreign Agricultural Service's Global Agriculture Trade System revealed tobacco imports of clove products to the United States from Indonesia shifted completely from clove cigarettes to cigars between 2006 and 2012 (Delnevo & Hrywna, 2015). Moreover, Nielsen's Convenience Track retail scanner data suggest unit sales of Kretek International's clove cigar brand increased from 444,192 units in 2009 to 6,750,665 units in 2012 (Delnevo & Hrywna, 2015).

One pre-post longitudinal cohort study reported on product substitution one year after Ontario's 2017 menthol sales restriction among a convenience sample of Ontario residents age 16+ who were current (past 30-day) cigarette smokers (n=913) (Chaiton et al. 2020). This study found that pre-policy occasional menthol smokers were more likely than pre-policy occasional non-menthol smokers to use flavored e-cigarettes (adjusted relative rate (aRR): 1.36, 95% CI: 0.88-2.11, p=0.172) after the ban. Additionally, relative to non-menthol cigarette smokers (n=306) at baseline, baseline menthol cigarette smokers (n=607) were more likely to use flavored cigar products after the policy (daily use: aRR: 1.53, 95% CI: 1.01, 2.31, p=.042; occasional use: aRR: 1.57, 95% CI: 1.06, 2.30, p=.023). Pre-policy occasional menthol smokers were more likely than pre-policy occasional non-menthol smokers to use flavored alternative tobacco products (i.e., e-cigarettes, cigars, smokeless, hookah, bidis, kreteks) (aRR: 1.56, 95% CI: 1.09, 2.24, p=0.016), or flavored e-cigarettes (aRR: 1.36, 95% CI: 0.88, 2.11, p=0.172) after the ban. Pre-policy daily menthol smokers were more likely than pre-policy daily non-menthol smokers to use flavored cigars after the ban (aRR: 1.53, 95% CI: 1.01, 2.31, p=0.042). Thirty-nine percent (n=23) of menthol smokers who at baseline predicted they would switch to another flavored tobacco product after the ban reported using flavored alternative products at follow-up.

Two studies examined the effect of the 2009 U.S. federal ban on flavored cigarettes (excluding menthol) (effective September 22, 2009) on youth tobacco use behaviors (Courtemanche et al., 2017; Rossheim et al., 2020). Courtemanche et al. (2017) used cross-sectional, nationally representative NYTS data from before the ban (data from 1999, 2000, 2002, 2004, 2006 and 2009, since the 2009 survey was administered before the ban took effect) and after it (data from 2011, 2012, 2013). They found the percent of students who reported smoking cigarettes in the past 30 days decreased by 34% from 14.0% during the pre-ban period to 9.3% post-ban period (p=0.003). In addition, the percent who reported any tobacco use (i.e., cigarette, cigar, smokeless tobacco, or pipe) in the past 30 days decreased by 19.6 percentage points, from 17.9% pre-ban to 14.4% post-ban (p=0.011). Adjusting for demographic variables, national-level tax inclusive price indices for cigarettes and non-cigarette tobacco products, youth unemployment rate, and time trends, banning flavored cigarettes was associated with a 17.1% reduction in the probability of youth being a cigarette smoker (OR: 0.829, SE: 0.0202; p<0.001) and a 6.1% reduction in the probability of youth reporting any tobacco use (i.e., cigarette, cigars, smokeless tobacco, or pipe tobacco) in the past 30 days (OR: 0.939, p<0.001). However, the proportion of smokers who typically smoked menthol cigarettes significantly increased by 15.9 percentage points (45.3% pre to 52.5% post, p=0.006), suggesting potential migration from flavored cigarettes to menthol cigarettes (allowed under the policy). Further, the federal flavored cigarette ban was associated with increases in the probability of youth reporting use of cigars (34.4%, p<0.001) and pipes (54.6%, p<0.001), potentially suggesting the substitution to other flavored products (allowed under the policy). The results imply that youth may have substituted flavored cigars or pipes for flavored cigarettes, however, the study did not differentiate flavored versus non-flavored use of cigars or pipes. In addition, the study did not assess separate trends before the ban compared to after the ban, which may limit the ability to attribute changes in tobacco use to the federal ban, especially if use of specific products was already increasing or declining before the ban. Similarly, using cross-sectional, nationally representative data from the National Survey on Drug Use and Health (NSDUH), Rossheim et al. (2017) found that, overall, the federal flavored cigarette ban was associated with significant immediate increases and reductions over time in youth (12-17 years) and young adult (18-25 years) use of any cigarettes and menthol cigarettes. Among youth, Rossheim et al. (2017) found a 17% increase in the odds of reporting any cigarette smoking in the past 30 days immediately after the flavor ban (OR: 1.17, 95% CI: 1.07, 1.29) compared to the pre-ban

period. However, there was a 2.2% reduction in the odds of youth reporting any cigarette smoking each quarter thereafter (OR: 0.98, 95% CI: 0.97, 0.98) over the pre-ban trend. Similarly, there was an immediate 33% increase in the odds of youth reporting menthol cigarette smoking in the past 30 days (OR: 1.33, 95% CI: 1.15, 1.54), followed by an additional 3.6% reduction in the odds each quarter (OR: 0.96, 95% CI: 0.96, 0.97) over the pre-ban trend. Findings among young adults are similar to youth. Among young adults, there was a 9% immediate increase in the odds of reporting any cigarette smoking in the past 30 days (OR: 1.09, 95% CI: 1.03, 1.16), followed by an additional 1.2% reduction in the odds of cigarette smoking each quarter thereafter (OR: 0.99, 95% CI: 0.99, 0.99) over the pre-policy trend. Additionally, there was an immediate increase of 29% in the odds of young adults reporting any menthol cigarette smoking in the past 30 days (OR: 1.29, 95% CI: 1.19, 1.41), followed by a 2.6% reduction in the odds of menthol cigarettes smoking each quarter (OR: 0.97, 95% CI: 0.97, 0.98) over the pre-policy trend. Overall, in 2017, the predicted probability of youth and young adult cigarette smoking were reduced by 43% and 27%, respectively, compared to the model predicted probabilities in absence of the policy. The predicted probability of menthol cigarette use was reduced by 60% and 55% for youth and young adults, respectively.

Dual users may be susceptible to product substitution if flavors are restricted in one product and not the other product. Dual use of cigarettes and cigars is a common pattern of multiple product use, among current adult cigar users (Sung et al. 2016). In the U.S. following the federal ban on flavored cigarettes (excluding menthol) in Ontario before all flavor cigars were included in policy, studies found some evidence of substitution between combustible products (Courtemanche et al., 2017; Chaiton et al., 2020). In Ontario, Chaiton et al. (2020) found that menthol cigarette smokers were more likely to use flavored cigar products when menthol cigarettes were no longer available.

Potential substitution of flavored ENDS was also observed by recent studies following sales and enforcement prioritization changes regarding certain ENDS products in the U.S. (Hammond et al., 2021; Morean et al., 2020; Wagoner et al., 2021). A convenience sample of Connecticut high school youth before and after JUUL's 2018 sales policy found that reported past 30-day use of enforcement-prioritized JUUL pod flavors decreased after the sales policy, while mint-flavored pods, not covered by the sales policy, significantly increased (Morean et al., 2020). Hammond et al. (2021) explored such potential substitution using data from the International Tobacco Control Policy Evaluation Project (ITC) Youth Tobacco and Vaping Survey, an online survey among youth in Canada, England, and the United States (Hammond et al., 2021). The authors analyzed cross-sectional data from July 2017 to August 2020 among past 30-day e-cigarette users ages 16 to 19 years. The authors found evidence that U.S. youth in 2020 had shifted from use of flavored, cartridge-based ENDS that were subject to FDA enforcement prioritization to use of disposable flavored ENDS that may not have been prioritized for enforcement in 2020 by FDA. The types of e-cigarette flavors reported by U.S. youth e-cigarette users and the proportion reporting use of flavored e-cigarettes relative to tobacco or unflavored e-cigarettes was similar before and after the restrictions on cartridge-based e-cigarettes were implemented in 2020, suggesting movement between types of e-cigarettes as a means of retaining the preferred non-tobacco flavor over unflavored or tobacco flavored options (Hammond et al., 2021).

Furthermore, a June 2019 qualitative study on JUUL use among middle and high school youth in North Carolina found that most participants reported flavor as a positive feature of JUUL that attracts youth to use (Wagoner et al., 2021). Participants reported previous use of the JUUL flavors that were removed from retail stores in 2018, including mango, crème, and cucumber, and indicated that they had switched to mint-flavored cartridges, used knock-off JUUL pods, or were refilling the pods with other

flavored e-liquids (Wagoner et al., 2021), suggesting that flavor also drove maintenance of product use even after some products were no longer available.

Public Health Impact Assessment of a U.S. Policy on Flavored Cigars

A 2019 publication utilized evidence regarding the impact of local flavored tobacco policies, as well as national estimates of cigar use and attributable mortality in the U.S., to quantify potential population health benefits of a national policy removing flavored cigars throughout the U.S (Rostron et al., 2019). Specifically, the authors calculated the population benefit from potential reductions in cigar smoking mortality due to increased cessation among current cigar smokers, as well as from the prevention of cigar smoking initiation and progression to regular use, under such a national policy scenario (Rostron et al., 2019). Monte Carlo simulation was used to estimate possible ranges for these values, accounting for the uncertainty inherent in projecting out the impact of such a policy. The authors used data from the PATH Study to quantify current cigar use as well as initiation with flavored cigars, and to inform a projected range of initiation with non-flavored cigars, under a scenario where flavored cigars are not present. The authors utilized PATH Study data to project a range of cigar initiates that would be prevented from progressing to regular cigar use under the policy scenario, to estimate the range of averted cigar use among each cohort of 18-year-olds. This analysis did not account for the potential for substitution of other tobacco product use by youth.

To estimate the potential impact of removing flavored cigars from the market on mortality, Rostron et al. (2019) utilized published estimates of annual cigar-attributable mortality in the U.S. (Nonnemaker et al., 2014), adjusting estimates for exclusive cigar smoking. Utilizing published evidence from multiple localities' flavored tobacco restrictions, information on the size of the flavored U.S. cigar market, and information about the impact of taxation policy on smoking behaviors, Rostron et al. (2019) estimated the potential range of cigar smoking cessation that could result under a national flavored cigar restriction. These estimates are then used to estimate the number of deaths in the U.S. that would be prevented each year among exclusive regular cigar smokers as a result of not having flavored cigars on the U.S. market. The authors estimated that a national policy removing flavored cigars throughout the U.S. would result in 780 (90% prediction interval = 400–1200) fewer cigar smoking-attributable deaths in the U.S. each year and 112,000 fewer cigar smokers (90% prediction interval = 76,000–139,000) or in other words current cigar users prevented. This represents a reduction in current cigar prevalence of 37.1% for each cohort of 18-year-olds.

Given that the analysis by Rostron et al. (2019) represents a projection of potential population health benefits based on real world experiences and ranges of plausible assumptions, a number of limitations should be noted. First, the authors restricted estimates of mortality benefits to exclusive cigar smokers. This is a conservative approach as it does not account for any potential health benefits among dual users who would quit cigar use if flavors were removed from cigar products. Second, the authors used data from Providence and New York City because these cities' restrictions on the sale of flavored tobacco products provided the best available U.S. data on the effect of real-world implemented bans on flavored cigars at the time of publication. Since that time, experiences from multiple additional localities have been published. Additionally, the effects of local policies that are constrained to flavored product sales restrictions may underestimate the effects of national-level restrictions that apply to product manufacturers, importers, distributors, and retailers. Lastly, cigar sales were used as a proxy for consumption. In response to a national restriction on flavored cigars, some consumers might quit smoking cigars entirely and others might cut back based on studies on the impacts of cigarette tax

increases on smoking behaviors (IARC Tax, 2011). Rostron et al. (2019) assumed that, among exclusive cigar smokers who would change their smoking behavior if characterizing flavors were removed from cigar products, approximately 50% would quit smoking entirely, while the other 50% would cut back. To be conservative, the authors assumed there were no benefits in avoided mortality among those who cut back and avoided mortality is only counted among those who quit cigar smoking entirely. This approach may be conservative as some studies have found some health and mortality benefits from substantial reductions in cigarette consumption, although these benefits are less than those from complete smoking cessation (Godtfredsen et al., 2005; Hart et al., 2013).

A 2021 study by Levy et al. simulated the future benefit of a menthol cigarette and menthol cigar ban on the whole U.S. population over the 2021-2060 period (Levy et al., 2021). This model compared a *Status Quo Scenario,* in which no menthol ban was implemented, to a simulated *Menthol Ban Scenario,* in which a complete ban on menthol cigarettes and cigars was implemented in 2021.

The model estimated smoking-attributable deaths averted and life-years lost (LYL) averted over the 2021-2060 period. Compared to the *Status Quo Scenario*, in which no menthol ban on cigarettes and cigars was implemented, under the *Menthol Ban Scenario* the estimated overall smoking prevalence declined 14.7% by 2026 and 15.1% by 2060. This overall decrease was due to a sharp reduction in menthol smoking (down 92.5% by 2026, and 96.5% by 2060), coupled with an increase in non-menthol smoking (up 47.4% by 2026, and 58.0% by 2060) over the same period. Totaling the effects of the above behaviors, the model estimated 654,000 premature deaths and 11,300,000 LYL averted by 2060.

As with all population health impact models, the estimates of public health benefits under similar menthol ban scenarios are subject to implicit and explicit model assumptions. In addition, the authors do not include flavored cigars other than menthol cigars in their model and they do not provide cigar-specific estimates. Therefore, the application of the model's findings to a national prohibition on characterizing flavors in cigars is limited.

Summary and Conclusion

Evaluations in New York, New York; Providence, Rhode Island; San Francisco, California; St. Paul and Minneapolis, Minnesota; and Canada examined the impact of sales restrictions on flavored tobacco products, including cigars, on tobacco product sales. Consistent with economic studies, these policy evaluations used sales or purchase data to measure the demand for tobacco products which can serve as a proxy for changes in levels of tobacco product consumption among existing users (Zheng et al., 2016; Zheng et al., 2017; Cotti et al., 2016). As detailed above, these studies generally found an association between a restriction on flavored cigars, and decreased sales of flavored cigars. The ability to account for potential substitution with non-flavored cigars or other tobacco products varied across studies, but multiple studies found that overall sales of cigars declined in relation to sales pre-policy implementation and in geographic comparison areas, suggesting that consumers did not appear to completely substitute cigars not covered by the restrictions for the flavored cigars included in the restrictions (Chaiton et al. 2019; Gammon et al. 2021; Olson et al. 2021; Rogers et al. 2017; Rogers et al. 2020).

Studies provide some evidence that sales of tobacco products in which flavor status is ambiguous may increase after a flavored tobacco sales restriction (e.g., increase in concept-flavor named cigars in Providence post-policy). However, in jurisdictions where sales of non-flavored and concept flavored cigars increased, there was an overall decline in cigar sales. Therefore, the concurrent decrease in flavored cigar sales was not offset by an increase in cigars not included in the restrictions or

any cross-border purchasing. Overall, we conclude that following a flavored tobacco sales restriction or ban, overall sales of tobacco products or specific tobacco product categories (e.g., cigarettes, cigars) decrease, suggesting that consumers did not completely substitute non-flavored tobacco products for flavored.

Evaluations in New York, New York; Providence, Rhode Island; Lowell, Massachusetts; Minneapolis and St. Paul, Minnesota; San Francisco, California; and Canada examined the impact of restrictions on flavored tobacco products, including cigars, on youth and young adult tobacco use. Each of these evaluations found a decrease in flavored tobacco product use, overall cigar use, or flavored cigar use after policy implementation or enforcement. Although the evaluation in Attleboro and Salem, Massachusetts found increases in flavored (excluding menthol) and nonflavored (including menthol) tobacco use before and after sales restrictions, these increases were significantly smaller relative to the comparison municipality, suggesting that the flavored tobacco restriction may have prevented increases in tobacco use.

We conclude that following sales restrictions on flavored tobacco products, including cigars, sales of flavored cigars and cigars overall decrease and youth use of flavored cigars decreases. Studies found some evidence of cross-border purchasing following local sales restrictions, as well as incomplete retailer compliance and exemptions from local policies, which each led to continued consumption of flavored products. It is likely that a federal policy that restricts the manufacturing as well as sale of flavored tobacco and covers the U.S. as a whole, as compared to state or local sales restrictions, would increase the impact of flavored tobacco restrictions on tobacco use among young people by reducing the extent of available and accessible restricted tobacco products nationwide. Studies estimating the population benefit from a national policy removing flavored cigars throughout the U.S. suggested the potential for an overall benefit from preventing youth from initiating flavored cigar use and a reduction in cigar-attributable mortality, based on inputs from sales-only restrictions. The public health impact of a national restriction on both manufacturing and sales of flavored tobacco would likely be higher, but not easily anticipated.

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Appendix 1: Literature Review Search Strategy: Cigars and Flavors

Quarterly reviews of the extant literature regarding flavored cigars were completed to identify relevant studies utilizing four electronic databases – PubMed, EMBASE, Web of Science, and Ebscohost. Relevant studies that were published in English in scholarly journals were retrieved. No limitation of the year of publication was imposed. The following types of studies were excluded from this evidence synthesis: studies that do not mention cigars, studies primarily on blunt or cannabis use, studies employing exclusively animal models, studies utilizing only participants from outside the United States (U.S.), studies utilizing participants from the United States and other countries where data on United States participants were not presented separately, and studies that were published only in a language other than English.

The databases PubMed, Web of Science, and Ebscohost (Academic Search Complete, PsycInfo, and CINAHL) were selected for the literature search. These databases were first searched on October 5, 2016 using search strings tailored to each respective database. These search strings are listed below in Table A.

The citations identified were exported to EndNote and de-duplicated. Articles were initially screened via reading each study's abstract for relevance to the broad topic of flavors and cigars. Remaining articles were screened via reading the full text of the article. The reference lists of the articles, as well as the reference lists of systematic or literature reviews, were reviewed to identify additional relevant articles that might not have been captured via the search strategy. Lastly, pre-publication copies of relevant articles were reviewed as they became available.

Table A. Search Strings Employed to Identify Literature Relevant to Flavored Cigars, by Database	
Database	**Search String**
PubMed	("vanillin" [Supplementary Concept] OR "Flavoring Agents"[Mesh] OR "Sweetening Agents"[Mesh] OR "Flavoring Agents" [Pharmacological Action] OR "Vanilla"[Mesh] OR "Mentha"[Mesh] OR Taste[Mesh] OR "Cinnamomum"[Mesh]) OR (Flavor*[TIAB] OR Flavour*[TIAB] OR Flavoring*[TIAB] OR flavorant*[TIAB] OR additive*[TIAB] OR taste[TW] OR sweet*[TIAB] OR vanillin[TIAB] OR vanilla[TIAB] OR benzaldehyde[TIAB] OR geraniol[TIAB] OR "isoamyl acetate"[TIAB] OR Menthol[Mesh] OR Menthol*[TIAB] OR Cinnamon[tiab] OR cinnamaldehyde[TIAB] OR cinnamyl[TIAB] OR licorice[TIAB] OR mint[TIAB] OR wintergreen[TIAB] OR citronellol[TIAB] OR sugar[TIAB] OR sucrose[TIAB] OR sucralose[TIAB] OR "high fructose corn syrup"[TIAB] OR candy[TIAB] OR Cocoa[TIAB] OR Chocolate[TIAB] OR coffee[TIAB] OR "Propylene glycol" OR taste[Mesh]) AND (cigar[TW] OR cigars[TW] OR cigarillo[TW] OR cigarillos[TW] OR cheroot[TW] OR cheroots[TW] OR stumpen[TW] OR stumpens[TW]) NOT (cigar-shape[TW] OR cigar-shaped[TW] OR “cigar body”[TW] OR “cigar-bodies”[TW] OR “cigar roll”[TW] OR “cigar rolls”[TW] OR “cigar-like”[TW])
EMBASE	'flavoring agent'/exp OR vanillin OR "sweetening agent*" OR vanilla OR mentha OR taste OR cinnamomum OR flavor* OR additive* OR taste OR sweet OR benzaldehyde OR geraniol OR "isoamyl acetate" OR menthol OR cinnamon OR cinnamaldehyde OR cinnamyl OR licorice OR mint OR wintergreen OR citronellol OR sugar OR sucrose OR sucralose OR candy OR cocoa OR chocolate OR coffee OR ‘propylene glycol’/exp AND (cigar:ti,ab OR cigars:ti,ab OR cigarillo:ti,ab OR cigarillos:ti,ab OR cheroot:ti,ab OR cheroots:ti,ab OR stumpen:ti,ab OR stumpens:ti,ab) NOT (“cigar-shape”:ti,ab OR “cigar-shaped”:ti,ab OR “cigar body”:ti,ab OR “cigar-bodies”:ti,ab OR “cigar roll”:ti,ab OR “cigar rolls”:ti,ab OR “cigar-like”:ti,ab)
Web of Science	(vanillin OR flavor* OR flavor* OR vanilla OR mentha OR taste OR cinnamomum OR additive* OR taste OR sweet* OR benzaldehyde OR geraniol OR "isoamyl acetate" OR menthol OR cinnamon OR cinnamaldehyde OR cinnamyl OR licorice OR mint OR wintergreen OR citronellol OR sugar OR sucrose OR sucralose OR "high fructose corn syrup" OR candy OR cocoa OR chocolate OR coffee OR "propylene glycol") AND (cigar OR cigars OR cigarillo OR cigarillos OR cheroot OR cheroots OR stumpen OR stumpens) NOT (“cigar-shape” OR “cigar-shaped” OR “cigar body” OR “cigar-bodies” OR “cigar roll” OR “cigar rolls” OR “cigar-like”)
Ebscohost (Academic Search Complete, PsycInfo, and CINAHL)	(vanillin OR flavor* OR flavor* OR vanilla OR mentha OR taste OR cinnamomum OR additive* OR taste OR sweet* OR benzaldehyde OR geraniol OR "isoamyl acetate" OR menthol OR cinnamon OR cinnamaldehyde OR cinnamyl OR licorice OR mint OR wintergreen OR citronellol OR sugar OR sucrose OR sucralose OR "high fructose corn syrup" OR candy OR cocoa OR chocolate OR coffee OR "propylene glycol") AND (cigar OR cigars OR cigarillo OR cigarillos OR cheroot OR cheroots OR stumpen OR stumpens) NOT (“cigar-shape” OR “cigar-shaped” OR “cigar body” OR “cigar-bodies” OR “cigar roll” OR “cigar rolls” OR “cigar-like”)

Appendix 2: Summary of Youth Prevalence Estimates

Youth Prevalence					
Estimate	**Subgroup**	**% or (95% CI)**	**Source**	**Year**	**Reference**
Past 30-day cigar use	Adolescents overall	3.5 (2.9, 4.3)	NYTS	2020	Gentzke et al. 2020
	High school students	5.0 (4.1, 6.2)			
	Middle school students	1.5 (1.2, 2.0)			
	NH Black high school	9.2 (7.0, 12.1)			
	NH White high school	4.2 (3.2, 5.5)			
	Sexual minority youth	6.0 (4.4, 8.3)			
	Heterosexual youth	3.1 (2.5, 3.7)			
Type of cigar used	Cigarillos	44.1 (37.0, 51.5)	NYTS	2020	Parms et al. 2022
	Traditional cigars	33.1 (27.1, 39.7)			
	Little cigars	22.6 (17.6, 28.6)			
	I don't know	21.8 (17.6, 26.6)			
Ever cigar use increasing odds of past 30-day cigarette use	NH Black youth	OR 2.68 (1.21, 5.93)	PATH Waves 1-4	2013-2018	Stokes et al. 2021
	NH White youth	OR 1.37 (0.69, 2.72)			
Transgender ever use of any tobacco product	Transgender youth	53.6 (40.2, 66.5)	PATH Wave 3	2015-2016	Johnson et al. 2019
	Non-transgender youth	31.5 (30.2, 32.8)			
	Transgender youth	10.2 (5.2, 19.1)	PATH Wave 3	2015-2016	Johnson et al. 2019

Transgender past 30-day use of >1 tobacco product	Non-transgender youth	3.5 (3.0-4.1)			
Lesbian, gay, bisexual (LGB) youth past 30-day use of any tobacco product	LGB youth	25.5 (21.8, 29.5)	NYTS	2020	Gentzke et al. 2020
	Heterosexual youth	15.1 (13.1, 17.3)			
Transgender ever cigar use	Transgender youth	16.1 (8.4, 27.8)	PATH Wave 3	2015-2016	Johnson et al. 2019
	Non-transgender youth	7.5 (6.8, 8.2)			
Proportion of 11th grade students with disability using little cigars	Disabled youth	7.0 (6.1, 8.1)	Oregon Healthy Teens Survey	2015, 2017	Senders & Horner-Johnson 2020
	Non-disabled youth	5.4 (4.8, 6.1)			
Past 30-day cigar users who used flavored cigars in past 30 days	Overall	44.0 (34.4, 53.7)	PATH Wave 5	2018-2019	PATH Study Data Tables and Figures
	Traditional cigar users	33.9 (18.2, 49.6) †			
	Cigarillo users	46.0 (33.6, 58.5)			
	Filtered cigar users	50.2 (19.2, 81.2) †			

Appendix 3: Summary of Adult Prevalence Estimates

Outcome	Participant age range	Participant characteristic	Cigar Product type	Prevalence Estimate % (95% CI), if available	Source	Year	Reference
Every day or some day use	18+	----	Cigars, all	3.6 (3.3, 3.9)	NHIS	2019	Cornelius et al. 2020
	18-24	----	Cigars, all	3.8 (2.8, 4.8)			
	25-44	----	Cigars, all	4.4 (3.9, 4.9)			
Past 30-day use	18-25	----	Cigars, all	10.9	NSDUH	2011	SAMHSA, 2020
	18-25	----	Cigars, all	7.7		2019	
	26+	----	Cigars, all	4.2		2011	
	26+	----	Cigars, all	4.0		2019	
Past 30-day use	18-24	----	Traditional cigars	4.8 (4.3, 5.4)	PATH Wave 5	2018-2019	PATH Study Data Tables and Figures
	25+	----	Traditional cigars	3.5 (3.2, 3.8)			
	18-24	----	Cigarillos	7.9 (7.3, 8.5)			
	25+	----	Cigarillos	3.3 (3.0, 3.5)			
	18-24	----	Filtered cigars	2.4 (2.0, 2.8)			
	25+	----	Filtered cigars	1.6 (1.4, 1.7)			
Past 30-day use of flavors, among past 30-day users of any cigars	18-24	----	Traditional cigars	17.7 (12.5, 24.0)	PATH Wave 5	2018-2019	PATH Study Data Tables and Figures
	25+	----	Traditional cigars	19.7 (16.4, 23.3)			
	18-24	----	Cigarillos	46.0 (40.5, 51.4)			
	25+	----	Cigarillos	46.5 (42.3, 50.7)			
	18-24	----	Filtered cigars	41.0 (29.8, 52.1)			
	25+	----	Filtered cigars	48.7 (42.1, 55.4)			
	18-24	----	Cigars, all	38.3 (34.2, 42.4)			
	25+	----	Cigars, all	36.0 (33.0, 39.1)			
Past 30-day use of flavors[a]	18+	----	All Cigars, flavored	2.8 (2.6, 3.1)	NATS	2009-2010	King et al. 2013
	18-24	----	All Cigars, flavored	9.1 (7.8, 10.5)			
	25-44	----	All Cigars, flavored	3.1 (2.7, 3.6)			
EDUCATION							

Past 30-day use	25+	Less than a high school diploma	Cigars, all	7.3 (6.3, 8.4)	PATH Wave 5	2018-2019	PATH Study Data Tables and Figures
	25+	College degree or higher	Cigars, all	3.8 (3.2, 4.4)			
LGBTQ+							
Past 30-day use	18+ years	Transgender	Cigars	26.8 (19.0, 36.4)	National cross-sectional online survey	2013	Buchting et al. 2017
	18+ years	Cisgender	Cigars	9.3 (8.8, 9.9)			
Past 30-day use of flavors[a]	18+ years	LGBT	All Cigars, flavored	8.2 (5.6, 11.9)	NATS	2009-2010	King et al. 2013
	18+ years	Heterosexual/straight	All Cigars, flavored	2.7 (2.5, 3.0)			
Past 30-day use of flavors, among past 30-day users of any cigars	all	Lesbian, gay, bisexual	large cigar and little cigar/cigarillo	11.1	Truth Initiative Young Adult Cohort Study	2011-2015	Glasser et al. 2017
	all	Heterosexual/straight	large cigar and little cigar/cigarillo	4			
RACE / ETHNICITY							
Past 30-day use	18-24	Non-Hispanic White	Cigarillos	11.0 (10.0, 12.2)	Wave 1	2013-2014	PATH Online Tables
	18-24	Non-Hispanic White	Cigarillos	10.5 (9.5, 11.5)	Wave 2	2014-2015	
	18-24	Non-Hispanic White	Cigarillos	9.3 (8.3, 10.4)	Wave 3	2015-2016	
	18-24	Non-Hispanic White	Cigarillos	9.3 (8.4, 10.3)	Wave 4	2016-2017	
	18-24	Non-Hispanic White	Cigarillos	6.9 (6.2, 7.7)	Wave 5	2018-2019	

Past 30-day use	18-24	Non-Hispanic Black	Cigarillos	21.6 (19.3, 24.1)	Wave 1	2013-2014	PATH Online Tables
	18-24	Non-Hispanic Black	Cigarillos	23.6 (20.7, 26.6)	Wave 2	2014-2015	
	18-24	Non-Hispanic Black	Cigarillos	19.2 (16.9, 21.6)	Wave 3	2015-2016	
	18-24	Non-Hispanic Black	Cigarillos	20.1 (17.9, 22.4)	Wave 4	2016-2017	
	18-24	Non-Hispanic Black	Cigarillos	15.1 (13.2, 17.2)	Wave 5	2018-2019	
Past 30-day use	25+	Non-Hispanic White	Cigarillos	2.4 (2.1, 2.6)	Wave 1	2013-2014	PATH Online Tables
	25+	Non-Hispanic White	Cigarillos	2.3 (2.0, 2.6)	Wave 2	2014-2015	
	25+	Non-Hispanic White	Cigarillos	2.3 (2.0, 2.6)	Wave 3	2015-2016	
	25+	Non-Hispanic White	Cigarillos	2.4 (2.1, 2.6)	Wave 4	2016-2017	
	25+	Non-Hispanic White	Cigarillos	2.1 (1.9, 2.4)	Wave 5	2018-2019	
Past 30-day use	25+	Non-Hispanic Black	Cigarillos	9.6 (8.5, 10.8)	Wave 1	2013-2014	PATH Online Tables
	25+	Non-Hispanic Black	Cigarillos	9.5 (8.4, 10.7)	Wave 2	2014-2015	
	25+	Non-Hispanic Black	Cigarillos	10.1 (9.0, 11.3)	Wave 3	2015-2016	
	25+	Non-Hispanic Black	Cigarillos	10.7 (9.6, 11.8)	Wave 4	2016-2017	
	25+	Non-Hispanic Black	Cigarillos	10.8 (9.7, 12.0)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users	18-24	Non-Hispanic White	Traditional cigars	22.6 (16.0, 30.5)	Wave 2	2014-2015	PATH Online Tables
	18-24	Non-Hispanic White	Traditional cigars	25.5 (17.9, 33.2)	Wave 3	2015-2016	

traditional cigars	18-24	Non-Hispanic White	Traditional cigars	19.5 (14.0, 26.2)	Wave 4	2016-2017	
	18-24	Non-Hispanic White	Traditional cigars	18.2 (11.5, 26.6)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users traditional cigars	18-24	Non-Hispanic Black	Traditional cigars	31.3 (16.4, 46.3)	Wave 2	2014-2015	PATH Online Tables
	18-24	Non-Hispanic Black	Traditional cigars	52.4 (34.6, 70.3)	Wave 3	2015-2016	
	18-24	Non-Hispanic Black	Traditional cigars	43.8 (19.0, 68.6)	Wave 4	2016-2017	
	18-24	Non-Hispanic Black	Traditional cigars	19.9 (5.9, 42.9)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users traditional cigars	18-24	Hispanic	Traditional cigars	31.4 (19.3, 43.4)	Wave 2	2014-2015	PATH Online Tables
	18-24	Hispanic	Traditional cigars	27.3 (11.8, 42.9)	Wave 3	2015-2016	
	18-24	Hispanic	Traditional cigars	26.7 (10.4, 43.0)	Wave 4	2016-2017	
	18-24	Hispanic	Traditional cigars	18.2 (6.3, 37.4)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users traditional cigars	25+	Non-Hispanic White	Traditional cigars	15.7 (12.0, 19.9)	Wave 2	2014-2015	PATH Online Tables
	25+	Non-Hispanic White	Traditional cigars	14.5 (11.0, 18.5)	Wave 3	2015-2016	
	25+	Non-Hispanic White	Traditional cigars	14.8 (10.5, 20.0)	Wave 4	2016-2017	
	25+	Non-Hispanic White	Traditional cigars	13.3 (9.9, 17.4)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users	25+	Non-Hispanic Black	Traditional cigars	55.8 (47.5, 64.2)	Wave 2	2014-2015	PATH Online Tables
	25+	Non-Hispanic Black	Traditional cigars	40.0 (32.2, 47.8)	Wave 3	2015-2016	

traditional cigars	25+	Non-Hispanic Black	Traditional cigars	41.3 (32.6, 50.0)	Wave 4	2016-2017	
	25+	Non-Hispanic Black	Traditional cigars	43.6 (34.0, 53.1)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users traditional cigars	25+	Hispanic	Traditional cigars	29.1 (18.5, 39.8)	Wave 2	2014-2015	PATH Online Tables
	25+	Hispanic	Traditional cigars	16.1 (8.6, 26.4)	Wave 3	2015-2016	
	25+	Hispanic	Traditional cigars	27.6 (16.3, 38.9)	Wave 4	2016-2017	
	25+	Hispanic	Traditional cigars	21.5 (13.0, 32.2)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users of filtered cigar	18-24	Overall	Filtered cigars	47.5 (39.3, 55.6)	Wave 4	2016-2017	PATH Online Tables
	18-24	Overall	Filtered cigars	41.0 (29.8, 52.1)	Wave 5	2018-2019	
Past 30-day flavor use, among past 30 day users of filtered cigar	25+	Overall	Filtered cigars	47.0 (42.4, 51.7)	Wave 4	2016-2017	PATH Online Tables
	25+	Overall	Filtered cigars	48.7 (42.1, 55.4)	Wave 5	2018-2019	

Appendix 4: Selected Methodological Characteristics of National Surveys Assessing Cigar Use

Survey	Year(s)	Study design type	Participants	Cigar subtypes assessed	Flavored cigar use assessed	Blunts use excluded*	Cigar images provided
PATH Wave 1	2013-2014	Longitudinal	Youth & Adults	Yes	Yes	No	Yes
PATH Wave 2	2014-2015	Longitudinal	Youth & Adults	Yes	Yes	No	Yes
PATH Wave 3	2015-2016	Longitudinal	Youth & Adults	Yes	Yes	No	Yes
PATH Wave 4	2016-2017	Longitudinal	Youth & Adults	Yes	Yes	No	Yes
PATH Wave 5	2018-2019	Longitudinal	Youth & Adults	Yes	Yes	No	Yes
NHIS	2019	Cross-sectional	Adults	No	No	Yes	No
NATS	2009-2010	Cross-sectional	Adults	No	Yes	Yes	No
NYTS	2020	Cross-sectional	Youth	Yes	Yes	Yes	Yes
NYTS	2019	Cross-sectional	Youth	Yes	Yes	Yes	Yes
YRBSS	2015	Cross-sectional	Youth	No	No	Yes	No
NSDUH	2019	Cross-sectional	Youth & Adults	No	No	No	No
NESARC-III	2012-2013	Cross-sectional	Adults	No	No	Yes	No
Truth Initiative Young Adult Cohort Study	2011-2015	Longitudinal	Adults	Yes	Yes	Yes	No

Abbreviations: PATH=Population Assessment of Tobacco and Health; NHIS= National Health Interview Survey; NATS= National Adult Tobacco Survey; NYTS= National Youth Tobacco Survey; YRBSS= Youth Risk Behavior Surveillance System; NSDUH= National Survey on Drug Use and Health; NESARC-III= National Epidemiologic Survey on Alcohol and Related Conditions III

* Some surveys instruct participants to not consider blunt use when responding to items about their cigar use (blunt use is assessed in separate items). Other surveys do not differentiate between blunt and cigar use, so it is possible that participants consider both behaviors when answering cigar use items. This column indicates whether blunt use was asked about separately, and thus, excluded from any cigar use prevalence estimates.

Appendix 5: Health Consequences of Cigar Smoking

Flavored cigar smokers, like all cigar smokers, are at increased risk for developing cancers of the mouth and throat, lung cancer, heart disease, and many other hazardous health consequences. Studies demonstrate that not only does cigar smoking present many of the same health risks as cigarette smoking, but cigar smoking risks can also exceed those related to cigarette use depending on the number of cigars smoked and the depth of smoke inhalation (Chang, Corey, Rostron, & Apelberg, 2015).

Cigars produce toxic smoke containing the same harmful constituents as cigarette smoke, and cigar smoke may have even higher levels of several harmful compounds (U.S. Dept. of Health and Human Services, 2014; IARC 2004; Nonnemaker et al., 2014). For example, high concentrations of cancer-causing nitrosamines are formed during the fermentation process for cigar tobacco, and these compounds are released when a cigar is smoked (U.S. Dept. of Health and Human Services, 2014; IARC, 2004). Researchers have found concentrations of NNAL (a hazardous tobacco-specific nitrosamine) measured in daily cigar smokers to be as high as those measured in daily cigarette smokers (Chen, Ketterman, Rostron, & Day, 2014; Chang et al., 2015). Like exposure to cigarette smoke, exposure to higher levels of cigar smoke for longer time periods increases the adverse health risks caused by cigar smoking (U.S. Dept. of Health and Human Services, 2010).

Using NATS data for 2009-2010, researchers have estimated that regular cigar smoking caused approximately 9,000 premature deaths or almost 140,000 years of lost potential life among adults 35 years or older (Nonnemaker et al, 2014). A study of healthcare expenditures from 2000-2015 found that cigar-attributable health care expenditures for adults totaled $1.75 billion per year, with $284 million attributed to exclusive cigar smoking and $1.5 billion attributed to poly cigar smoking (i.e., cigar plus cigarette or smokeless tobacco use) (Wang, Sung, Yao, Lightwood, & Max, 2018). The overall mortality rates for cigar smokers who inhale generally approach the same mortality rates observed for cigarette smokers (National Cancer Institute, 1998, p. 110-112). In addition, overall mortality rates for all cigar smokers (i.e., those who report inhaling as well as those who report not inhaling cigar smoke) are higher than rates for those who have never smoked, although they may be generally lower than the rates observed for cigarette smokers (National Cancer Institute, 1998, p. 112). A recently published analysis using more contemporary data from the National Longitudinal Mortality Study, following participants for mortality from 1980 through the end of 2011, also found that exclusive cigar smokers had an elevated risk of all-cause mortality compared to never tobacco users (Hazard Ratio (HR): 1.20; 95% CI: 1.03, 1.38), but lower than exclusive cigarette smokers (Christensen et al., 2018). Another similar analysis using the restricted-use National Health Interview Survey-Linked Mortality Files (NHIS-LMF), following participants for mortality from 2000 through 2015, observed that current, daily cigar smokers had elevated risk of all-cause mortality compare to never tobacco users (HR: 1.53; 95% CI: 1.10, 2.13) (Inoue-Choi et al., 2019). In addition, researchers studying cigar smokers in 2009 and 2010 found that the average cigar or pipe smoker loses approximately 15 life-years (Nonnemaker et al., 2014).

1. Cancers of the Mouth and Throat

The NCI's Monograph No. 9, which provides a comprehensive, peer-reviewed analysis of the trends in cigar smoking and potential public health consequences, identified a dose-response relationship for cigar smoking and certain types of cancer (National Cancer Institute, 1998, p. 120-130). Specifically, NCI's Monograph No. 9 identified a dose-response relationship for cigar smoking and oral, laryngeal, pharyngeal, and esophageal cancers, finding an increased risk of these diseases with greater numbers of cigars smoked per day and deeper inhalation (National Cancer Institute, 1998, p. 120-130; Iribarren, Tekawa, Sidney, & Friedman, 1999; Wyss et al., 2013; Blot et al., 1988; Garrote et al., 2001). Likewise, a systematic review of the mortality risks associated with cigar smoking that identified 22 studies observed similar dose trends (Chang et al., 2015).

Cigar smoking can cause cancers of the mouth and throat even in smokers who do not inhale (National Cancer Institute, 1998). According to the NCI's Smoking and Tobacco Control Monograph No. 9, the data clearly establish that cigar smoking is a cause of oral cancer (National Cancer Institute, 1998). Regular cigar smokers who have never smoked cigarettes, including those who report that they do not inhale, experience significantly elevated risks for oral, laryngeal, pharyngeal, and esophageal cancers (National Cancer Institute, 1998). Although former cigarette smokers who currently smoke cigars are more likely to inhale more deeply than cigar smokers who never smoked cigarettes, "the mouth and oral cavity are exposed to the carcinogens in smoke whether the smoke is inhaled or not" (National Cancer Institute, 1998). The systematic review of the mortality risks associated with cigar smoking also noted that the relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancer among primary cigar smokers reporting no inhalation (Chang et al., 2015). Cigar smokers, including those who do not inhale, have a similar risk of death from mouth and throat cancer as do cigarette smokers, with an overall risk 7 to 10 times higher than for those who have never smoked (National Cancer Institute, 1998). This similarity in risk is likely due to the similar doses of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Baker et al., 2000). Cigar smokers are also more likely to develop mouth and throat cancer than those who have never smoked. In a large retrospective cohort study that included more than 17,000 men, researchers found that cigar smokers were nearly three times more likely than nonsmokers to develop cancer of the oropharynx (relative risk (RR): 2.61; 95% CI: 1.18, 5.76) and twice as likely to develop cancer of the upper aerodigestive tract (which includes oral cavity, pharynx, larynx, and esophagus) (RR: 2.02; 95% CI: 1.01, 4.06) (Iribarren et al., 1999). Those risks increased to roughly seven and five times, respectively, among those who smoked five or more cigars per day (Iribarren et al., 1999).

NCI researchers found that the scientific data that are described in the Monograph, taken as a whole, support the conclusion that cigar smoking is a cause of laryngeal and esophageal cancers (National Cancer Institute, 1998). The likelihood of cigar smokers developing laryngeal cancer is similar to that of cigarette smokers who smoke fewer than 20 cigarettes per day (Stockwell & Lyman, 1986). The relative risk of death from laryngeal cancer for those who smoke five or more cigars per day, or who inhale moderately or deeply, approaches the risk for cigarette smokers (National Cancer Institute, 1998). This similarity in risk is likely due to the similar amounts of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Baker et al., 2000). Regardless of whether smoke is inhaled, the mouths and tongues of cigar smokers are exposed to a high level of smoke (Baker et al., 2000). The esophagus is exposed to the carcinogens of tobacco smoke, which collect on the mouth's surface and are swallowed with saliva, rendering cigar smoking a cause of esophageal cancer (Baker et al., 2000). The risk of esophageal cancer is several times higher for cigar smokers than for those who have never smoked, and the relative risk of occurrence is higher for cigar smokers than for cigarette smokers, even when compared to the heaviest cigarette smokers (Ferraroni et al., 1989).

Several multinational research studies also have noted that cigar smoking can cause oral and other cancers, even in those who do not inhale smoke. For example, the European Prospective Investigation into Cancer and Nutrition (EPIC) examined 102,395 men from Denmark, Germany, Spain, Sweden, and the United Kingdom, and compared the incidence of cancer in smokers who used cigars exclusively with cigar smokers who also smoked cigarettes. (McCormack et al., 2010). According to the EPIC study findings, exclusive cigar smokers who report not inhaling had approximately a two-fold higher risk of lung, upper aerodigestive tract, and bladder cancers combined compared to those who never smoked (McCormack et al., 2010). This increased risk was raised to 6- or 7-fold higher in cigar smokers who inhaled smoke compared to noninhalers (McCormack et al., 2010). This increased risk by comparison to never-smokers was lowest for smokers who had quit both cigarettes and cigars and higher for those who switched from cigarettes to only cigars, demonstrating the additional risk associated with cigar smoking compared to stopping smoking altogether (McCormack et al., 2010).

Researchers confirmed a carcinogenic effect from cigar smoking with regard to upper aerodigestive tract cancers and found that the risk of these hazards increased with increased duration of smoking over the smoker's lifespan, increased intensity of use per week, and increased degree of smoke inhalation per episode (McCormack et al., 2010). A recently published international pooled cohort study found that ever cigar smokers had a non-significantly elevated risk of head and neck cancer (HR: 1.40; 95% CI: 0.98, 2.00) and no elevated risk of esophageal cancer (Malhotra et al., 2017).

In addition, the WHO International Agency for Research on Cancer (IARC) published a monograph evaluating the carcinogenic risk to humans from tobacco smoke and involuntary smoke exposure. The IARC explained: "Cigar and/or pipe smoking is strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx, and esophagus, the magnitude of risk being similar to that from cigarette smoking. These risks increase with the amount of cigar . . . smoking and with the combination of alcohol and tobacco consumption" (IARC, 2004).

2. Lung Cancer

The evidence clearly establishes that cigar smoking can cause lung cancer, although the risk varies by number of cigars per day and level of exposure (National Cancer Institute, 1998, p. 119-120; IARC, 2004, p. 1180; and Chang et al., 2015). A recently published international pooled cohort study found that ever cigar smokers had a significantly elevated risk of lung cancer (HR: 2.73; 95% CI: 2.06, 3.60) (Malhotra et al., 2017).

Like the dose-response relationship between cigar smoking and mouth and throat cancers, the risk of death and disease from lung cancer increases as the number of cigars smoked per day and the depth of smoke inhalation increases (National Cancer Institute, 1998; Joly, Lubin, & Caraballoso, 1983; Lubin, Richter, & Blot, 1984; Boffetta et al., 1999; Chang et al., 2015). Overall lung cancer risk for cigar smokers is lower than the overall risk for cigarette smokers (Iribarren et al., 1999; Higgins, Mahan, & Wynder, 1988; Shaper, Wannamethee, & Walker, 2003; Abelin & Gsell, 1967; Shapiro, Jacobs, & Thun, 2000), but the risk of death from lung cancer for cigar smokers may be similar to the risk of death from lung cancer for cigarette smokers (Iribarren et al., 1999; Joly et al., 1983; Lubin et al., 1984; Boffetta et al., 1999; Higgins et al., 1988; Shaper et al., 2003; Abelin & Gsell, 1967; Chang et al., 2015) once the rates are adjusted for differences in inhalation levels and quantity of cigars smoked daily (National Cancer Institute, 1998, p. 120). Cigar smokers in the Cancer Prevention Study I (CPS I), conducted from 1959-1972, who smoked five or more cigars daily with moderate inhalation had a similar risk of death from lung cancer as did pack-a-day cigarette smokers (National Cancer Institute, 1998).

Former cigarette smokers who currently smoke cigars are more likely to inhale deeply than cigar smokers who have never smoked cigarettes, increasing their lung cancer risk (U.S. Dept. of Health and Human Services,2014, citing National Cancer Institute, 1998). Although cigarette smokers who switch to smoking only cigars have lower lung cancer risks than they would have if they had continued smoking cigarettes, these risks appear to be substantially greater than for individuals who have quit smoking altogether (National Cancer Institute, 1998, p. 155; Boffetta et al., 1999; Higgins et al., 1988).

Likewise, according to data from the Cancer Prevention Study II (CPS II, a 12-year study of 1.2 million men and women, in which men were asked about cigar use), the risk of lung cancer mortality was approximately five times higher for men who were current smokers of only cigars at the start of the follow-up study period compared with men who never smoked (Shapiro et al., 2000). In an analysis of a subset of men who participated in the CPS II study, researchers found that men who smoked three or more cigars per day, who reported inhaling cigar smoke, or who had smoked cigars for 25 years or more experienced a substantially greater risk of mortality from lung cancer than those men who reported less frequent cigar use (RR: 7.8; 95% CI: 5.9, 10.3), not inhaling (RR: 11.3; 95% CI: 7.9, 16.1), and smoking cigars for 25 years or less (RR: 5.9; 95% CI: 4.5, 7.7) (Shapiro et al., 2000). Even male cigar smokers who

reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked (RR: 3.3; 95% CI: 2.3, 4.7) (Shapiro et al., 2000).

The type of cigar used also may impact the risk of lung cancer in cigar smokers. One large European case-control study found that lung cancer patients had 5.6 (95% CI: 2.9, 10.6) times greater odds than controls of being an exclusive user of cigars other than cigarillos, compared to a 12.7 (95% CI: 6.9, 23.7) times greater odds of being an exclusive cigarillo user (Boffetta et al., 1999). The researchers attributed these differences in excess risk to differences between cigars and cigarillos in inhalation patterns, with cigarillo users being more likely to inhale than cigar users and inhalers were at higher risk of lung cancer than noninhalers (Boffetta et al., 1999). These findings suggest that cigarette smokers who switch to cigars (or dual use) may transfer their cigarette inhaling behaviors to cigars, thereby increasing their lung cancer risk to levels similar to cigarettes (Boffetta et al., 1999; National Cancer Institute, 1998; Koszowski et al., 2015).

3. Heart Disease and Aortic Aneurysm

Researchers have identified a pattern of elevated rates of death from coronary heart disease and aortic aneurysm among primary cigar smokers who smoke heavily or inhale deeply (Chang et al., 2015). The CPS I, which evaluated nearly one million men and women in 25 states, found evidence that the rate of death from coronary heart disease increases with the number of cigars smoked and the depth of smoking inhalation (National Cancer Institute, 1998; Chang et al., 2015). Researchers also identified a significantly elevated risk of developing coronary heart disease in those individuals who smoked five or more cigars per day and exhibited moderate and deep inhalation (National Cancer Institute, 1998; Chang et al., 2015; Nyboe, Jensen, Appleyard, & Schnohr, 1991). Long-established CPS I data also suggest that cigar smokers are at an increased risk for aortic aneurysm, the risk rate approaching that observed for cigarette smokers (National Cancer Institute, 1998; Chang et al., 2015).

Researchers analyzing CPS II data also examined death rates resulting from coronary heart disease related to cigar smoking. The 1999 CPS II reviewed approximately 7,000 current cigar smokers, 7,000 former cigar smokers, and 113,000 men who had never regularly smoked tobacco to determine the risk of heart disease for cigar smokers (Baker et al., 2000). Among men younger than 75 years old, current cigar smokers experienced a coronary heart disease death rate about one-third higher than those who had never smoked (Baker et al., 2000).

Additional studies provide supporting evidence that cigar smokers have elevated rates of developing coronary heart disease compared with nonsmokers (Iribarren et al., 1999; Shaper et al., 2003; Matroos, Magnus, & Strackee, 1979). One large study examined primary (i.e., current, exclusive with no previous history of cigarette or pipe tobacco use) and secondary (i.e., current, exclusive with previous history of cigarette or pipe tobacco use) cigar smokers compared with never smokers (Shaper et al., 2003). It found that both primary and secondary cigar smokers were at increased risk of major coronary heart disease compared to nonsmokers (Sharper et al., 2003). Secondary cigar smokers also had a higher risk of major stroke compared with nonsmokers (Sharper et al., 2003). Primary and secondary cigar smokers had similar risks of major coronary heart disease and stroke and experienced outcomes similar to those who smoked less than a pack of cigarettes per day (Sharper et al., 2003). In the recently published NHIS-LMF, current, daily cigar smokers had a non-significantly elevated risk of death due to coronary heart disease compared to never tobacco users (HR: 1.32; 95% CI: 0.76, 2.30) (Inoue-Choi et al., 2019).

In addition, in 2010, the Surgeon General found that for older adult cigar smokers, particularly those who smoke more than one cigar per day or inhale the smoke, the risk of heart disease is moderately higher than that for nonsmokers (U.S. Dept. of Health and Human Services, 2010). In support of the Surgeon General's findings, one study conducted from 1964 to 1973 involved 17,774 men ranging in age from 30 to 85, of which 1,546 smoked cigars and 16,228 did not, all of whom reported

that they had never smoked cigarettes and did not currently smoke pipes (Iribarren et al., 1999). This study determined that cigar smoking was associated with a moderate, but significant, increase in the risk of coronary heart disease (Iribarren et al., 1999).

International researchers have reached similar conclusions about the impact of cigar smoking on the risk of developing heart disease. For example, in a study of more than 12,000 Danish people aged 30 years and older that looked at the risk of first acute myocardial infarction (MI), researchers found the risk of first acute MI escalated with increasing depth of smoke inhalation and with increasing number of cigars smoked per day (National Cancer Institute, 1998, citing Nyboe et al., 1999). Another Danish study found the highest rates of myocardial infarction for smokers of cheroots (a type of cigar that is traditional in India and Burma with ends that do not taper) to be for those individuals who smoked six or more cheroots per day, with a relative risk of myocardial infarction of more than four times the risk of individuals who had never smoked (National Cancer Institute, 1998, citing Gyntelberg et al., 1981).

4. Other Health Outcomes

Research studies have found that cigar smokers have approximately 40 to 45 percent higher risk of COPD than never tobacco users. A cohort study of Kaiser Permanente plan members found a relative risk of COPD diagnosis of 1.45 for cigar smokers (95% CI: 1.10, 1.91) (Iribarren et al., 1999), and CPS I data revealed a similar elevated relative risk of COPD among primary cigar smokers of 1.42 (95% CI: 0.96, 2.03) (Shanks & Burns, 1998).

The risk of bladder cancer in CPS I data was also approximately 40% higher for cigar smokers, with a relative risk of 1.38 (95% CI: 0.89, 2.04) (Shanks & Burns, 1998, p. 134-136). In a recently published study using data from the Agricultural Health Study, ever cigar use was significantly associated with risk of urinary cancer (HR: 2.50; 95% CI: 1.27, 4.93) (Andreotti et al., 2017).

There are other health outcomes attributable to cigar smoking that were not assessed using CPS I or II mortality data. For example, one study found statistically significant increased risks of colon and rectal cancers among cigar smokers in a cohort of nearly 250,000 World War I era veterans who were followed for mortality for 26 years (Heineman et al., 1994). While most research has focused on cigar-attributable mortality, limited research has addressed cigar-attributable morbidity. Besides dying from cigar-attributable disease, lifelong cigar smokers may live many years with serious medical conditions, such as cancers (Iribarren et al., 1999; Garrote et al., 2001), heart disease (Iribarren et al., 1999; Matroos et al., 1979), and increased airflow obstruction (Rodriguez et al., 2010) that can lead to major physical impairments, and significantly reduce functioning and quality of life.

5. Impact on Individuals Who Report That They Do Not Inhale Smoke

Studies suggest that even cigar smokers who do not intend to inhale smoke, and who are unaware they are doing so, nonetheless inhale some amount of smoke (Rodriguez et al., 2010; McDonald, Bhatia, & Hollett, 2002). While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, significant risks still exist for those cigar smokers who may not intentionally inhale smoke. Relative mortality risks for oral, esophageal, and laryngeal cancers are high even among those primary cigar smokers who reported that they do not inhale cigar smoke (Chang et al., 2015; National Cancer Institute, 1998; Wyss et al., 2013; Shanks & Burns, 1998). Researchers found that the risk of stomach cancer mortality was also significantly higher among cigar users who reported they did not inhale smoke when compared to individuals who did not use tobacco products (Chao et al., 2002). Regardless of whether cigar smokers inhale, they are still subject to cigars' addictive and other adverse health effects through absorption of nicotine and other harmful constituents, including those discussed in section V.B of this document (McDonald et al., 2002; Chao et al., 2002). Buccal absorption of nicotine occurs even if cigar smoke is not inhaled, and cigar smokers may also absorb nicotine through the lips due to the alkalinity of cigar tobacco (Henningfield, Hariharan, & Kozlowski, 1996;

Henningfield, Fant, Radzius, & Frost, 1999). This greater nicotine yield and absorption increases the risk of nicotine addiction from cigar smoking.

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Appendix 6: Summary of Evaluation Studies on Sales Restrictions including Flavored Cigars

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
New York, NY	Flavored tobacco products containing tobacco, including cigars, cigarillos, little cigars, chewing tobacco, snuff, snus, tobacco, pipe tobacco, roll-your-own tobacco, and dissolvables	Menthol cigarettes E-cigarettes/e-liquid	Menthol, mint, and wintergreen	Tobacco bars with ≥10% gross income from tobacco sales	Effective: July 2010 Enforcement: November 2010	Pre/Post Design (Farley & Johns 2017)	Sales: Flavored cigars dollar sales declined. Cigar dollar sales of non-flavored cigars increased. Youth Tobacco Use: Youth had lower odds of ever trying a flavored tobacco product and of ever using tobacco products.
						Pre/Post Design with Comparison (Rogers et al. 2017)	Sales: Overall cigar sales declined. Flavored cigar sales declined. Flavored cigar sales increased in comparison counties.
Providence, RI	Flavored tobacco products containing tobacco or nicotine, including but not limited to cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, bidis, snus, dissolvable tobacco products, and e-	Menthol cigarettes	Menthol, mint, and wintergreen	All smoking bars	Effective: January 2013	Pre/Post Design with Comparison (Rogers et al. 2020)	Sales: Decrease in flavored cigar sales. Decreases in overall cigar sales. Flavored cigar sales increased in the rest of the state.
						Post-only Design (Pearlman et al. 2019)	Youth Tobacco Use: Current youth use of any tobacco product declined.

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
	cigarette cartridges/e-liquid						Youth Cigar Use: Current youth use of cigars/cigarillos declined.
Lowell, MA	Flavored tobacco products, including but not limited to cigars, little cigars, chewing tobacco, pipe tobacco, snuff, e-cigarettes	Menthol cigarettes	Menthol, mint, and wintergreen	Adult-only (21+ years old) retail tobacco stores with ≥90% of sales from tobacco products	Effective: October 2016	Post-only Design with Comparison (Kingsley et al. 2019)	Youth Flavored Tobacco Use: Current youth use of any flavored tobacco products decreased in Lowell and increased in the comparison community, a statistically significant difference. Youth Non-Flavored Tobacco Use: Current youth use of any non-flavored tobacco products also decreased in Lowell and increased in the comparison community, a statistically significant difference.
Attleboro & Salem, MA	Flavored tobacco products, including but not limited to	Menthol cigarettes	Menthol, mint, and wintergreen	Adult-only (21+ years old) retail tobacco stores	Effective: Attleboro – January 2016	Pre/Post Design with Comparison	Youth Flavored Tobacco Use: Significantly smaller increases in current use of flavored

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
	cigars, little cigars, chewing tobacco, pipe tobacco, snuff, e-cigarettes			with ≥90% of sales from tobacco products Smoking bars	Salem - March 2017	(Kingsley et al. 2021)	in the municipalities with flavored tobacco restrictions than in the comparison. <u>Youth Non-Flavored Tobacco Use:</u> Significantly smaller increases in current use of non-flavored or menthol tobacco in the municipalities with flavored tobacco restrictions than in the comparison.
Minneapolis & St. Paul, MN	Flavored non-menthol tobacco products, including but not limited to smokeless tobacco, cigars, e-cigarettes	Menthol cigarettes	Menthol, mint, and wintergreen	Minneapolis: Adult-only (18 years and older) licensed tobacco product shops with ≥90%	Effective: Minneapolis – January 2016 St. Paul – April 2016	Pre/Post Design with Comparison (Olson et al. 2021)	<u>Sales:</u> Significant pre/post policy decreases were also observed in sales of cigars overall and flavored cigars in Minneapolis and St. Paul.

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
				revenue from sale of tobacco St. Paul: Adult-only (18 years and older) retail stores with ≥90% revenue from sale of tobacco		Pre/Post Design with Comparison (Olson et al. manuscript accepted)	Youth Cigar Use (6-12th grade students): Before and after the 2016 restriction on flavored tobacco products except menthol, mint, and wintergreen, cigar use did not change in the Twin Cities but increased in the rest of the state.
	Flavored tobacco products, including but not limited to cigarettes, smokeless tobacco, cigars e-cigarettes	None	None	Minneapolis: Sales of mint-, menthol-, and wintergreen-flavored tobacco products at adult only (21 years and older) liquor stores St. Paul: Sales of mint-, menthol-, and wintergreen-flavored tobacco	Effective: Minneapolis – August 2018 St. Paul – November 2018	Pre/Post Design with Comparison (Olson et al. manuscript accepted)	Youth Cigar Use (8,9,11th grade students): Before and after the 2018 restriction on flavored tobacco products including menthol, mint, and wintergreen, cigar use declined more in the Twin Cities compared to the rest of the state.

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
				products at liquor stores that also hold a license for tobacco sales			
San Francisco, CA[2]	Flavored e-cigarettes, menthol cigarettes, and other non-tobacco flavored tobacco products including cigars, cigarillos, and little cigars; hookah/waterpipe; and smokeless/dissolvable tobacco	None	None	None	Effective: July 2018 Enforcement: January 2019 Enforcement with routine retailer compliance inspections: April 2019	Post-only Design (Yang et al. 2020)	<u>Young Adult (18-24)</u> <u>Cigar Use:</u> Decrease in overall cigar use, but the decline was not statistically significant. Statistically significant decrease in flavored cigar use. <u>Young Adult (25-34)</u> <u>Cigar Use:</u> Decreases in overall cigar use and flavored cigar use, but the declines were not statistically significant.
						Pre/Post Design with Comparison (Gammon et al. 2021)	<u>Sales</u>: Statistically significant decreases in overall tobacco and flavored tobacco unit sales. The comparison cities had more modest decreases or did not significantly change.

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
Canada[3]	Non-menthol Policy: Non-menthol and clove flavor additives in cigarettes, blunt wraps, and cigars ≤1.4 grams or having a cigarette filter (April/July 2010) Non-menthol flavors in cigars weighing >1.4 grams and ≤6 grams with tipping paper or non-spiral wrapper (December 2015) Required unflavored cigarillos to be sold in packs of at least 20 units	Cigars weighing >6 grams Smokeless tobacco Waterpipe Pipe tobacco Heated tobacco Roll-your-own tobacco	Wine, port, whiskey and rum flavored cigars weighing >1.4 grams and ≤6 grams with spiral wrapper and no tipping paper in December 2015 Menthol until October 2017 Clove until November 2018	None	Effective: April 2010 at the manufacturer/importer level and July 2010 at the retail level	Pre/Post Design (Chaiton et al. 2019)	Sales: Decreases in overall cigar and flavored cigar sales. Increase unflavored cigars, but not a substantial increase.
						Pre/Post Design (Nguyen & Grootendorst, 2015)	Youth (15-24) Cigarillo Use: Decreases in past 30-day cigarillo use.
Ontario (Province)	Non-menthol Policy: Most non-menthol or clove flavored tobacco products Menthol Policy: Addition of menthol	Pipe tobacco other than waterpipe Cigars ≥6 grams with spiral wrapper	Wine, port, whiskey, and rum flavored cigars weighing >1.4 grams and ≤6 grams	None	Non-menthol Policy Effective: January 2016 Menthol Policy Effective: January 2017	Pre/Post Design (Chaiton et al. 2020)	Adult tobacco use: Daily and occasional menthol cigarette smokers at baseline (vs. non-menthol smokers) were more likely to use flavored cigar products

Jurisdiction	Tobacco Products Included in the Sales Restriction or Ban [1]	Excluded Products	Excluded Flavors	Retailer Exemptions	Effective and/or Enforcement Year	Study Design & Reference	Key Findings
	and clove tobacco products, including menthol cigarettes	and no tipping paper or filter Wine, port, whiskey, and rum flavored cigars weighing >1.4 grams and ≤6 grams with spiral wrapper, no tipping paper or filter	Menthol and clove until January 2017				after the policy. Occasional menthol cigarette smokers at baseline were more likely to use other tobacco products or flavored other tobacco products.

[1] Information about each flavored tobacco sales restrictions and bans were obtained from studies included in the Scientific Assessment as referenced.

[2] Of the various local flavored tobacco sales restrictions included in this review, San Francisco's flavored tobacco sales restriction is the only policy that is comprehensive – covering all tobacco products, including e-cigarettes, menthol/mint/wintergreen flavor, and with no retailer exemptions.

[3] "Vaping products" are not considered "tobacco products" in Canadian laws.