

FDA's Response to External Peer Review on The Scientific Assessment of the Impact of Flavors in Cigar Products, March 30, 2022

I. INTRODUCTION

FDA recently undertook a scientific assessment of the impact of flavors in cigar products. The completed scientific assessment document, entitled "Scientific Assessment of the Impact of Flavors in Cigar Products," presents a synthesis of scientific evidence regarding the role that characterizing flavors play in increasing the appeal and use of tobacco products, particularly cigars, among youth, young adults, and adults in the United States. FDA focused its review on the published literature from the past 10-15 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 were as follows: (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?; and (3) What impact do local policies restricting the sale of flavored cigars and other flavored tobacco products have on cigar sales and use?

Versar, Inc., an independent contractor, coordinated an external letter peer review of the scientific assessment document on the impact of flavors in cigar products. The peer review was conducted for FDA's Center for Tobacco Products. For this peer review, four experts were selected by Versar, Inc. to evaluate and provide written comments on the scientific support for FDA's conclusions in the scientific assessment document, additional publicly available information that should have been included in the assessment, and any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.

In Section II of this peer review response report, we list the charge questions given to the reviewers regarding the objective of the peer review and specific advice sought through the peer review. In Section III of this report, we provide a table containing the individual (anonymized) peer reviewers' comments along with FDA's responses to those comments, including either a description of any changes made to the scientific assessment document in response to peer reviewer comments or an explanation of our decision to not make suggested changes. We also provide an Appendix at the end of this report, providing itemized responses to a list of additional papers submitted by one of the peer reviewers.

Based on this external peer review, the scientific assessment document was updated where appropriate and subsequently finalized. The final version can be found at <https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews>.

Below are the names and affiliations of the peer reviewers:

Michael Chaiton, PhD

Centre for Addiction and Mental Health
University of Toronto

Rachel Denlinger, PhD

Wake Forest University

Andrew Hyland, PhD

Roswell Park Comprehensive Cancer Center

Shyanika W. Rose, PhD

University of Kentucky

II. CHARGE TO REVIEWERS

Charge Questions:

1. For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.
2. Are you aware of additional publicly available information that should have been included? If so, please specify what that information is and discuss its relevance to the scientific assessment.
3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.

III. FDA RESPONSES TO INDIVIDUAL REVIEWER COMMENTS

In the following sections, FDA's responses to individual comments from the reviewers are organized according to the sequence of the charge questions, i.e., general impressions followed by questions 1 through 3. Comments from all four reviewers were itemized and listed under each charge question.

The Scientific Assessment of the Impact of Flavors in Cigar Products

I. General Impressions		
REVIEWER	COMMENT	RESPONSE
Reviewer #1	The <i>Scientific Assessment of the Impact of Flavors in Cigar Products</i> is a comprehensive review of the available literature. Overall, the conclusions stated for each question are sound and supported by the presented evidence. The organizational structure of the document is appropriate and easy to follow. Many studies included in the current review report complex outcomes and analyses from longitudinal surveys with multiple age categories. In general, the review does a good job providing an appropriate level of detail and information about these complex studies.	We appreciate the reviewer’s support of the review.
Reviewer #1	The prevalence section at the beginning of the document highlights the importance of the three questions being examined in the current review. The disparities section emphasizes the need for policies targeting flavored combusted tobacco products, including cigars, to reduce commercial tobacco use among priority populations like Black and African American persons and members of the LGBTQ+ community. Including both behavioral outcome data and sales data provides converging evidence about the impact of flavored tobacco product restrictions or bans. The section about flavors in food science also contributed meaningful information about how youth and adults differ with respect to flavor appeal.	We appreciate the reviewer’s support of the review.
Reviewer #1	The review could be improved by adding more detail within the main text about the inclusion and exclusion criteria for studies rather than reporting this information exclusively in the appendices. For example, “studies employing exclusively animal models” should be excluded from the review based on the eligibility criteria listed in Appendix 1. However,	We revised the “Purpose and Scope” section to clarify the methodology used, which included both a structured quarterly database search, and complementary approaches, such as hand-searching reference lists, to fully capture the literature on abuse liability, health

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	<p>there is a subsection on abuse liability for Question 1 that includes studies with animal models. Are these animal studies part of the literature review or providing explanatory information? Additionally, figures displaying the article selection process for each question would also be useful to include.</p>	<p>effects, and evidence for other tobacco products where appropriate. The search terms outlined in the Scientific Assessment’s Appendix 1 only apply to the standardized quarterly search. Articles that did not meet the summarized inclusion/exclusion criteria, such as animal studies, may have been included if they were identified through our complementary search approaches.</p> <p>We decline to include figures displaying the article selection processes because we engaged in an iterative review (i.e., many searches over several years), making it impossible to estimate and report the total number of articles across each stage of the search and review process.</p>
Reviewer #1	<p>Finally, throughout the document there are often very long sentences and paragraphs. Many studies report multiple outcomes by flavored tobacco product use, overall tobacco use, cigar use by subtype, age category, etc., so I would recommend trying to simplify sentence structures and breaking up paragraphs to enhance readability. The positive spin to this critique is there is a substantial amount of evidence supporting regulations for flavored tobacco products, including cigars, presented in this review.</p>	<p>We edited text throughout the document to simplify sentence structure and break up paragraphs.</p>
Reviewer #2	<p>The overall impression of this information is that this is a rigorous literature review. Methodology for the review is appropriate and comprehensively included most relevant documents. The material for each section was presented clearly and comprehensibly. The documents show that the addition of flavors to tobacco products including cigars can reinforce the effects of nicotine, can increase abuse liability, that flavors</p>	<p>We appreciate the reviewer’s support of the review.</p>

I. General Impressions		
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	appeal to youth and that this is consistent with the role of flavors in food. The document also shows that flavors are a reason for youth to start using cigars, and are associated with progression to regular use and nicotine dependence.	
Reviewer #2	The document also presents data from evaluations of local restrictions. The soundness of the conclusions would also be improved by a specific section for a discussion on enforcement and compliance. The effectiveness and impact of a ban will rely on enforcement and compliance and consequently, this should be highlighted and evaluated carefully to make recommendations for policy.	When such information was available in the literature, we added information related to retailer compliance with flavored tobacco product policies for each jurisdiction with policy evaluation studies. We added several references to support these additions (Kingsley et al. 2020; Pearlman et al. 2019; Kingsley et al. 2019; D’Silva et al. 2021; Brock et al. 2019; Bosma et al. 2021; Vyas et al. 2020; Kephart et al. 2020; Borland et al. 2017; Jo et al. 2015; Kurti et al. 2020; Farley et al. 2020; Czaplicki et al. 2019; Schroth et al. 2021). Since the impact of flavored tobacco product restrictions depends on the level of enforcement and compliance with these policies, we also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings.
Reviewer #2	Most conclusions for each document and the underlying data were sound. However, the primary overall concern is the conflation of three different definitions of flavors. While concept flavors are discussed, the issue is broader and affects all sections. Flavors can be characterizing, ingredients (which could, but not necessarily, lead to a characterizing flavor) or labelled. Each of the studies included may be responsive to one or two of these definitions, but not necessarily characterizing flavors.	The reviewer suggested we include the definition for flavor used by each study cited in the Scientific Assessment, noting there are several ways in which flavors have been defined. We agree that researchers have used all the criteria described by the reviewer to define and classify flavors in tobacco products. Most surveys, including those cited in the Prevalence of Cigar

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	<p>The definitions used by each study are needed and the conclusions associated with that definition.</p>	<p>Use sections, assess respondents’ self-reported use or appeal of flavors.</p> <p>Participants’ self-reports may be influenced by any or all these criteria and survey items may not align cleanly with researchers’ conceptualizations of flavors. We note these points in a new subsection added to the Prevalence section on Methodological Considerations.</p> <p>For studies in the Local and National Policy Evaluation section in which researchers categorized the flavors of cigar products, we noted the criteria researchers used to do so. For example, we now describe how several local policy evaluation studies used Universal Product Code (UPC) data to categorize flavor.</p> <p>Overall, evidence suggests flavors are appealing to users regardless of whether the flavor information is conveyed implicitly or explicitly, and FDA does not expect there to be meaningful differences across definitions in the observed patterns of flavor appeal and use. As we note in the Scientific Assessment, the chemical flavor profiles of concept flavored and explicitly flavored tobacco products are similar (Farley et al., 2018). Colors on packaging and flavor descriptions on concept flavors often make it easy for users to attribute a flavor to the product (Delnevo, Jeong, Ganz, et al., 2021; Viola et al., 2016), and users’ perceptions of flavors are influenced by their sensory experience and other factors beyond packaging or marketing materials (Rose et al., 2020).</p>

I. General Impressions		
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Reviewer #3	<p>Overall, the review accurately presents the information of <i>reviewed</i> studies and the conclusions are largely in line with my own reading of the literature. Conclusions that flavors in cigars contribute to appeal, initiation, and experimentation and that flavor restrictions on cigars lead to reductions in sales and youth use are generally well supported. In particular, the review of the evaluation literature on flavor policies in various localities is thorough and does a good job of pointing out study limitations given the wide heterogeneity in this literature. However, as a comprehensive review of the published literature in this area there are some significant gaps in the review as detailed extensively below. Inclusion of missing studies and newer studies would strengthen the conclusions of this document. Lack of inclusion of these studies makes the evidence base weaker than would otherwise be the case.</p>	<p>We appreciate the reviewer’s support of the conclusions drawn from the review. In response to the reviewer’s suggestion to add additional studies to strengthen our conclusions, we reviewed each suggested reference, added the majority of them, and in the Appendix of this response document, we provide an article-specific rationale for our decision whether or not to add the reference.</p>
Reviewer #3	<p>Overall changes that would strengthen the document include the following. Where possible, young adults should be separated out from youth and adults 25+. It would be clearer to understand use patterns if data on use patterns over time by age and race/ethnicity was included as graphs rather than just including prevalence estimates from the most current data wave. Cigar use appears to be increasing over time which is not easily determined from the cross-sectional data. A more nuanced discussion of disparities in cigar use could include literature on gender, mental health, substance use, and medical co-morbidities and a broader discussion of differences by race/ethnicity beyond Black/White differences would provide a fuller picture of the potential health equity impacts of a flavored cigar ban. Where possible, more data on cigar cessation patterns over time would be useful. Discussion of flavored blunt use is missing. The discussion of ‘concept flavors’ should be incorporated into the main document as this is likely to be a significant</p>	<p>In response to the reviewer’s suggestion to report separate estimates for youth, young adults, and adults aged 25 and over, we revised the adult prevalence section to include separate prevalence estimates for young adults and adults. We also revised Questions 1 and 2 so that all results from studies are reported for youth, young adults, and adults sequentially. We also specified the age of adult participants (e.g., 18+) for each study cited.</p> <p>In response to the reviewer’s suggestion to graph patterns over time, we revised Appendices 2 and 3 in the Scientific Assessment to provide prevalence estimates for each wave of the PATH study by race/ethnicity and age. We now also include National Survey on Drug Use and Health (NSDUH) in the adult prevalence section to</p>

I. General Impressions		
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	<p>area where implementation of flavored cigar bans will face challenges in practice. Finally, the impacts of flavored cigar bans should be clearly noted in relation to the comprehensiveness of flavor policies and the extent of compliance with implementation. Additional specific recommendations are listed below.</p>	<p>illustrate trends over time which suggest that cigar use prevalence in adults has been relatively stable between 2011 to 2019. We also include a recent publication (Delnevo et al., 2021) on trends in flavored cigar sales over time which increased between 2009 and 2020. We discuss this study in the section on concept flavors in cigars.</p> <p>We did not identify additional citations regarding cigar cessation, so we did not add information on this topic.</p> <p>Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for blunting is beyond the scope of the Scientific Assessment.</p> <p>The reviewer suggested a more nuanced discussion of disparities in cigar use. We expanded our discussion of disparities in cigar use among youth to include additional literature (including references recommended by reviewers) on sexual and gender minorities and</p>

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		<p>individuals with poor mental health. We also added several citations to the Disparities in Cigar Use Among Adults section, particularly related to physical and mental health, transgender individuals, LGBT+ individuals, and intersectionality.</p> <p>In response to the request to move concept flavors to the main document, we moved our prior discussion of concept flavors from Appendix 2 to the main Scientific Assessment document. We also introduce and define the term “concept flavors” in the Purpose and Scope section.</p> <p>Regarding the request for more discussion of the comprehensiveness of flavor policies, we expanded Appendix 6 to include information that reflects the comprehensive of the policies. We now list the tobacco products restricted by each policy and any policy exemptions (e.g., products, flavors, and types of retailers that were exempt). We also highlighted in the text and added as a footnote that San Francisco’s flavored tobacco sales restriction is the only policy included in this review that covers all tobacco product categories, including e-cigarettes, and all non-tobacco flavors, including menthol, mint, and wintergreen flavors, and with no retailer exemptions. We also added a discussion of compliance and enforcement to the text to provide context for evaluation findings.</p>
Reviewer #4	Overall, the literature review presents accurate, timely, and wide-reaching evidence that flavored cigars are commonly used, that they are	We appreciate the reviewer’s support of the review.

I. General Impressions		
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	appealing to young people, that flavors are one of the main reasons those products are appealing to young people, and that community interventions to restrict or eliminate flavored cigars have been effective to reduce the appeal and use of these products especially to young people. The conclusions in the literature review are supported by the data presented, and the data is presented in a fair and objective manner.	
Reviewer #4	<p>There are three points that I believe were not adequately addressed, which serve to underestimate the adverse public health impact of flavored cigars. These include:</p> <ul style="list-style-type: none"> • Studies that do not assess the use of different types of cigars may be systematically underestimating cigar use compared to studies that do. In order to assess the prevalence of each type of cigar, studies should make use of both pictures and descriptive text. More details could be provided in the literature review on these measurement issues. 	<p>We added a table in Appendix 4 of the Scientific Assessment describing key methodological details of all cited national surveys, as well as a new Methodological Considerations subsection to the Prevalence section describing the points that the reviewer raises.</p> <p>Information in the table of methodological details includes which cigar subtypes were assessed by the cigar items and whether images were included in the instructions to participants. The purpose of this table is to serve as context that can be taken into consideration when interpreting the estimates reported in the Assessment.</p>
Reviewer #4	<ul style="list-style-type: none"> • The use of cigars for the purpose of blunts was generally not considered in this review. Exclusive blunt use is more than a trivial behavior and by not including it in the review the scope of cigar use in the population is systematically underestimated. 	<p>Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the</p>

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		interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for blunting is beyond the scope of the Scientific Assessment.
Reviewer #4	<ul style="list-style-type: none"> More careful attention to studies that examine ‘youth’ cigar use should be taken to define ‘youth’ as those 20 years of age and younger because in today’s regulatory environment, nationally it is illegal to sell tobacco products to those under the age of 21. Failure to consider those under 21 years of age as ‘youth’ systematically underestimates the scope of underage cigar use. 	<p>We used the term “youth” in the Scientific Assessment to define the developmental period that precedes adulthood, with most literature using a cut-off around age 18 or at the end of high school. In the Assessment, we report the age categories designated by the authors and no relevant studies categorized individuals using an age of 21 as the cut-off. Therefore, we do not include prevalence estimates for “aged 20 and under” as a group. However, young adulthood, including those aged 18-20 years, is among the most common life stages for cigar initiation and this age group has access to cigars despite being younger than the legal purchase age through underage sales, friends, and other sources (e.g., Dai, Hao, & Catley, 2020; Trapl et al., 2017). Therefore, any regulatory actions related to flavored cigar products would be expected to influence use of these products among aged 18-20-year-olds by cutting off access to their sources, particularly underage sales.</p> <p>We added a new “Age of Initiation” subsection to the Youth Prevalence section that describes ages of initiation, including initiation among those aged 18-20. In that section, we also note the differences in</p>

I. General Impressions		
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		categorization approaches and implications for prevalence estimates.
Reviewer #4	<p>None of these issues detracts from the conclusions made in the report, but rather addressing these points should lend even greater support to those conclusions.</p> <p>In addition to the comments above, several comments are provided to improve the flow and clarity of the literature review including providing more evidence on the health risks from cigar smoking, defining ‘characterizing flavor’, and presenting the literature on relevant cigar use progression transition points more clearly, among other feedback provided elsewhere.</p>	<p>We made several revisions to the Scientific Assessment, including a new section on the health risks of cigar use and a definition of flavors in both the Purpose and Scope and Question 1 sections. We also reorganized Questions 1 and 2 to better reflect the cigar use progression transition points (e.g., appeal, initiation, progression to regular use).</p> <p>This summary is a compilation of studies that may have defined ‘characterizing flavor’ in a variety of ways. We now include a footnote in the Purpose and Scope section to clarify our use of terms including ‘characterizing flavor,’ ‘explicit flavor,’ and ‘concept flavor’ and that we are deferring to the methodology of the study’s definition.</p>

II. Response to Charge Questions

CHARGE QUESTION 1. *For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.*

REVIEWER	COMMENT	RESPONSE
Reviewer #1	<p>Question 1: How Does the Addition of Characterizing Flavors to Tobacco Products, Including Cigars, Impact Product Appeal and Product Use? – The conclusions that characterizing flavors in tobacco products increases appeal and ease of use, especially among youth, is supported by the literature reviewed in this section. This section had an exhaustive review of the literature ranging from qualitative research to nationally-representative longitudinal surveys. Clinical research supports the conclusion that flavors contribute to increased abuse liability for tobacco products. In focus groups, youth often cite flavors as appealing and the reason for use. Analyses from the PATH survey found that flavors are the primary reason youth use cigars. Finally, four systematic reviews also report that flavors are appealing to youth and contribute to experimentation and progression to regular use. Overall, the review appropriately concludes that flavors in tobacco products appeal to youth.</p>	We appreciate the reviewer’s support of the review.
Reviewer #1	<p>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? – The conclusion that characterizing flavors are associated with increased likelihood of experimentation and progression to regular use is supported by the literature reviewed in this section. Two qualitative studies and one systematic review highlight the appeal of flavors among youth and young adults who use cigars. Several strong, longitudinal studies using nationally-representative samples find that</p>	We appreciate the reviewer’s support of the review.

CHARGE QUESTION 1. For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.		
REVIEWER	COMMENT	RESPONSE
	experimentation with flavored tobacco products is associated with subsequent tobacco use. Evidence also suggests that experimenting with cigars can lead to nicotine dependence, which is associated with sustained tobacco use.	
Reviewer #1	Question 3: What Impact Do Local Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products Have on Cigar Sales and Use? – The conclusion that sales of flavored cigars and cigars overall decreased after flavored tobacco restrictions or bans is supported by the literature. This section reviewed sales data after flavored tobacco policy implementation in several municipalities in the US and Canada. Most studies reported significant reductions in sales of flavored tobacco products, including cigars; however, some studies observed increases in concept flavor sales following the flavored tobacco restrictions or bans, indicating some product switching.	We appreciate the reviewer's support of the review, and we agree with the reviewer's summary of the evidence in the Scientific Assessment regarding concept flavors.
Reviewer #1	The conclusion that reductions in youth use of flavored tobacco products also decreases after flavored tobacco restrictions or bans is also supported by the literature. Most studies across jurisdictions with flavored tobacco restrictions or bans (NYC, Providence, Lowell, Minneapolis, St. Paul and Canada) reported decreases in youth use after the ban. However, evidence from San Francisco suggests potential product substitution among youth after banning flavored tobacco products. Friedman, 2021 reported increases in cigarette smoking among high school students in San Francisco post-ban. Importantly, the study does not report changes in flavored tobacco use or overall tobacco use, so caution should be used when interpreting these findings with respect to tobacco use behavior among youth.	We expanded on the discussion of the limitations of the Friedman (2021) study and now include findings from another study (Liu et al., 2022) that reported a methodological mistake in the Friedman (2021) findings. Liu et al. (2022) reported that the 2019 YRBS was conducted in Fall 2018 prior to when the San Francisco flavor policy was enforced in April 2019 and indicating that the Friedman (2021) analysis was a pre-only design. Given this, findings from Friedman (2021) do not reflect the impact of San Francisco's flavored tobacco sales restriction on youth cigarette use.

CHARGE QUESTION 1. For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.		
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Reviewer #2	<p>Overall, the conclusions of each of the sections were scientifically supported with the following exceptions below.</p> <p>The document across all of the sections, even including the section on concept flavors, uses characterizing flavors to describe these. Generally, pre-clinical studies assess ingredients and other types of studies vary. For instance, Chaiton (2018) assessed labelled flavor, not ingredients or presence of characterizing flavor. Or on page 155, tobacco flavored Black and Milds may still have non-characterizing flavor ingredients, but are unlabeled. Relatedly on page 12, for ENDS tobacco flavored are flavored—i.e., have flavor ingredients. For appendix 2, reference to concept flavor can also include the experience in Ontario, in which alcohol labels were used as concept flavors (i.e., wine replacing berry labelling) (Chaiton 2018). I would recommend that the definition of characterizing flavors, ingredients, and labelled flavor be provided upfront and be clear for each identified study which is being assessed or discussed. Conclusions may depend upon these definitions</p>	<p>We revised the Purpose and Scope section and added a footnote to clarify our use of terms including ‘characterizing flavor,’ ‘explicit flavor,’ and ‘concept flavor,’ and to specify that we defer to the cited studies’ definitions of flavored tobacco products, which varied and did not always align directly with these definitions. Most survey results described in the Prevalence section do not align precisely with the definitions used by researchers, and we note this point in a new subsection titled “Methodological Considerations.”</p> <p>In the remaining sections of the Assessment, for studies that distinguished between explicit and ambiguous flavor names (i.e., concept flavors), we explained the criteria that researchers used to categorize flavors in greater detail. For studies in which researchers categorized the flavors of cigar products based on descriptors or labels, we note the criteria researchers used to do so. For example, we now provide a fuller description of the methods researchers used to assess flavor in Chaiton (2019) and clarified the qualitative study approach of Antognoli et al. (2018) regarding respondent perceptions of Black and Mild. In addition, in the section where we discuss systematic review findings that includes a discussion of ENDS, we now describe findings as provided in the referenced articles that compare non-flavored and tobacco-flavored ENDS to other flavors. In the sections on local policies restricting</p>

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		<p>the sales of flavored tobacco products (Question 3), we included evidence, when available, of the effects of restrictions on concept flavors specifically.</p> <p>Although concept flavors may raise unique considerations related to policy compliance and enforcement, evidence suggests flavors are appealing to users regardless of whether the flavor information is conveyed implicitly or explicitly, and FDA does not expect there to be meaningful differences across definitions in the conclusions drawn in the Scientific Assessment about the appeal and use of flavored cigars. As we note in the Scientific Assessment, the chemical flavor profiles of concept flavored and explicitly flavored tobacco products are similar (Farley et al., 2018). Colors on packaging and flavor descriptions on concept flavors often make it easy for users to attribute a flavor to the product (Delnevo, Jeong, Ganz, et al., 2021; Viola et al., 2016), and users’ perceptions of flavors are influenced by their sensory experience and other factors beyond packaging or marketing materials (Rose et al., 2020).</p>
Reviewer #2	For Question 2, page . 19 on the discussion of attention and impulsivity, data on the familial confounding can be cited. For instance: Skoglund C, Chen Q, D’ Onofrio BM, Lichtenstein P, Larsson H. Familial confounding of the association between maternal smoking during pregnancy and ADHD in offspring. Journal of Child Psychology and Psychiatry. 2014 Jan;55(1):61-8.	We included the article suggested by the reviewer as an example of unmeasured confounding in the section describing the relation between nicotine and attention and impulsivity changes among adolescents.

CHARGE QUESTION 1. For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.		
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Reviewer #3	<p>Conclusions for question 1 and 2 are supported but I suggest breaking out conclusions by youth vs. young adults. Flavors are also used to appeal to young adults and the evidence for this should be separated out from the youth data. The conclusions also state that adolescence is a critical time period for tobacco use experimentation which is true but initiation of tobacco use and experimentation is increasingly moving into the young adult years. This is particularly true for African American young adults who disproportionately use flavored cigars. For this group young adulthood is a time when lower youth substance use patterns “cross over” to higher use prevalence compared with White tobacco users (e.g., Watt, 2008 The race/ethnic age crossover effect in drug use and heavy drinking. <i>Journal of Ethnicity in Substance Abuse</i>). Additional discussion of young adulthood as a time of initiation/experimentation would strengthen this conclusion, particularly in relation to disparities.</p>	<p>The reviewer suggests separating the youth and young adult evidence for Questions 1 and 2. For all studies cited in these sections, we specified the age of participants, and for studies that included more than one participant age group, we report results sequentially, beginning with youth.</p> <p>The reviewer also notes that initiation of tobacco use is prevalent in young adulthood, especially for African American young adults, and the discussion of initiation during young adulthood should be expanded. In response, we added a new subsection titled “Age of Initiation” to the Youth Prevalence section. We also provide separate prevalence estimates for both young adults aged 18-24 and adults aged 25 and over in the Adult Prevalence section, given that the patterns for young adults often differ from the patterns for adults aged 25 and over. In the Adult Disparities section, we specify age categories for every racial/ethnic comparison.</p> <p>Although the cross-over patterns that the reviewer notes have been observed for several drugs and alcohol, and for cigarettes, we are not aware of studies demonstrating such a pattern for cigars specifically, so we have not added citations for this topic.</p>
Reviewer #3	<p>Conclusions for question 3 are supported but rely on a limited evidence base – additional potentially relevant papers are listed below. The</p>	<p>In response to the reviewer’s suggestion to expand the evidence described in Question 3, we added literature</p>

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	<p>studies included discuss reduced sales and reduced youth use, but omit papers on reduced retail availability (i.e., retail compliance papers) and policy impact on reduced flavored advertising. As this is a fast-moving area, continuing to monitor the literature will be critical. Additionally, the paper on modeling the effects of this policy (pages 35-36) should be reviewed in more detail to actually detail the main morbidity and prevalence reduction estimates from this study (i.e., number of reduced deaths, number of fewer cigar smokers). The San Francisco studies should also be more clearly noted as the impact of a comprehensive flavor ban and not simply a ban on flavored cigars. For instance, the potential substitution effect with smoking in the Friedman 2021 by the author’s own discussion is likely due to the inclusion of flavored vape products not because of a ban on flavored cigars. Additionally, San Francisco also banned all e-cigarette sales in 2019 with enforcement starting Jan 29 2020 which may have had some effects beyond flavor restrictions. While there is likely to be substitution with existing (non-banned) products, the conclusion is based specifically on San Francisco data and should have these caveats or should be broadened.</p>	<p>on retailer compliance with flavored tobacco product policies when available for each jurisdiction that had a policy evaluation study (e.g., Kingsley et al. 2020; Pearlman et al. 2019; Kingsley et al. 2019; D’Silva et al. 2021; Brock et al. 2019; Bosma et al. 2021; Vyas et al. 2020; Kephart et al. 2020; Borland et al. 2017; Jo et al. 2015; Kurti et al. 2020; Farley et al. 2020; Czaplicki et al. 2019; Schroth et al. 2021). We also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings. We added available findings regarding the indirect effects of flavored tobacco product restrictions on the prevalence of advertising/marketing of flavored tobacco products when discussing evaluation findings for each jurisdiction (e.g., Brock et al. 2019; D’Silva et al. 2021; Usidame et al. 2019).</p> <p>We revised the language describing the San Francisco policy to emphasize it was a flavor ban that included menthol and all tobacco products, including e-cigarettes rather than just a sales restriction on flavored cigars. We also expanded Appendix 6 to include, for additional context on each policy discussed in the Scientific Assessment, information regarding: tobacco products restricted; excluded products; excluded flavors; and retailer exemptions.</p>

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REVIEWER	COMMENT	RESPONSE
		We also revised the Public Health Impact Assessment section to include additional information on the outcomes from the modeling studies that are cited.
Reviewer #4	<p>Yes, each section of the literature on flavored cigars was thorough and had conclusions that were supported by the studies described in the report. If anything, I believe the literature review is conservative with its conclusions because it does not consider the following three points in sufficient detail:</p> <ul style="list-style-type: none"> • <i>Type of Cigar.</i> Studies that do not assess the use of different types of cigars may be systematically underestimating cigar use compared to studies that do. In order to assess the prevalence of each type of cigar, studies should make use of both pictures and descriptive text. More details could be provided in the literature review on these measurement issues. 	We appreciate the reviewer’s support of the conclusions drawn in the Scientific Assessment. The reviewer suggested greater attention be given to the type of cigar when describing use patterns. In response, we added several estimates for each cigar type to the Youth and Adult Prevalence sections. We also added a table summarizing the methodological details of all national surveys that we cite, including whether cigar subtypes were assessed, and added a new subsection titled “Methodological Considerations” in which we note the importance of variability across cigar subtypes.
Reviewer #4	<ul style="list-style-type: none"> • <i>Blunts.</i> The use of cigars for the purpose of blunts was generally not considered in this review. Exclusive blunt use is more than a trivial behavior and by not including it in the review the scope of cigar use in the population is systematically underestimated. 	Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for

CHARGE QUESTION 1. For each section that you reviewed, were the conclusions scientifically supported given the available evidence? If not, provide specific examples as to where conclusions are not supported.		
REVIEWER	COMMENT	RESPONSE
		blunting is beyond the scope of the Scientific Assessment.
Reviewer #4	<ul style="list-style-type: none"> Define ‘youth’ as under 21. More careful attention to studies that examine ‘youth’ cigar use should be taken to define ‘youth’ as those 20 years of age and younger because in today’s regulatory environment, nationally it is illegal to sell tobacco products to those under the age of 21. Failure to consider those under 21 years of age as ‘youth’ systematically underestimates the scope of underage cigar use. 	<p>We used the term “youth” in the Scientific Assessment to define the developmental period that precedes adulthood, with most literature using a cut-off around age 18 or at the end of high school. In the Assessment, we report the age categories designated by the authors and no relevant studies categorized individuals using an age of 21 as the cut-off. Therefore, we do not include prevalence estimates for “aged 20 and under” as a group. However, young adulthood, including those aged 18-20 years, is among the most common life stages for cigar initiation and this age group has access to cigars despite being younger than the legal purchase age through underage sales, friends, and other sources (e.g., Dai, Hao, & Catley, 2020; Trapl et al., 2017). Therefore, any regulatory actions related to flavored cigar products would be expected to influence use of these products among aged 18-20-year-olds by cutting off access to their sources, particularly underage sales.</p> <p>We added a new “Age of Initiation” subsection to the Youth Prevalence section that describes ages of initiation, including initiation among those aged 18-20. In that section, we also note the differences in categorization approaches and implications for prevalence estimates.</p>

CHARGE QUESTION 2. Are you aware of additional publicly available information that should have been included? If so, please specify what that information is and discuss its relevance to the scientific assessment.		
REVIEWER	COMMENT	RESPONSE
Reviewer #1	<p>There are publications about retailer compliance for selling and advertising flavored and menthol tobacco products after flavored tobacco policy restrictions in Minnesota and Massachusetts that could be included under Question 3. Although the studies do not report explicit sales figures for cigar products, they report observed changes in product availability in retail stores in the affected jurisdictions. According to the study eligibility criteria listed in Appendix 1, retailer compliance studies are not explicitly excluded from the review. However, if such studies are not appropriate for inclusion in this review, then the eligibility criteria should be revised accordingly.</p>	<p>We added findings on retailer compliance with flavored tobacco product policies when available for each jurisdiction with policy evaluation studies (e.g., Kingsley et al. 2020; Pearlman et al. 2019; Kingsley et al. 2019; D’Silva et al. 2021; Brock et al. 2019; Bosma et al. 2021; Vyas et al. 2020; Kephart et al. 2020; Borland et al. 2017; Jo et al. 2015; Kurti et al. 2020; Farley et al. 2020; Czaplicki et al. 2019; Schroth et al. 2021). We also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings.</p>
Reviewer #1	<p>D’Silva et al., 2021 examined sales restrictions for menthol tobacco products in four Minnesota cities (Minneapolis, St. Paul, Duluth, and Falcon Heights). The authors used the Standardized Tobacco Assessment for Retail Settings (STARS) tool to examine sales and advertising of menthol tobacco products in retail stores. They assessed compliance rates of stores in cities with menthol tobacco policies versus comparison cities without menthol tobacco restrictions. They found significant reductions in the availability of menthol tobacco products across grocery/convenience stores and gas stations.</p> <p>D’Silva J, Moze J, Kingsbury JH, et al. Local sales restrictions significantly reduce the availability of menthol tobacco: Findings from four Minnesota cities. <i>Tobacco Control</i> 2021;30:492-497.</p>	<p>We added this study to the discussion of flavored tobacco sales restriction evaluation studies in Minneapolis and St. Paul, Minnesota. We also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings and cited this study as evidence of high rates of retailer compliance after policy implementation.</p>

CHARGE QUESTION 2. Are you aware of additional publicly available information that should have been included? If so, please specify what that information is and discuss its relevance to the scientific assessment.		
REVIEWER	COMMENT	RESPONSE
Reviewer #1	<p>Brock et al., 2019 examined sales restrictions for flavored tobacco products in Minneapolis and St. Paul. They found reductions in the availability of flavored tobacco products in retail stores with youth-access but the proportion of unflavored tobacco products increased after the policy.</p> <p>Brock B, Carlson SC, Leizinger A, <i>et al.</i> A tale of two cities: Exploring the retail impact of flavoured tobacco restrictions in the twin cities of Minneapolis and Saint Paul, Minnesota. <i>Tobacco Control</i> 2019;28:176-180.</p>	<p>We added this study to the discussion of flavored tobacco sales restriction evaluation studies in Minneapolis and St. Paul, Minnesota. We also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings and cited this study as evidence of high rates of retailer compliance after policy implementation.</p>
Reviewer #1	<p>Kephart et al., 2020 examined sales restrictions for flavored tobacco products in Boston, Massachusetts. They found most retailers were compliant and access to flavored tobacco products in youth-accessible stores declined significantly after the policy</p> <p>Kephart L, Setodji C, Pane J, <i>et al</i> Evaluating tobacco retailer experience and compliance with a flavoured tobacco product restriction in Boston, Massachusetts: Impact on product availability, advertisement and consumer demand. <i>Tobacco Control</i> 2020;29:e71-e77.</p>	<p>We created a new Limitations section as part of Question 3 that includes enforcement and compliance as a consideration when interpreting policy evaluation findings. We cite Kephart et al. (2020) as evidence of high rates of retailer compliance after policy implementation.</p>
Reviewer #2	<p>Bosma LM, D'Silva J, Moze J, Matter C, Kingsbury JH, Brock B. Restricting Sales of Menthol Tobacco Products: Lessons Learned from Policy Passage and Implementation in Minneapolis, St. Paul, and Duluth, Minnesota. <i>Health Equity</i>. 2021 Jun 1;5(1):439-47.</p> <p>This paper assesses implementation challenges from Minnesota.</p>	<p>We added this study to the discussion of flavored tobacco sales restriction evaluation studies in Minneapolis and St. Paul, Minnesota. We also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings and cited this study as</p>

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REVIEWER	COMMENT	RESPONSE
		evidence of high rates of retailer compliance after policy implementation.
Reviewer #2	<p>Chaiton M, Schwartz R, Cohen JE, Soule E, Zhang B, Eissenberg T. Prior Daily Menthol Smokers More Likely to Quit 2 Years After a Menthol Ban Than Non-menthol Smokers: A Population Cohort Study. <i>Nicotine & Tobacco Research</i>. 2021 Mar 10.</p> <p>Two year data with 6 month abstinence quit definition of effects in Ontario for cigarette but also shows the impact of substitution of other flavored products on likelihood of quit success.</p>	We added this study to the discussion of the effects of Canada’s flavored tobacco policy.
Reviewer #2	<p>Chaiton MO, Schwartz R, Cohen JE, Soule E, Zhang B, Eissenberg T. The use of flavor cards and other additives after a menthol ban in Canada. <i>Tobacco control</i>. 2021 Sep 1;30(5):601-2.</p> <p>Assesses impact of availability of flavor cards (and other menthol additives) on successful quitting after the ban in Ontario. Flavor cards can also be used for other tobacco products particularly waterpipe.</p>	We discuss the potential for tobacco product substitution in the Implications for Tobacco Product Substitution section. Given that the suggested reference does not have cigar-specific outcomes, we did not add this reference to the Scientific Assessment.
Reviewer #2	Denlinger-Apte RL, Cassidy RN, Carey KB, Kahler CW, Bickel WK, O’Connor R, Thussu S, Tidey JW. The impact of menthol flavoring in combusted tobacco on alternative product purchasing: A pilot study using the Experimental Tobacco Marketplace. <i>Drug and Alcohol Dependence</i> . 2021 Jan 1;218:108390.	We added an additional subsection under Question 2 titled “Evidence from Hypothetical Scenario Studies.” We include this reference in that section.

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REVIEWER	COMMENT	RESPONSE
	Experimental marketplace study showing that menthol little cigars and vapes were significant substitutes.	
Reviewer #2	<p>Borland T, Dubray J, Chaiton M, Schwartz R. Monitoring and Evaluating Ontario's New Tobacco Policy Measures: Flavored Tobacco Prohibition. Toronto, ON: Ontario Tobacco Research Unit, September 2017. Available at: https://otru.org/wp-content/uploads/2017/08/special_nm_flavors_2017.pdf</p> <p>Report on the implementation of the flavored cigar ban. Includes assessment of challenges such as relabeling, new products that attempt to find exemptions, and products that are not marked as flavored but appear to be. Also shows lack of public awareness and challenges in enforcement.</p>	We added an overall discussion of enforcement and compliance to the limitations section of Question 3. The limitations should serve as a consideration when interpreting policy evaluation findings. We cited this report to describe high rates of retailer compliance after policy implementation in Canada.
Reviewer #2	<p>Silver KK, Hiscock R. Tobacco industry tactics to circumvent and undermine the TPD menthol ban in the UK. Tobacco Prevention & Cessation. 2020 Oct 22;6(Supplement).</p> <p>Branston JR, Hiscock R, Silver K, Arnott D, Gilmore AB. Cigarette-like cigarillo introduced to bypass taxation, standardized packaging, minimum pack sizes, and menthol ban in the UK. Tobacco Control. 2021 Nov 1;30(6):708-11.</p> <p>These two papers include assessment of the use of menthol flavored cigarillos to circumvent the menthol tobacco ban.</p>	We added these references to Question 3 in the "Tobacco Product Substitution" subsection.
Reviewer #3	<p>1. Additional potential references are shown below (but are not comprehensive). General types of missing information are listed.</p>	We added most of the additional references suggested by peer reviewers. In the Appendix of this response

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REVIEWER	COMMENT	RESPONSE
		document, we provide an article-specific rationale for our decision whether or not to add the reference.
Reviewer #3	2. The focus on only use estimates from the current waves of PATH, NYTS, NSDUH and other national datasets obscures changes over time from recent prior waves especially in longitudinal datasets. Including discussion of the data on cigar and flavor use from prior waves would help to highlight how both the policy environment, secular trends, and changes in the tobacco product marketplace may influence flavor use and cigar use more broadly and provide a fuller picture of how these elements may be changing. Additionally, in addition to a table in appendix 5, a graph of the PATH study prevalence estimates over time would be helpful.	<p>We added additional information in the youth and adult prevalence sections to describe trends from prior waves of NYTS and NSDUH. We revised Appendices 2 and 3 to provide prevalence estimates for each wave of the PATH Study. We also include a recent publication (Delnevo et al., 2021) on trends in flavored cigar sales over time which increased between 2009 and 2020. We discuss this study in the section on concept flavors in cigars.</p> <p>In response to the reviewer’s suggestion of a graph, we updated estimates in Appendices 2 and 3 to reflect prior waves of the PATH Study but not additionally provided in graphs.</p>
Reviewer #3	3. Additionally, papers on any tobacco use that separate out flavor use or use patterns by product (including cigar use) are generally not included and could provide good information on cigar use patterns. They should also be used to compare with other tobacco products, since cigars are more likely to be flavored than other products like cigarettes, but less likely than products such as hookah or e-cigarettes.	We added the following sentence to the youth prevalence section to provide information about flavor use with other tobacco products for comparison: “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).”
Reviewer #3	4. Papers on cigar use appeal more broadly should be reviewed – many of these include discussion of flavors.	We reviewed our search terms and re-ran our search to identify any additional papers on cigar use appeal that

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REVIEWER	COMMENT	RESPONSE
		<p>were published recently and not originally included in the Scientific Assessment. We identified one new article (below) and now cite in the Perceived Harm section of Question 1.</p> <p>Dunn, D. S., Johnson, A. L., Sterling, K. L., & Cohn, A. M. (2021). Differences in reasons for little cigar/cigarillo use across white and black/African American young adult users. <i>Addictive behaviors</i>, 118, 106884.</p>
Reviewer #3	<p>5. Including data on race/ethnicity beyond Black non-Hispanic and White non-Hispanic would be useful – these data should exist in the papers already cited. Additionally, where possible disaggregating data for Asian and Hispanic populations is useful. For example, while overall use rates for Asians may be low, use is higher for Filipinos and for those of more than one race. Even if these data do not show higher use rates for some groups it would be good to have a sense of how a flavored cigar policy may affect all sub-populations.</p>	<p>We added additional prevalence data pertaining to Hispanic and Asian populations, including results from studies that disaggregated Asian subgroups.</p>
Reviewer #3	<p>6. Studies of local evaluations of flavored cigar restrictions can be linked to information in the Truth Initiative flavored policy database to have a better comparison between the comprehensiveness of policies https://truthinitiative.org/research-resources/emerging-tobacco-products/local-restrictions-flavored-tobacco-and-e-cigarette</p>	<p>We expanded the table in Appendix 6 to include information regarding the tobacco products restricted by each local policy, any products and flavors that were excluded, and retailer exemptions. These features are the key objective metrics that published studies used to characterize tobacco flavor restrictions. We also include a footnote indicating that San Francisco’s flavored tobacco sales restriction is the only policy included in this review that covers all tobacco product categories, including e-cigarettes, and all non-tobacco flavors,</p>

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		including menthol, mint, and wintergreen flavors, and has no retailer exemptions.
Reviewer #3	7. Studies from relevant journals that are not currently indexed in PubMed should be reviewed for inclusion including Tobacco Regulatory Science and Tobacco Induced Diseases	<p>Several articles from Tobacco Regulatory Science and Tobacco Induced Diseases were already cited in the Scientific Assessment. In response to the reviewer's suggestion, we reviewed each issue of Tobacco Regulatory Science and Tobacco Induced Diseases from the past two years. Two articles that were not originally included in the Scientific Assessment (below) are now cited in the discussion of blunt use (Albert et al.) and the appeal and perceived harm of flavors in Question 1 (Evans et al.).</p> <p>Albert, E. L., Ishler, K. J., Perovsek, R., Trapl, E. S., & Flocke, S. A. (2020). Tobacco and Marijuana Co-use Behaviors among Cigarillo Users. Tobacco Regulatory Science, 6(5), 306-317.</p> <p>Evans AT, Wilhelm J, Abudayyeh H, Perreras L, Cohn AM. (2020) Impact of Package Descriptors on Young Adults' Perceptions of Cigarillos. Tobacco Regulatory Science, 6(2), 118-135.</p>
Reviewer #3	8. Studies from the recent Tobacco Regulatory Science conference should be reviewed for inclusion as pre-publication materials.	<p>We reviewed the 2021 Tobacco Regulatory Science Meeting content and added the following references to the Scientific Assessment:</p> <p>Gonzalez, S.K., Quisenberry, A., Pike Moore, S., Kaur, M., Osborn, C., Klein, E., & Trapi, E. Flavor perceptions of</p>

CHARGE QUESTION 2. <i>Are you aware of additional publicly available information that should have been included? If so, please specify what that information is and discuss its relevance to the scientific assessment.</i>		
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		<p>cigarillo and e-cigarette products: A qualitative evaluation. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.</p> <p>Pakdaman, S., Broun, A., Duarte, D., Ajith, A., Jewett, B., Mead-Morse, E., et al. The Hypothetical Impact of Flavored Cigar Sales Restrictions Among Black Young Adult Cigar Smokers: An in-Depth Interview Study. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.</p> <p>Shang, C., Nonnemaker, J., Sterling, K., Pikowski, J., & Weaver, S. Impact of little cigars and cigarillos packaging features on product preference. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.</p> <p>Sterling, K., Masyn, K., Pike Moore, S., Fryer, C., Trapl, E., Gunzler, D., & Lee, E. Tobacco Whack-a-Mole: Assessing Cigar and Other Combustible Tobacco Product Use Among a Nationally-Representative Sample of Young Adults. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.</p> <p>Trapl, E.S., Otieno, C., Abeyesundere, N., Osborn, C., Klein, E., & Quisenberry, A. Young Adult Substitution of Flavored Cigarillos with Menthol Cigarettes. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.</p>

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REVIEWER	COMMENT	RESPONSE
Reviewer #3	<p>POTENTIAL ADDITIONAL PAPERS FOR REVIEW</p> <p><i>[Reviewer #3 provides a list of additional papers. The full list and FDA's individual responses to each suggestion can be found in the Appendix to this response document.]</i></p>	<p>Thank you for these suggested potential additions. We reviewed each reference and added all references that were within the scope of the guiding research questions, contained evidence that was not already supported in the Assessment with more recent literature, and/or was not already cited in the Scientific Assessment. We provide a specific rationale for the decision whether to add each citation to the Scientific Assessment in the Appendix of this response document.</p>
Reviewer #4	<p>Generally, I believe the literature review captures the totality of evidence that is publicly available on the topics explored. In my detailed comments below there are a limited number of places I suggest additional review is undertaken to determine if added data sources might be available.</p>	<p>We appreciate the reviewer's support of the review.</p>
Reviewer #4	<p>For example, data from the PATH Study may be available to assess blunt use in more detail as well as to assess the prevalence of flavored cigar use by demographics, especially those age 20 and under. I do not believe this information is currently publicly available, but I do believe the data is being collected that could be analyzed to address these points.</p>	<p>Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled "Methodological Considerations." We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for</p>

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		<p>blunting is beyond the scope of the Scientific Assessment.</p> <p>As the reviewer notes, the prevalence of flavored cigar use among those aged 20 and under (as an age group) is not currently available in the published literature. Future studies and analyses may examine this topic, but none was available to cite in the Scientific Assessment. We did, however, add a new “Age of Initiation” subsection to the Youth Prevalence section that describes ages of initiation, including initiation among those aged 18-20. In that section, we also note the differences in categorization approaches and implications for prevalence estimates.</p>

CHARGE QUESTION 3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.		
REVIEWER	COMMENT	RESPONSE
Reviewer #1	Under Question 1, there is a subsection called “systematic reviews on appeal, use and progression to regular use of tobacco products.” The content reported in this section could also belong under Question 2 since that is addressing experimentation and progression to regular use. It may be worth including another short section under Question 2 briefly restating the findings from the systematic reviews reported under Question 1.	We now reference some of the referenced systematic reviews summarized in the Systematic Review subsection under Question 1 in the first paragraph in response to Question 2.
Reviewer #1	For the Minneapolis and St. Paul, Minnesota flavored tobacco restrictions, the policies allow flavored tobacco product sales to adult-only venues, like tobacco and alcohol retailers (https://www.publichealthlawcenter.org/sites/default/files/resources/US-sales-restrictions-flavored-tobacco-products.pdf). This should be explicitly stated in the study description narrative on page 25.	We expanded the table in Appendix 6 to include indicators of policy comprehensiveness, including retailer exemptions.
Reviewer #1	PATH Study Memo and PATH Study Online Tables have placeholders in the reference section. Since I was not able to examine these documents, I cannot verify their content or accuracy.	The estimates contained within these references were provided in the text of the Scientific Assessment and can all be obtained from publicly available data at https://www.icpsr.umich.edu/web/NAHDAP/studies/36231 . The references “PATH Study Memo” and “PATH Study Online Tables” describe the locations of the study data and present the data in online formats, respectively.
Reviewer #1	The citations Palmatier et al., 2013 and Palmatier et al., 2020 are missing from the reference list. Please review all cited to work to ensure they are included in the reference list.	We added the references that the reviewer noted to the bibliography and reviewed all in-text citations to ensure they are included in the bibliography.

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REVIEWER	COMMENT	RESPONSE
Reviewer #1	One minor suggestion is to include an abbreviations list at the beginning of the review document.	We reviewed all abbreviations used in the Assessment and created a table on page 3.
Reviewer #2	My primary suggestion would be specifically to discuss the challenges with enforcement as a separate section. Some of this detail can be found occasionally when mentioned by some articles, but there is additional literature (see above) and additional detail within existing studies. The effectiveness and impact of a ban will rely on enforcement and compliance and consequently this should be highlighted and evaluated carefully to make recommendations for policy.	When such information was available in the literature, we added information related to retailer compliance with flavored tobacco product policies for each jurisdiction with a policy evaluation study. We added several references to support these additions. Since the impact of flavored tobacco product restrictions depends on the level of enforcement and compliance with these policies, we also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings.
Reviewer #2	A second issue to highlight is the impact of flavor tobacco bans on the effectiveness of menthol cigarette bans. The Canadian ban and other local bans on menthol were in the context of the flavor cigar bans and availability of menthol cigars may affect the effectiveness of the menthol restrictions in cigarettes so that these issues must be considered in conjunction, particularly for little cigars and cigarillos. Some citations are provided above.	The reviewer raises the issue that having multiple flavored tobacco policies in place at the same time (e.g., in the reviewer's example of local and national Canadian flavored tobacco product bans) may impact flavored tobacco product use if potential substitution between remaining available products occurs. The reviewer gives the example of potential menthol cigar substitution when menthol cigarettes were restricted. While it is difficult to disentangle the extent to which use of a specific type of flavored product (e.g., menthol cigars or cigarettes) is due to one policy compared to another similar policy in effect, we discuss the potential for substitution if cigar users move to available flavored

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REVIEWER	COMMENT	RESPONSE
		products when one type of flavored product is no longer available in the section titled “Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products and the Implications for Tobacco Product Substitution.” We added most of the suggested citations to the Scientific Assessment. In Appendix 1 of this document, we provide an article-specific rationale for our decision whether or not to add the reference.
Reviewer #2	In the methodology it should be clarified that research prior to 2010 was eligible for inclusion.	We revised the Purpose and Scope section to clarify the methodology.
Reviewer #2	There should be discrimination between studies that use longitudinal pre-post designs vs cross-sectional re-post designs (e.g. Chaiton 2020 is longitudinal while Chaiton 2018 is a cross sectional time series) as the former allows for control of within-person characteristics especially compared to cross-sectional population surveys.	We developed a new table summarizing the methodological details for all national surveys cited in the Prevalence sections of the Scientific Assessment. Study design is included as a column in this table.
Reviewer #2	Product substitution is discussed.	We appreciate the reviewer’s positive comment.
Reviewer #3	1. More longitudinal studies examining cessation (and not just initiation) or switching outcomes would also be useful if these exist.	Thank you for this comment. We are not aware of additional studies.
Reviewer #3	2. General information about morbidity and mortality from cigar smoking as a combustible tobacco product should be briefly added to the introduction. This would help to contextualize the particular harms of use of these products as well as how cigar use disparities translate into health disparities.	We added a new Appendix 5 in the Scientific Assessment with information on the health effects of cigars. We also added a brief Health Effects subsection to the end of the Prevalence section.

CHARGE QUESTION 3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.		
REVIEWER	COMMENT	RESPONSE
Reviewer #3	3. There is some discussion of flavor use differences by cigar product type (e.g., traditional cigar, little filtered cigars, cigarillos), but there is not much discussion of flavor differences by brand use (e.g., Delnevo, et al. Tobacco Control 2015). About half of the cigars sold are flavored and some brands such as White Owl have a much higher proportion of flavored sales than other brands. If available, papers examining specific brands that are highly flavored should also be reviewed as contributing to the literature on flavor use.	A complete assessment of the prevalence of flavored cigar use at the brand level was beyond the scope of the Scientific Assessment. However, in the section on concept flavors, we added that the use of ambiguous flavor descriptors in advertisements varies widely across cigar brands and cite the reference below. Sterling KL, Vishwakarma M, Ababseh K, Henriksen L. Flavors and Implied Reduced-Risk Descriptors in Cigar Ads at Stores Near Schools. Nicotine Tob Res. Oct 7 2021;23(11):1895-1901.
Reviewer #3	4. Studies of exposure to cigar marketing should be added to the section on appeal.	We added a new "Marketing of Flavored Cigars" subsection to Question 1, as suggested by the reviewer.
Reviewer #3	5. Studies of cigarillo packaging perceptions (e.g., experimental studies, behavioral economics studies) including differences in perceptions by color should be added to the section on appeal.	We added several new references to the "Concept Flavors in Cigars" section in the main text of the Scientific Assessment describing the consistent finding that the public associates certain colors with flavors and this type of packaging information influences appeal and use of products.
Reviewer #3	6. Studies of harm perceptions of cigars and cigar flavors are largely missing from this review and should have their own section.	We now include a subsection titled "Perceived Harm of Flavored Cigars" to Question 1. This section describes the interplay between flavors and harm perceptions as predictors of flavored cigar use.
Reviewer #3	7. Discussion of Blunt use is missing as a reason for flavored cigar use. Those using blunts often use flavored blunt wrappers. Use of blunts still has the issues of tobacco use and nicotine	Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-

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REVIEWER	COMMENT	RESPONSE
	dependence and leaving out these studies/estimates may under report cigar use patterns and the impact of flavored cigar restrictions.	Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for blunting is beyond the scope of the Scientific Assessment.
Reviewer #3	8. Discussion of dual/poly use of cigars with other tobacco products is limited. Given that most cigar users also use other products, discussion of broader risk patterns is important to fully understand the additional risk of these products. This is also important to contextualize the potential for substitution with alternative products in flavored cigar policies.	Thank you. We expanded our discussion of dual and poly use of cigars with other tobacco products in the section titled, “Evidence on Developing Nicotine Dependence During Tobacco Product Experimentation.” We note that cigar use with other tobacco products is common and discuss the implications for further tobacco use and dependence, particularly during adolescence. Also, we note the potential susceptibility of dual and poly users for substitution with products not covered in flavored cigar policies in the section titled, “Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products and the Implications for Tobacco Product Substitution.”
Reviewer #3	9. Papers discussing flavored vape restrictions and menthol bans should also be more broadly reviewed for substitution with	We discuss substitution and other unintended consequences of restrictions on flavored tobacco

CHARGE QUESTION 3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.		
REVIEWER	COMMENT	RESPONSE
	flavored cigars (i.e., for unintended consequences of other flavor tobacco restrictions) but information on these types of policies should be included in their own sections.	products under Question 3. We added new content specifically about how tobacco manufacturers responded to flavor restrictions by creating or promoting flavored cigar products.
Reviewer #3	10. If available, studies of behavioral intentions (e.g., survey studies asking about hypothetical bans, behavioral economic studies) of what those who smoke flavored cigars would do if flavored cigars were unavailable should be included to better estimate the potential policy impacts. Several studies from the recent TRS meeting addressed these issues and should be considered as pre-publication materials.	We added an additional “Evidence from hypothetical scenario studies” subsection under Question 2 and cite the 2 abstracts from the 2021 TRS meeting listed below: Trapl, E.S., Otieno, C., Abeyesundere, N., Osborn, C., Klein, E., & Quisenberry, A. Young Adult Substitution of Flavored Cigarillos with Menthol Cigarettes. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021. Pakdaman, S., Broun, A., Duarte, D., Ajith, A., Jewett, B., Mead-Morse, E., et al. The Hypothetical Impact of Flavored Cigar Sales Restrictions Among Black Young Adult Cigar Smokers: An in-Depth Interview Study. Abstract presented at the annual Tobacco Regulatory Science Meeting. 2021.
Reviewer #3	11. Separating out the youth and young adult literature would be helpful. Both of these age groups are important for initiation and progression to regular use. With Tobacco 21 as a national policy (including young adults) and increases of tobacco initiation into the young adult years, young adults are a critical age group for flavored cigar use. The current literature combines studies of both age groups and conclusions to question 1 and 2 do not clearly call out the impacts on young adults. General	We reorganized Questions 1 and 2, as well as the Prevalence sections to ensure that estimates are provided for both young adults and adults as separate age groups. We decline to create separate subsections for each of the age groups, since most of the evidence derives from the same research studies, meaning

CHARGE QUESTION 3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.		
REVIEWER	COMMENT	RESPONSE
	literature on how patterns of tobacco initiation have expanded into the young adult years should be more fully examined.	separating them out would create considerable unnecessary duplication of study information.
Reviewer #3	12. Gender differences should also be discussed more fully. Cigars are used more frequently by males but flavored cigar use is typically higher among women including pregnant women.	We added gender differences to the subsection on “Flavored Cigar Use Among Adults” within the Adult Prevalence section.
Reviewer #3	13. Where possible, issues of intersectionality should be more clearly addressed (e.g., racial/ethnic disparities in flavored cigar use among sexual and gender minority populations).	We added a new subsection to the “Disparities in Cigar Use Among Adults” section on intersectionality.
Reviewer #3	14. There are several studies of flavor use and mental health/substance use/medical co-morbidities/homelessness and should be included to assess disparities.	We added several new references to the “Disparities in Cigar Use Among Adults” section centering on mental and physical health.
Reviewer #3	15. Studies on retail availability of flavored tobacco after policy change should be included. These include studies on compliance/adherence with flavor restrictions from store audits or littered packs can help to determine why some policies may or may not have had adequate impacts (i.e., if compliance/enforcement was poor). Examination of reduced flavor advertising should also be included.	We have added findings on retailer compliance with flavored tobacco product policies when available for each jurisdiction with policy evaluation studies (Kingsley et al. 2020; Pearlman et al. 2019; Kingsley et al. 2019; D’Silva et al. 2021; Brock et al. 2019; Bosma et al. 2021; Vyas et al. 2020; Kephart et al. 2020; Borland et al. 2017; Jo et al. 2015; Kurti et al. 2020; Farley et al. 2020; Czaplicki et al. 2019; Schroth et al. 2021). Since the impact of flavored tobacco product restrictions depends on the level of enforcement and compliance with these policies, we also added an overall discussion of enforcement and compliance in the limitations section as a consideration when interpreting policy evaluation findings. When available, findings regarding flavored tobacco product restrictions on flavored

CHARGE QUESTION 3. Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.		
REVIEWER	COMMENT	RESPONSE
		advertising/marketing have been added when discussing evaluation findings for each jurisdiction (Brock et al. 2019; D’Silva et al. 2021; Usidame et al. 2019).
Reviewer #4	I have no methodological concerns that diminish my confidence in the conclusions drawn from the literature review, and the review is done in an objective manner. I do believe that addressing the three points raised in response to Charge Question #1 - considering the type of cigar for all studies when possible, including blunt users, and including those under 21 years of age as ‘youth’ - will further expand the scope of cigar use in the population. Specific comments are provided in section III Specific Observations for FDA’s consideration.	<p>We added a table in Appendix 4 in the Scientific Assessment describing key methodological details of all cited national surveys, as well as a new Methodological Considerations subsection to the Prevalence section. The table includes which cigar subtypes were assessed by the cigar items, whether images were included in the instructions to participants, and whether blunt use was purposefully excluded from the prevalence estimates. This information is intended to serve as context that can be taken into consideration when interpreting the estimates reported in the Assessment.</p> <p>We used the term “youth” in the Scientific Assessment to define the developmental period that precedes adulthood, with most literature using a cut-off around age 18 or at the end of high school. We did not add additional prevalence estimates for the “under age 21” group because no currently available literature provides this information.</p> <p>However, young adulthood, including those aged 18-20 years, is among the most common life stages for cigar initiation and this age group has access to cigars despite being younger than the legal purchase age through underage sales, friends, and other sources (e.g., Dai,</p>

CHARGE QUESTION 3. <i>Provide any additional comments, such as methodological concerns, objectivity and strength of the data, limitations, or outcomes not discussed.</i>		
REVIEWER	COMMENT	RESPONSE
		Hao, & Catley, 2020; Trapl et al., 2017). Therefore, any regulatory actions related to flavored cigar products would be expected to influence use of these products among aged 18-20-year-olds by cutting off access to their sources, particularly underage sales. We added a new “Age of Initiation” subsection to the Youth Prevalence section that describes ages of initiation, including initiation among those aged 18-20. In that section, we also note the differences in categorization approaches and implications for prevalence estimates.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #1	4	1	Typographical error in the third sentence: "...by non-Hispanic Black high school students <u>as</u> twice as high..." – the first 'as' should be 'is'	Revised to "was."
Reviewer #1	4	1	Revise to say 'high school student' instead of "high schooler" in the second sentence.	Revised as suggested.
Reviewer #1	4	1	Add 'persons' or 'individuals' after Whites or African Americans in this paragraph.	Revised to include the term "youth" after each race/ethnicity.
Reviewer #1	6	2	Add 'persons' or 'individuals' after Whites, Blacks, Hispanics or African Americans in this paragraph	We made revisions throughout the Prevalence section to ensure racial/ethnic categories are followed by terms, such as "adults" or "individuals."
Reviewer #1	6	2	Black non-Hispanic is used in sentence two but non-Hispanic Black is used elsewhere in the paragraph. Revise for consistency.	We revised to "non-Hispanic Black" for consistency in two places.
Reviewer #1	6	3	The last sentence on the page has inconsistent reference formatting for the Hinds citation.	We reviewed and updated all in-text citations, including Hinds et al., to ensure consistency and accuracy.
Reviewer #1	7	3	The second sentence has the citation, Johnson et al., 2019, listed twice.	We removed the second in-text citation in this sentence.
Reviewer #1	8	2	The second sentence requires a citation.	We added a citation to this sentence.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #1	9	2	Consider revising the two, long sentences in this paragraph into shorter, more concise sentences to enhance readability.	We revised this sentence (which is now located in Question 2) for clarity.
Reviewer #1	12	5	Consider dropping the Kool Aid brand name for drink mixes since the authors did not include brand names for candy.	As opposed to the candy, for which there were several types, Kool-Aid was the only drink mix examined. Therefore, this phrase was revised to: "several brands of candy (e.g., Life Savers) and one drink mix (Kool-Aid)"
Reviewer #1	13	1	Typographical error in the second sentence: "...flavors <u>area</u> a leading..." should be 'are'.	We revised this error.
Reviewer #1	14	3	The third paragraph is comprised of one long sentence. Consider revising into shorter, more concise sentences to enhance readability.	This sentence appeared in Question 1 as well. In Question 1, it was revised to "In one qualitative study with cigar users, nearly half of all youth and young adult 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)." It was removed from Question 2 in response to reviewers' suggestions to reduce redundancy between the two questions.
Reviewer #1	16	1	Capitalize the 'w' in Wave 2	We revised this error.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #1	16	5	Villanti et al., 2020 – Does this paragraph refer to any cigar use or should there be differentiation by cigar subtype?	We clarified which results were for cigars overall and which were for cigar subtypes.
Reviewer #1	17	2	Consider separating this paragraph into two shorter paragraphs since the content is quite dense. The break could be before “Youth who first used...”	We revised this section so that each paragraph focuses on a different age group (youth, young adults, and adults).
Reviewer #1	17	2	Potential typographical error: “Youth who had first used a flavored <u>cigar</u> other than menthol or mint had a significantly higher prevalence of past 30-day cigarillo use compared to those who first used a non-flavored cigarillo (aPR 1.58; 95% CI: 1.02, 2.43).” Should the underlined word be cigarillo rather than cigar?	Thank you. We made the suggested revision.
Reviewer #1	17	3	Should the word “traditional” be the descriptor included before each instance of cigar in this paragraph?	We revised this section so that each paragraph specifies the results for cigars overall and cigar subtypes. For subtypes, we clarify each type.
Reviewer #1	18	2	What does “ <u>delayed</u> past 30-day users” mean?	We revised this sentence to clarify and no longer use the word “delayed.”
Reviewer #1	18	3	Consider separating this paragraph into two shorter paragraphs since the content is quite	We revised this section and paragraphs are now much shorter.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			dense. The break could be before "Researchers analyzing data from the..."	
Reviewer #1	18	3	The last sentence in the paragraph is quite long. Consider revising into shorter, more concise sentences to enhance readability.	We revised this sentence to shorten and clarify.
Reviewer #1	19	2	The last sentence in the paragraph is quite long. Consider revising into shorter, more concise sentences to enhance readability.	We revised this sentence to improve clarity and respond to other reviewer comments.
Reviewer #1	22	1	The last sentence in the paragraph is quite long. Consider revising into shorter, more concise sentences to enhance readability.	We revised this sentence to shorten and clarify.
Reviewer #1	24	2	Typographical error in the fifth sentence: "...current user of flavored cigars..." should be 'use'	We revised this error.
Reviewer #1	24	3	Possible typographical error: Should it be Difference-in-differences with the second difference plural?	We did not revise this text as it was written as noted in the referenced citation.
Reviewer #1	25	2	In the second sentence, consider clarifying what products are included in the regulations, such as e-cigarettes and menthol cigarettes (if accurate).	We revised this sentence to clarify that e-cigarettes and menthol cigarettes are included in the 2018 sales restrictions.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #1	26	2	No limitations are reported for Yang et al., 2020's manuscript.	We now include limitations in describing the Yang et al. (2020) study.
Reviewer #1	26	3	Does active implementation mean policy enforcement? If so, consider revising for clarity.	We removed this sentence and now describe the San Francisco policy enforcement timeline in the beginning of the San Francisco description.
Reviewer #1	31	2	Avoid use of contractions: revise to 'did not' in the fifth sentence.	We revised this error.
Reviewer #1	32	4	There is an extra parenthesis in the second sentence.	We revised this error.
Reviewer #1	33	2	Why does the 2009 NTYS data have the descriptor of "Spring 2009" when all others are just the year?	Spring is specified for 2009 because the federal ban went into effect in September of 2009, but the survey was administered in the spring, meaning the 2009 wave is a pre-policy wave. We revised this sentence to clarify.
Reviewer #1	35	1	The first sentence has the citation, Rostron et al., 2019, listed twice.	We revised this error.
Reviewer #1	35	1	Typographical error in the third sentence: "...then utilize PATH Study data..." should be 'utilized' (past tense).	We revised this error.
Reviewer #1	43	References	[Placeholder for National Youth Tobacco Survey Memo (2021)]- This citation is included in the reference list but I did not see it in the main document.	We revised this error in text and in the reference list.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #1	51	Appendix 2	The citation format for the appendix is different from the main document. Consider revising for consistency.	We added the references that the reviewer noted to the bibliography and reviewed all in-text citations to ensure they are included in the bibliography.
Reviewer #1	56	Appendix 3	Effective or Enforcement Year is a more accurate column title than Effective or Enforcement Date.	We made this revision.
Reviewer #1	57	Canada row	Spell out minimum vs min	We revised this error.
Reviewer #1	62	Last row	Capitalize Black	We revised this error.
Reviewer #2	36	3	Final paragraph is missing citation to the discussed study	We revised this paragraph to summarize the additional references now included in Question 3. This paragraph now summarizes this broader set of studies.
Reviewer #3	5	2	Our study Rose SW, Johnson AL, Glasser AM, et al. Flavour types used by youth and adult tobacco users in wave 2 of the Population Assessment of Tobacco and Health (PATH) Study 2014-2015. <i>Tob Control</i> . Jul 2020;29(4):432-446. doi:10.1136/tobaccocontrol-2018-054852 included tables on concordance between self-report and brand assessed flavors including for cigars which may help with the discussion of self-reported flavors assessment.	Thank you for this suggestion. We added the citation to Question 1.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #3	9	1	"They also found that abuse liability can differ with cigar flavor (Bono et al 2020)" Please clarify in which direction and which flavor(s).	We revised this sentence and provided more information on this finding.
Reviewer #3	13	1	"... showing that flavors are a leading..."	We revised this phrase to "flavors are a primary reason for use of cigars among all age groups."
Reviewer #3	16	1	Paragraph is about adults 25+ but last sentence is about youth and should be moved to the discussion of youth. This entire section should be reorganized to discuss the findings for youth, young adults, and then adults 25+ separately. Currently the discussion goes back and forth making it hard to follow.	We moved the youth findings to the beginning of the description of this study. We did not reorganize the entire section to separate findings for youth, young adults, and adults, but we did revise the organization so that for each study, we report the results in the same order, beginning with youth, followed by young adults and adults. Separating the sections by age group would have created a large amount of duplication in study design information, given that the same studies are cited for each age group. Thus, retaining the current structure was determined to be the most efficient approach.
Reviewer #3	20	2	"...consumers did not appear to completely substitute non-flavored cigars or concept flavored cigars for flavored cigars."	We did not revise this sentence to include concept flavors as a separate category given that the researchers in this study coded concept flavors within their flavor category.
Reviewer #3	24	3 rd	The section is titled Lowell, Massachusetts but also includes review studies based in Attleboro and Salem	We revised Question 3 and the table in Appendix 6 to describe Lowell and Attleboro/Salem as two separate jurisdictions.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #3	27	2 nd	Discussion of the Yang study repeats discussion of articles already reviewed on page 26. This information should be put together or deleted since including the same study more than once makes it seem like there is more evidence than actually exists.	We revised this error in repeating discussion of the Yang et al. study.
Reviewer #3	29	2 nd	Paragraph repeats discussion of articles already reviewed as part of the discussion of each city policy. Including this information more than once makes it seem like there is more evidence than actually exists.	We moved this discussion to the Summary and Conclusion subsection in Question 3 to summarize findings across localities without repeating information in the initial descriptions above.
Reviewer #3	34	1 st	Discussion of Courtemanche article is duplicated from page 33	We removed this duplication.
Reviewer #3	35	2 nd	"...estimate the potential range of cigar..."	We revised this error.
Reviewer #3	35-36	1 st	<p>Add specific mortality decrease and prevalence decrease estimates to this discussion.</p> <p>It seems that the Rostron 2019 study referenced on pages 35-36 is miscited in the reference list (L Rostron, B., G Corey, C., Holder-Hayes, E., & K Ambrose, B. (2019). Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US. International</p>	We corrected the Rostron et al. 2019 citation in the reference list and added the key outcomes from the modeling study to the Public Health Assessment section of the Scientific Assessment

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			journal of environmental research and public health, 16(18), 3234. https://doi.org/10.3390/ijerph16183234 instead of Rostron BL, Corey CG, Gindi RM. Cigar smoking prevalence and morbidity among US adults, 2000–2015. Preventive Medicine Reports. 2019/06/01/2019;14:100821. doi: https://doi.org/10.1016/j.pmedr.2019.100821 which is in the references)	
Reviewer #3	36	Last sentence	Add “The study did not account for tobacco product...”	We revised this paragraph to reflect new references added in response to Question 3.
Reviewer #4	3	Purpose and Scope section	Recommend adding sections on 1) health risks from cigar use; and 2) the evidence that cigars are smoking cessation aids. I believe the data will show that cigars pose significant health risks and NCI Monograph 6 among other review documents describe this in detail. Linking the behavior to health outcomes is needed in this Review to make that case that cigars pose a risk to individual and public health. The 2 nd point about whether cigars are a cessation aid, which I don't believe there is any evidence to indicate that, simply makes	As the reviewer notes, cigars pose considerable health risks. We added a brief section on Health Risks to the main Assessment and created an in-depth appendix (Appendix 5) on the topic as well. We agree with the reviewer that there is no available evidence examining cigars as a cigarette cessation aid. Indeed, given that cigars pose comparable or potentially even greater health risks than cigarettes, such product substitution would not confer any health benefits, as the reviewer notes. Included in the health risks section are several studies that examined the relative health risks of cigars and cigarettes, thus underscoring the reviewer's comment.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			<p>the case that there is no upside benefit to public health from the use of cigars.</p> <p>Walk the reader through the full spectrum: from cigars being harmful, to they are commonly used, and part of that is due to the appealing flavors, and there’s no benefit to having appealing cigars for public health...or something like that, of course, guided by what the summary of the literature in each area indicates.</p>	
Reviewer #4	3	Purpose and Scope section, bullet #1	Define ‘characterizing flavor’ and how does this differ from a flavor that is not ‘characterizing’. How is characterizing flavors defined for the purposes of this review and the studies that comprise it, which I believe make assumptions that certain brand names have characterizing flavors, but is there evidence to link the product names to the product formulations that produce the characterizing flavor?	This summary is a compilation of studies that may have defined ‘characterizing flavor’ in a variety of ways. We now include a footnote in the Purpose and Scope section to clarify our use of terms including ‘characterizing flavor,’ ‘explicit flavor,’ and ‘concept flavor’ and that we are deferring to the methodology of the study’s definition.
Reviewer #4	3	Prevalence of Cigar Use Among Youth section	Three general comments about methods for assessing cigar use among youth. The first is that the PATH Study demonstrates that assessment of the different types of cigars is necessary to better estimate cigar prevalence. Many past studies assess cigar use as a single question, which yields lower	In response to this comment, we added a table of the methodological features of each of the national surveys cited in the Assessment. The information includes whether cigar subtypes were assessed, whether images were included with instructions for participants, and

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			<p>estimates of cigar use. The PATH Study and some more recent studies use better methods to show pictures and provide a description of different types of cigars, which provide a more detailed, and in my opinion, superior method for assessing cigar use. The importance of this is that studies that assess cigar use with a single item and does not differentiate between the different types of cigars are likely underestimating the true prevalence of cigar use.</p> <p>The 2nd comment is that blunt use is a common behavior that involves the use of cigars for cannabis intake. Relatively few studies capture cigar use in the context of blunts and, thus, those studies will underestimate cigar use. The methods for this review indicate that studies primarily of blunt users are excluded, which is a condition I believe should be reconsidered because regardless of blunt use, by definition, is the use of cigars and omitting blunt use will systematically bias the results, particularly with respect to certain minority populations. Results from the PATH Study may be available to assess this in more detail.</p>	<p>whether blunt use was explicitly excluded from cigar prevalence estimates.</p> <p>We also added additional estimates broken out by cigar subtype throughout the Assessment to better illustrate the variability that the reviewer noted.</p> <p>Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a more extensive review of the use of flavored cigars for blunting is beyond the scope of the Scientific Assessment.</p> <p>We used the term “youth” in the Scientific Assessment to define the developmental period that precedes adulthood, with most literature using a cut-off around age 18 or at the end of high school. In the Assessment, we report the age categories designated by the authors and no relevant studies categorized individuals using an age of 21 as the cut-off. Therefore, we do not include prevalence estimates for “aged 20 and under” as a</p>

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			<p>The 3rd comment is that past studies of ‘youth’ are underestimating the number of underage cigar smokers in the population. The minimum sales age for tobacco products is 21 years of age, therefore, all those age 20 and below are underage users to whom it is illegal to sell tobacco. The literature review should be clearer on this point and what the definition of ‘youth’ is. The takeaway point is that virtually all of the studies cited in this review define youth as <18 year of age; therefore, they underestimate the number of underage cigar smokers in the current policy setting where 21 is the minimum sales age.</p>	<p>group. However, young adulthood, including those aged 18-20 years, is among the most common life stages for cigar initiation and this age group has access to cigars despite being younger than the legal purchase age through underage sales, friends, and other sources (e.g., Dai, Hao, & Catley, 2020; Trapl et al., 2017). Therefore, any regulatory actions related to flavored cigar products would be expected to influence use of these products among aged 18-20-year-olds by cutting off access to their sources, particularly underage sales.</p> <p>We added a new “Age of Initiation” subsection to the Youth Prevalence section that describes ages of initiation, including initiation among those aged 18-20. In that section, we also note the differences in categorization approaches and implications for prevalence estimates.</p>
Reviewer #4	4	Disparities in Cigar Use Among Youth section	<p>Assessment of blunt use may differ by race/ethnicity and other factors, so it is particularly important to include an assessment of cigar use in the context of blunting for this review.</p>	<p>Since blunt use can influence the estimated prevalence of cigar use obtained from survey data (Delnevo, Bover-Manderski, & Hrywna, 2011; Kong et al., 2019), we added this point to the Prevalence section in a new subsection titled “Methodological Considerations.” We also added an additional table with methodological information about each national survey, including whether blunt use was excluded from prevalence estimates. This information is intended to inform the interpretation and comparison of estimates. However, a</p>

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
				more extensive review of the use of flavored cigars for blunting is beyond the scope of the Scientific Assessment.
Reviewer #4	8	Addition of Characterizing Flavors in Tobacco Products section	Confirm this refers to ‘characterizing flavors’. It probably does, but the term ‘characterizing’ is subjective, but the point made here addresses the chemistry of the product.	This summary is a compilation of studies that may have defined ‘characterizing flavor’ in a variety of ways. We now include a footnote in the Purpose and Scope section to clarify our use of terms including ‘characterizing flavor,’ ‘explicit flavor,’ and ‘concept flavor’ and that we are deferring to the methodology of the study’s definition.
Reviewer #4	8	Addition of Characterizing Flavors in Tobacco Products section	Recommend using the term ‘cigar manufacturers’ instead of ‘tobacco industry’ throughout when referring specifically to cigars as it is more precise and doesn’t pin practices necessarily for certain types of manufacturers on other types (i.e., vaping product manufacturers that are not involved in work with smoke chemistry, bitter tobacco leaves, etc.).	Throughout the Scientific Assessment, we now use the term “tobacco manufacturers” instead of “tobacco industry.”
Reviewer #4	8	Abuse Liability of Flavored Tobacco Products	I found this section to be under-developed and suggest incorporating it with the more compelling studies in the following section. There are just a limited number of studies with some of them using hypothetical purchase tasks, which are a great method, without a lot of empirical evidence.	We made several organizational changes in response to this comment: we moved the “Abuse Liability of Flavored Tobacco Products” subsection to Question 2 and moved all content related to the appeal of flavors to Question 1. We also added two new subsections to Question 1: “Perceived Harm of Flavored Cigars” and “Marketing of

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
			<p>Consider framing this new section that describes the literature on the appeal and abuse liability of flavored cigars in the following way:</p> <p>There are two relevant issues – initial trial and progression to more regular use.</p> <p>For initial trial, appealing flavors can promote trying the flavored cigars, which studies show will greatly increase the likelihood of becoming a current or regular user in the future. This can work both through the marketing and advertising angle as well as making the first experience with the flavored product appealing and then the nicotine takes over to promote dependence. In other words, the flavors themselves don’t need to produce dependence directly, but just their making the product worth trying, it can produce dependence indirectly.</p> <p>The progression to more regular use issue would include some of the studies that are in this section here on abuse liability in the area of transition from occasional to more regular use.</p>	<p>flavored cigars,” which describe harm perceptions and marketing in the context of the appeal of cigars and flavored cigars.</p> <p>We added one new subsection to Question 2 titled “Evidence from Hypothetical Scenario Studies,” which describes the literature that has used hypothetical scenarios to assess dependence and related factors.</p> <p>With these changes, Question 1 exclusively focuses on the appeal of flavored cigars and flavors as a reason for use. Question 2 focuses on progression to regular use, dependence, and abuse liability.</p>
Reviewer #4	9	Appeal of Flavored	The studies described here are strong and a compelling case is made.	We made several organizational changes in response to this comment: we moved the “Abuse Liability of Flavored

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
		Tobacco Products	<p>However, I think it is preferable to organize the section according to behavioral transitions and include the studies across the current subsections. I see now that question #2 addresses the issue of progression in use so that in large part addresses my comment; however, there may be opportunities to be clearer with the presentation that question 1 and question 2 are connected and flow sequentially.</p> <p>Transitions include initial trial – what is the evidence that flavored cigars promote trying the product?</p> <p>Then the transition from trial to occasional use – evidence like Villanti’s recent PATH Study paper showing, I think, that those who start with a flavored cigar were more likely to be a past 30 day user at follow-up.</p> <p>Then transition to frequent/regular/daily use, which gets it to the issues of dependence and abuse liability... and this is the pattern of use that has most of the evidence of harm to health.</p>	<p>Tobacco Products” subsection to Question 2 and moved all content related to the appeal of flavors to Question 1.</p> <p>We also added two new subsections to Question 1: “Perceived Harm of Flavored Cigars” and “Marketing of flavored cigars,” which describe harm perceptions and marketing in the context of the appeal of cigars and flavored cigars.</p> <p>We added one new subsection to Question 2 titled “Evidence from Hypothetical Scenario Studies,” which describes the literature that has used hypothetical scenarios to assess dependence and related factors.</p> <p>With these changes, Question 1 exclusively focuses on the appeal of flavored cigars and flavors as a reason for use. Question 2 focuses on progression to regular use, dependence, and abuse liability.</p>
Reviewer #4	9	Appeal of Flavored	To what extent has the marketing of flavored cigars been shown to be associated with these measures of use/progression?	We added a subsection titled “Marketing of flavored cigars” to Question 1 that includes this statement about the relation between exposure to advertising and

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
		Tobacco Products	Consider adding this component to make a stronger case for accompanying conditions to limit marketing to those under 21 as part of any rule making process. The marketing component is very important to incorporate.	tobacco use: "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..."
Reviewer #4	13	Last paragraph on this page	Great to see this is being considered elsewhere. It's necessary to document the literature on health risks of cigars.	We added a brief section titled Health Effects of Cigar Use to Prevalence section, and we added a more in-depth review of the health risks as Appendix 5.
Reviewer #4	13	Last paragraph on this page	Is it also appropriate to cite appropriate rules/regulations that limit the use of characterizing flavors in other types of tobacco products under FDA/CTPs authority?	We include evidence on the impact of local and federal restrictions on flavored tobacco products in response to Question 3. Given that this is a description of the scientific literature, discussion of FDA/CTP's authority more broadly is outside of the scope of the Scientific Assessment.
Reviewer #4	20	Local and National Policy Evaluation Studies section	Somewhere in here I recommend considering the difference between a local and a nationally implemented policy. Local policy effects are likely a lower bound of their impact because it's easier to circumvent the policy by traveling outside the jurisdiction; however, this is generally not practical for nationally implemented policies and this is particularly true for young people.	In the Conclusion section of Question 3, we added a discussion of how evaluations of local flavored product sales restriction policies likely underestimate the effects of national policies. For example, any national policy would minimize the likelihood of cross-border purchasing from jurisdictions that sell restricted products, would address distribution and manufacturing in addition to sales restrictions, and would also eliminate the retailer exceptions that were in local restrictions.

III. Specific Observations				
REVIEWER	Page	Paragraph/ Line	Comment	RESPONSE
Reviewer #4	28	Last full paragraph on this page	<p>I believe there is a Letter to the Editor and response by Dr. Friedman recently published that identifies and addresses some of the criticisms raised, which should be checked out.</p> <p>The main conclusion in this paper is that cigarette smoking increased in San Francisco where there was a policy, compared to other locations where no flavored policy was present. I don’t believe any data on cigar use or vaping is reported. As such this study is not a direct evaluation of the flavor policy with respect to cigars. However, it does speak to potential unintended consequences of a broad flavor policy.</p> <p>The literature review should address whether any of the other local policy evaluations found evidence of unintended consequences including pushing people to use cigarettes, increasing contraband product, increasing use of third party product add-ons for flavor enhancement, or cross-border sales.</p>	<p>We expanded on the discussion of the limitations of the Friedman (2021) study and now include findings from another study (Liu et al., 2022) that reported a methodological mistake in the Friedman (2021) findings. Liu et al. (2022) reported that the 2019 YRBS was conducted in Fall 2018 prior to when the San Francisco flavor policy was enforced in April 2019 and indicating that the Friedman (2021) analysis was a pre-only design. Given this, findings from Friedman (2021) do not reflect the impact of San Francisco’s flavored tobacco sales restriction on youth cigarette use.</p> <p>We also expand our discussion of tobacco product substitution by including findings from other policy evaluation studies in the “Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products and the Implications for Tobacco Product Substitution” section.</p>

Appendix 1: Responses to Reviewer #3’s Suggested Potential Additional Papers for Review

POTENTIAL ADDITIONAL PAPERS	RESPONSE
<p>1. Alizaga NM, Hartman-Filson M, Elser H, Halpern-Felsher B, Vijayaraghavan M. Alternative flavored and unflavored tobacco product use and cigarette quit attempts among current smokers experiencing homelessness. <i>Addict Behav Rep.</i> Dec 2020;12:100280. doi:10.1016/j.abrep.2020.100280</p>	<p>We added this reference to the “Disparities in Cigar Use Among Adults” subsection of the Prevalence section (specifically, the discussion of the relation between SES and cigar use).</p>
<p>2. Andersen-Rodgers E, Zhang X, Vuong TD, et al. Are California's Local Flavored Tobacco Sales Restrictions Effective in Reducing the Retail Availability of Flavored Tobacco Products? A Multicomponent Evaluation. <i>Eval Rev.</i> Oct 25 2021;193841X211051873. doi:10.1177/0193841X211051873</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>3. Bonhomme, M.G., Holder-Hayes, E., Ambrose, B.K., Tworek, C., Feirman, S.P., King, B.A. and Apelberg, B.J., 2016. Flavoured non-cigarette tobacco product use among US adults: 2013–2014. <i>Tobacco control</i>, 25(Suppl 2), pp.ii4-ii13.</p>	<p>We added this reference to the Adult Prevalence section.</p>
<p>4. Bosma LM, D'Silva J, Moze J, Matter C, Kingsbury JH, Brock B. Restricting Sales of Menthol Tobacco Products: Lessons Learned from Policy Passage and Implementation in Minneapolis, St. Paul, and Duluth, Minnesota. <i>Health Equity.</i> 2021;5(1):439-447. doi:10.1089/heq.2020.0137</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>5. Brock B, Carlson SC, Leizinger A, D'Silva J, Matter CM, Schillo BA. A tale of two cities: exploring the retail impact of flavoured tobacco restrictions in the twin cities of Minneapolis and Saint Paul, Minnesota. <i>Tob Control.</i> Mar 2019;28(2):176-180. doi:10.1136/tobaccocontrol-2017-054154</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>6. Brown EM, Gammon DG, Rogers T, et al. Changes in retail sales of tobacco products in Ontario after a menthol sales restriction. <i>Tob Control.</i> Jul 13 2021;doi:10.1136/tobaccocontrol-2021-056489</p>	<p>This study measured retail sales of menthol cigarettes and possible substitute products before and after policy implementation in Ontario. Cigar sales data were unavailable, however, and therefore, we declined to include this article. We include other references describing evaluations of flavored tobacco product bans in Canada that included cigar use.</p>

<p>7. Brown EM, Rogers T, Eggers ME, et al. Implementation of the New York City Policy Restricting Sales of Flavored Non-Cigarette Tobacco Products. <i>Health Educ Behav.</i> Oct 2019;46(5):782-789. doi:10.1177/1090198119853608</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>8. Cadham, C.J., Sanchez-Romero, L.M., Fleischer, N.L. <i>et al.</i> The actual and anticipated effects of a menthol cigarette ban: a scoping review. <i>BMC Public Health</i> 20, 1055 (2020). https://doi.org/10.1186/s12889-020-09055-z (supplemental table reviews flavor ban restrictions that do not include menthol)</p>	<p>We reviewed the references cited in this scoping review, identified Jo et al. (2015) as relevant and added it to Question 3. Jo, C.L., Williams, R.S., Ribisl, K.M. (2015). Tobacco Products Sold by Internet Vendors Following Restrictions on Flavors and Light Descriptors, <i>Nicotine & Tobacco Research</i>, 17(3), 344–349.</p>
<p>9. Chaiton M, Papadhima I, Schwartz R, et al. Product Substitution After A Real-World Menthol Ban: A Cohort Study. <i>Tob Regul Sci.</i> May 2020;6(3):205-212. doi:10.18001/trs.6.3.5</p>	<p>This reference was already included in Scientific Assessment in the Canada section of Question 3.</p>
<p>10. Cohn A, Cobb CO, Niaura RS, Richardson A. The Other Combustible Products: Prevalence and Correlates of Little Cigar/Cigarillo Use Among Cigarette Smokers. <i>Nicotine Tob Res.</i> Dec 2015;17(12):1473-81. doi:10.1093/ntr/ntv022</p>	<p>We added this reference to a section on dual and poly-use of tobacco products under Question 2.</p>
<p>11. Cohn A, Johnson A, Ehlke S, Villanti AC. Characterizing substance use and mental health profiles of cigar, blunt, and non-blunt marijuana users from the National Survey of Drug Use and Health. <i>Drug Alcohol Depend.</i> Mar 1 2016;160:105-11. doi:10.1016/j.drugalcdep.2015.12.017</p>	<p>We added this reference to the Adult Disparities section.</p>
<p>12. Coleman-Cowger, V. H., Pickworth, W. B., Lordo, R. A., & Peters, E. N. (2018). Cigar and Marijuana Blunt Use Among Pregnant and Nonpregnant Women of Reproductive Age in the United States, 2006-2016. <i>American journal of public health</i>, 108(8), 1073–1075. https://doi.org/10.2105/AJPH.2018.304469</p>	<p>The results of this study suggest there were no statistically significant differences among the survey years included (2006-2016) for cigar smoking. Nonpregnant women were more likely to smoke cigars than pregnant women. Given that these results do not reveal any new pattern of findings that is not already described in the Scientific Assessment, we opted to not add this study.</p>
<p>13. Conway KP, Green VR, Kasza KA, et al. Co-occurrence of tobacco product use, substance use, and mental health problems among youth: Findings from wave 1</p>	<p>We added this reference to the Youth Disparities section.</p>

<p>(2013-2014) of the population assessment of tobacco and health (PATH) study. <i>Addict Behav.</i> Jan 2018;76:208-217. doi:10.1016/j.addbeh.2017.08.009</p>	
<p>14. Conway KP, Green VR, Kasza KA, et al. Co-occurrence of tobacco product use, substance use, and mental health problems among adults: Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study. <i>Drug Alcohol Depend.</i> Aug 1 2017;177:104-111. doi:10.1016/j.drugalcdep.2017.03.032</p>	<p>We added this reference to the “Disparities in Cigar Use Among Adults” subsection of the Prevalence section.</p>
<p>15. Corey CG, Holder-Hayes E, Nguyen AB, et al. US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014. <i>Nicotine Tob Res.</i> Nov 15 2018;20(12):1457-1466. doi:10.1093/ntr/ntx209</p>	<p>We added this reference to several sections, including Adult Prevalence and the discussion of concept flavors in Question 3.</p>
<p>16. Cullen J, Mowery P, Delnevo C, et al. Seven-year patterns in US cigar use epidemiology among young adults aged 18-25 years: a focus on race/ethnicity and brand. <i>Am J Public Health.</i> Oct 2011;101(10):1955-62. doi:10.2105/AJPH.2011.300209</p>	<p>This publication analyzed National Survey on Drug Use and Health, 2002–2008 data. The conclusions are consistent with those from more recent publications that are already cited. Therefore, we opted to not add this citation.</p>
<p>17. Dai H, Hao J. Flavored Tobacco Use Among U.S. Adults by Age Group: 2013-2014. <i>Subst Use Misuse.</i> 2019;54(2):315-323. doi:10.1080/10826084.2018.1521428</p>	<p>This article does not report cigar-specific findings; “flavored tobacco use” is assessed broadly. Also, 2013–2014 National Adult Tobacco Survey data are analyzed, and the Scientific Assessment draws similar conclusions using more recent data. Therefore, we opted to not add this reference.</p>
<p>18. Dai H. Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017. <i>JAMA Pediatr.</i> Mar 1 2019;173(3):282-284. doi:10.1001/jamapediatrics.2018.4595</p>	<p>We added this reference to the Disparities subsection of the Youth Prevalence section.</p>
<p>19. Dai H. Single, Dual, and Poly Use of Flavored Tobacco Products Among Youths. <i>Prev Chronic Dis.</i> Jun 28 2018;15:E87. doi:10.5888/pcd15.170389</p>	<p>Given that this publication used data from 2014 and more recent data are available, we did not add this reference.</p>
<p>20. Delnevo CD, Bover-Manderski MT, Hrywna M. Cigar, marijuana, and blunt use among US adolescents: Are we accurately estimating the prevalence of cigar</p>	<p>We added this reference to the section on Methodological Considerations in the Prevalence section.</p>

<p>smoking among youth? <i>Prev Med.</i> Jun 2011;52(6):475-6. doi:10.1016/j.ypmed.2011.03.014</p>	
<p>21. Delnevo CD, Giovenco DP, Miller Lo EJ. Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act. <i>Tob Regul Sci.</i> Apr 2017;3(2 Suppl 1):S8-S16. doi:10.18001/trs.3.2(suppl1).2</p>	<p>We added this reference to the concept flavor sections in Question 3.</p>
<p>22. Delnevo CD, Giovenco DP, Miller Lo EJ. Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act. <i>Tob Regul Sci.</i> Apr 2017;3(2 Suppl 1):S8-S16. doi:10.18001/trs.3.2(suppl1).2</p>	<p>This reference is a duplication of the one above it.</p>
<p>23. Delnevo CD, Hrywna M. Clove cigar sales following the US flavoured cigarette ban. <i>Tob Control.</i> Dec 2015;24(e4):e246-50. doi:10.1136/tobaccocontrol-2013-051415</p>	<p>We added this reference to Question 3 (impact of local policies on product substitution).</p>
<p>24. Delnevo CD, Jeong M, Ganz O, Giovenco DP, Miller Lo E. The Effect of Cigarillo Packaging Characteristics on Young Adult Perceptions and Intentions: An Experimental Study. <i>Int J Environ Res Public Health.</i> Apr 19 2021;18(8)doi:10.3390/ijerph18084330</p>	<p>We added this reference to the concept flavor sections in Question 3.</p>
<p>25. Denlinger-Apte, R.L., Cassidy, R.N., Carey, K.B., Kahler, C.W., Bickel, W.K., O'Connor, R., Thussu, S. and Tidey, J.W., 2021. The impact of menthol flavoring in combusted tobacco on alternative product purchasing: A pilot study using the Experimental Tobacco Marketplace. <i>Drug and Alcohol Dependence</i>, 218, p.108390.</p>	<p>We added this to a new section under Question 2 titled "Evidence from hypothetical scenario studies."</p>
<p>26. D'Silva J, Moze J, Kingsbury JH, et al. Local sales restrictions significantly reduce the availability of menthol tobacco: findings from four Minnesota cities. <i>Tob Control.</i> Sep 2021;30(5):492-497. doi:10.1136/tobaccocontrol-2019-055577</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>27. Dunn, D.S., Johnson, A.L., Sterling, K.L. and Cohn, A.M., 2021. Differences in reasons for little cigar/cigarillo use across white and black/African American young adult users. <i>Addictive Behaviors</i>, 118, p.106884.</p>	<p>We added this reference to a new section on harm perceptions (Question 1).</p>

<p>28. Erinoso, O., Smith, K.C., Iacobelli, M., Saraf, S., Welding, K. and Cohen, J.E., 2021. Global review of tobacco product flavour policies. <i>Tobacco control</i>, 30(4), pp.373-379.</p>	<p>This article does not provide unique or new information relevant to the questions that serve as the framework for the Scientific Assessment. Therefore, we opted to not add this reference.</p>
<p>29. Farley SM, Sisti J, Jasek J, Schroth KRJ. Flavored Tobacco Sales Prohibition (2009) and Noncigarette Tobacco Products in Retail Stores (2017), New York City. <i>Am J Public Health</i>. May 2020;110(5):725-730. doi:10.2105/AJPH.2019.305561</p>	<p>We added this reference to the concept flavor sections in Question 3.</p>
<p>30. Feld AL, Rogers T, Gaber J, et al. Impact of Local Flavored Tobacco Sales Restrictions on Policy-Related Attitudes and Tobacco Product Access. <i>Health Educ Behav</i>. Aug 16 2021:10901981211027520. doi:10.1177/10901981211027520</p>	<p>This study examined attitudes toward flavored tobacco sales policies and perceived accessibility of flavored tobacco products in local stores. Our review of evaluations of local policies in Question 3 included sales data and behavioral data; perceptions and beliefs were beyond the scope of the Scientific Assessment. Therefore, we did not add this article to the Scientific Assessment.</p>
<p>31. Fishbein, H., Bauer, D., Yu, Q., Mermelstein, R., Jones, D., Miller, A., Harrell, M., Loukas, A., Sterling, K., Colip, B. and Mittl, B., 2021. Harmonizing Cigar Survey Data Across Tobacco Centers of Regulatory Science, Center for Tobacco Products, and Population Assessment of Tobacco and Health Studies: The Cigar Collaborative Research Group. <i>Nicotine and Tobacco Research</i>, 23(1), pp.212-218.</p>	<p>We added this reference to the Youth Prevalence section.</p>
<p>32. Freitas-Lemos R, Stein JS, Tegge AN, et al. The Illegal Experimental Tobacco Marketplace I: Effects of Vaping Product Bans. <i>Nicotine Tob Res</i>. Aug 29 2021;23(10):1744-1753. doi:10.1093/ntr/ntab088</p>	<p>We opted to not include this study because it entailed an experimental tobacco marketplace laboratory experiment with an exclusive focus on the effects of a hypothetical flavored vaping ban. Given that this was a hypothetical study about a product other than cigars, we considered it to have limited relevance to the research questions outlined in the Scientific Assessment.</p>
<p>33. Gaiha SM, Henriksen L, Halpern-Felsher B, et al. Sources of flavoured e-cigarettes among California youth and young adults: associations with local</p>	<p>We opted to not include this study because the focus was on e-cigarette access without cigar-specific or overall tobacco product outcomes, which limited its relevance to Research Question 3</p>

<p>flavoured tobacco sales restrictions. <i>Tob Control</i>. Apr 13 2021;doi:10.1136/tobaccocontrol-2020-056455</p>	<p>regarding the effects of local policies on the sale and use of cigars.</p>
<p>34. Gammon DG, Rogers T, Coats EM, et al. National and state patterns of concept-flavoured cigar sales, USA, 2012-2016. <i>Tob Control</i>. Jul 2019;28(4):394-400. doi:10.1136/tobaccocontrol-2018-054348</p>	<p>This reference was already included in Scientific Assessment in the concept flavors section.</p>
<p>35. Ganz O, Cohn AM, Goodwin RD, et al. Internalizing problems are associated with initiation and past 30-Day use of flavored tobacco products. <i>Addictive behaviors</i>. 2022/02/01/ 2022;125:107162. doi:https://doi.org/10.1016/j.addbeh.2021.107162</p>	<p>We added this reference to the “Disparities in Cigar Use Among Adults” subsection of the Prevalence section.</p>
<p>36. Ganz O, Hrywna M, Schroth KRJ, Delnevo CD. Innovative promotional strategies and diversification of flavoured mass merchandise cigar products: a case study of Swedish match. <i>Tob Control</i>. Feb 1 2021;doi:10.1136/tobaccocontrol-2020-056145</p>	<p>We added this reference to the “Local and National Policy Evaluation Study Summary and Limitations” subsection of Question 3.</p>
<p>37. Ganz O, King JL, Giovenco DP, Hrywna M, Strasser AA, Delnevo CD. Associations between Black and Mild Cigar Pack Size and Demographics and Tobacco Use Behaviors among US Adults. <i>Int J Environ Res Public Health</i>. Jun 20 2021;18(12)doi:10.3390/ijerph18126628</p>	<p>Although this article is relevant to cigars, it does not examine the impact of flavors on appeal, use, or other key outcomes. Therefore, we opted to not add it to the Scientific Assessment.</p>
<p>38. Giovenco DP, Miller Lo EJ, Lewis MJ, Delnevo CD. "They're Pretty Much Made for Blunts": Product Features That Facilitate Marijuana Use Among Young Adult Cigarillo Users in the United States. <i>Nicotine Tob Res</i>. Nov 1 2017;19(11):1359-1364. doi:10.1093/ntr/ntw182</p>	<p>We added this reference to the section on the appeal of flavors in cigars (Question 1).</p>
<p>39. Giovenco DP, Spillane TE, Mauro CM, Martins SS. Cigarillo sales in legalized marijuana markets in the U.S. <i>Drug Alcohol Depend</i>. Apr 1 2018;185:347-350. doi:10.1016/j.drugalcdep.2017.12.011</p>	<p>This study found that the most popular types and brands of cigars differed between localities that did and did not legalize marijuana. The potential impact of marijuana legislation on the cigar marketplace is beyond the scope of this Scientific Assessment, and, therefore, we did not add this citation.</p>

<p>40. Harrell MB, Loukas A, Jackson CD, Marti CN, Perry CL. Flavored Tobacco Product Use among Youth and Young Adults: What if Flavors Didn't Exist? <i>Tob Regul Sci.</i> Apr 2017;3(2):168-173. doi:10.18001/TRS.3.2.4</p>	<p>We added this to a new section under Question 2 titled "Evidence from hypothetical scenario studies."</p>
<p>41. Hefner K, Valentine G, Sofuoglu M. Electronic cigarettes and mental illness: Reviewing the evidence for help and harm among those with psychiatric and substance use disorders. <i>Am J Addict.</i> Jun 2017;26(4):306-315. doi:10.1111/ajad.12504</p>	<p>We did not add this reference because it was not specific to cigars. Instead, we draw nearly identical conclusions about the relation between mental illness and cigar use based on cigar-specific literature.</p>
<p>42. Henriksen, L., Schleicher, N.C., Ababseh, K., Johnson, T.O. and Fortmann, S.P., 2018. Marijuana as a 'concept' flavour for cigar products: availability and price near California schools. <i>Tobacco control</i>, 27(5), pp.585-588.</p>	<p>This study assessed the retail availability of cigar products that refer to marijuana (i.e., marijuana co-marketing). The potential impact of marijuana marketing on cigar use is beyond the scope of this Scientific Assessment, and, therefore, we did not add this citation.</p>
<p>43. Kephart, L., Setodji, C., Pane, J., Shadel, W., Song, G., Robertson, J., Harding, N., Henley, P. and Ursprung, W.W.S., 2020. Evaluating tobacco retailer experience and compliance with a flavoured tobacco product restriction in Boston, Massachusetts: impact on product availability, advertisement and consumer demand. <i>Tobacco control</i>, 29(e1), pp.e71-e77.</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>44. King, Brian A., Michael A. Tynan, Shanta R. Dube, and Rene Arrazola. "Flavored-little-cigar and flavored-cigarette use among US middle and high school students." <i>Journal of Adolescent Health</i> 54, no. 1 (2014): 40-46.</p>	<p>We added this reference to the "Disparities in Cigar Use Among Adults" subsection of the Prevalence section.</p>
<p>45. Kong G, Bold KW, Simon P, Camenga DR, Cavallo DA, Krishnan-Sarin S. Reasons for Cigarillo Initiation and Cigarillo Manipulation Methods among Adolescents. <i>Tob Regul Sci.</i> Apr 2017;3(2 Suppl 1):S48-S58. doi:10.18001/TRS.3.2(Suppl1).6</p>	<p>This reference is already cited in the Scientific Assessment in the "Systematic Literature Reviews on Appeal, Use, and Progression to Regular Use of Flavored Tobacco Products" subsection of Question 1.</p>
<p>46. Kong G, Cavallo DA, Bold KW, LaVallee H, Krishnan-Sarin S. Adolescent and Young Adult Perceptions on Cigar Packaging: A Qualitative Study. <i>Tob Regul Sci.</i> Jul 2017;3(3):333-346. doi:10.18001/TRS.3.3.9</p>	<p>This reference is already cited in the Scientific Assessment (in the "Qualitative Literature on Appeal and Use of Flavored Cigars" section).</p>

<p>47. Kong G, Cavallo DA, Goldberg A, LaVallee H, Krishnan-Sarin S. Blunt Use among Adolescents and Young Adults: Informing Cigar Regulations. <i>Tob Regul Sci.</i> Sep 2018;4(5):50-60. doi:10.18001/TRS.4.5.5</p>	<p>This qualitative study examined cigar product features perceived as useful for blunts. Given that blunt use is beyond the scope of the research questions that guided this Scientific Assessment, we decline to add this citation.</p>
<p>48. Kuiper NM, Gammon D, Loomis B, et al. Trends in Sales of Flavored and Menthol Tobacco Products in the United States During 2011-2015. <i>Nicotine Tob Res.</i> May 3 2018;20(6):698-706. doi:10.1093/ntr/ntx123</p>	<p>We added this reference to Question 3 in the discussion of NYC evaluation findings.</p>
<p>49. Kurti MK, Schroth KRJ, Delnevo C. A discarded cigar package survey in New York City: indicators of non-compliance with local flavoured tobacco restrictions. <i>Tob Control.</i> Sep 2020;29(5):585-587. doi:10.1136/tobaccocontrol-2019-055035</p>	<p>We added this reference to Question 3 (impact of local policies on flavored cigar sales).</p>
<p>50. Lawyer GR, Jackson M, Prinz M, et al. Classification of flavors in cigarillos and little cigars and their variable cellular and acellular oxidative and cytotoxic responses. <i>PLoS One.</i> 2019;14(12):e0226066. doi:10.1371/journal.pone.0226066</p>	<p>We added a new section on the health effects of cigars, but we decline to add this reference because the evidence in this area is inconclusive (e.g., Gosch Nethery, Herring, & Tarran (2017) found flavored and unflavored cigars caused comparable levels of toxicity and activation of apoptosis). A full review of the toxicity of flavors is beyond the scope of this review.</p>
<p>51. Levy, D.T., Meza, R., Yuan, Z., Li, Y., Cadham, C., Sanchez-Romero, L.M., Travis, N., Knoll, M., Liber, A.C., Mistry, R. and Hirschtick, J.L., 2021. Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. <i>Tobacco Control.</i></p>	<p>We added this reference to the subsection in Question 3 titled "Public Health Impact Assessment of a U.S. Policy on Flavored Cigars."</p>
<p>52. Liu, Jessica, Divya Ramamurthi, and Bonnie Halpern-Felsher. "Inside the adolescent voice: A qualitative analysis of the appeal of different tobacco products." <i>Tobacco induced diseases</i> 19 (2021).</p>	<p>This article is already cited in the "Qualitative Literature on Appeal and Use of Flavored Cigars" section.</p>
<p>53. Meernik C, Ranney LM, Lazard AJ, et al. The effect of cigarillo packaging elements on young adult perceptions of product flavor, taste, smell, and appeal. <i>PLoS One.</i> 2018;13(4):e0196236. doi:10.1371/journal.pone.0196236</p>	<p>We added this reference to sections on appeal of flavors in Question 1 and concept flavors in Question 3.</p>

<p>54. Nali MC, Purushothaman V, Xu Q, Cuomo RE, Mackey TK. Characterizing and assessing compliance of online vendors to the state of Massachusetts ENDS product sales ban. <i>Tob Induc Dis.</i> 2021;19:05. doi:10.18332/tid/131199</p>	<p>This study examined online vendor compliance with Sept 2019 Massachusetts executive order that placed a comprehensive temporary 4-month ban on selling ENDS products both online and offline. Because the order banned all ENDS and not just flavored ENDS (and the evaluation of it likewise focused on all ENDS), the article was beyond the scope of the Scientific Assessment, which was guided by a research question focused on flavor-related restrictions: "What Impact Do Local Policies Restricting the Sale of Flavored Cigars and Other Flavored Tobacco Products Have on Cigar Sales and Use?" Therefore, we did not add this citation.</p>
<p>55. Nguyen AB. Disaggregating Asian American and Native Hawaiian and Other Pacific Islander (AANHOP) Adult Tobacco Use: Findings from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014. <i>J Racial Ethn Health Disparities.</i> Apr 2019;6(2):356-363. doi:10.1007/s40615-018-00532-1 1.</p>	<p>We added this reference to the section on Adult Disparities.</p>
<p>56. Jeong M, Wackowski OA, Schroth KRJ, Strasser AA, Delnevo CD. Influence of cigarillo packaging characteristics on young adults' perceptions and intentions: findings from three online experiments. <i>Tob Control.</i> Oct 28 2021;doi:10.1136/tobaccocontrol-2021-056785</p>	<p>This article was already cited in Scientific Assessment.</p>
<p>57. Nyman AL, Sterling KL, Weaver SR, Majeed BA, Eriksen MP. Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use. <i>Tob Regul Sci.</i> Jul 2016;2(3):239-251. doi:10.18001/TRS.2.3.4</p>	<p>We added this reference to the concept flavor sections in Question 3.</p>
<p>58. Posner H, Romm K, Henriksen L, Bernat D, Berg CJ. Reactions to sales restrictions on flavored vape products or all vape products among young adults in the US. <i>Nicotine Tob Res.</i> Jul 31 2021;doi:10.1093/ntr/ntab154</p>	<p>We opted to not include this study because it assessed participants' support for e-cigarettes sales restrictions and, among e-cigarette users, participants' predictions about how such a ban would affect their e-cigarette and cigarette use. Because this study was entirely hypothetical and focused exclusively on e-cigarettes, it had minimal relevance to the</p>

	specific research questions addressed in the Scientific Assessment.
59. Printz C. JUUL sales recovered after self-imposed flavor ban. <i>Cancer</i> . Nov 1 2020;126(21):4629. doi:10.1002/cncr.33250	We opted to not include this article because the focus was exclusively on e-cigarettes and JUUL in particular.
60. Rao M, Bar L, Yu Y, et al. Disaggregating Asian American Cigarette and Alternative Tobacco Product Use: Results from the National Health Interview Survey (NHIS) 2006-2018. <i>J Racial Ethn Health Disparities</i> . Apr 28 2021;doi:10.1007/s40615-021-01024-5	We added this reference to the "Disparities in Cigar use Among Adults" section.
61. Ribisl KM, D'Angelo H, Feld AL, et al. Disparities in tobacco marketing and product availability at the point of sale: Results of a national study. <i>Preventive medicine</i> . 2017/12/01/ 2017;105:381-388. doi:https://doi.org/10.1016/j.ypmed.2017.04.010	We added this reference to the subsection of Question 1 on the "Marketing of flavored cigars," and to Question 3 (impact of local policies on flavored cigar sales).
62. Rogers T, Brown EM, McCrae TM, et al. Compliance with a Sales Policy on Flavored Non-cigarette Tobacco Products. <i>Tob Regul Sci</i> . 2017;3(2 Suppl 1):S84-S93. doi:10.18001/TRS.3.2(Suppl1).9	Already cited in the Scientific Assessment
63. Rose SW, Amato MS, Anesetti-Rothermel A, et al. Characteristics and Reach Equity of Policies Restricting Flavored Tobacco Product Sales in the United States. <i>Health Promot Pract</i> . Jan 2020;21(1_suppl):44S-53S. doi:10.1177/1524839919879928	We added this reference to the new section on marketing in Question 1.
64. Rose SW, Anesetti-Rothermel A, Westneat S, et al. Inequitable distribution of FTP marketing by neighborhood characteristics: further evidence for targeted marketing. <i>Nicotine Tob Res</i> . Oct 23 2021;doi:10.1093/ntr/ntab222	We added this reference to the new section on marketing in Question 1, and to Question 3 (impact of local policies on flavored cigar sales).
65. Rose SW, Johnson AL, Glasser AM, et al. Flavour types used by youth and adult tobacco users in wave 2 of the Population Assessment of Tobacco and Health (PATH) Study 2014-2015. <i>Tob Control</i> . Jul 2020;29(4):432-446. doi:10.1136/tobaccocontrol-2018-054852	We added this reference to Question 1.
66. Rostron BL, Cheng YC, Gardner LD, Ambrose BK. Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave	The findings reported in this manuscript duplicate evidence cited in the Scientific Assessment based on the PATH Online Tables.

<p>4 of the PATH Study, 2016-2017. <i>Am J Health Behav.</i> Jan 1 2020;44(1):76-81. doi:10.5993/AJHB.44.1.8</p>	<p>Since this reference would be entirely duplicative, we decline to add it.</p>
<p>67. Rostron, B, C GC, Holder-Hayes E, B KA. Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US. <i>Int J Environ Res Public Health.</i> Sep 4 2019;16(18)doi:10.3390/ijerph16183234</p>	<p>This article is already described in detail in the Public Health Assessment section (Q3), but it was mistakenly omitted from the reference list. We added it to the reference list.</p>
<p>68. Safi Z, Ganz O, Giovenco DP, Delnevo C, Lewis MJ. White Owl launches sweepstakes to promote new dessert-flavoured cigar. <i>Tob Control.</i> May 24 2021;doi:10.1136/tobaccocontrol-2021-056590</p>	<p>This article describes new flavors of cigars being released by the company White Owl. Given that the article does not describe empirical evidence and the main messages are consistent with those already in the Scientific Assessment regarding the appeal of flavors and flavor information on packaging, we decline to add this additional citation.</p>
<p>69. Schneller LM, Li D, Tavarez ZQ, et al. Flavor Inconsistencies between Flavored Tobacco Products among US Adults. <i>Am J Health Behav.</i> Sep 1 2020;44(5):617-630. doi:10.5993/AJHB.44.5.6</p>	<p>We added this reference to Question 1.</p>
<p>70. Schroth KRJ, Kurti M, Delnevo CD. Flavored cigar availability in Oakland after a partial ban. <i>Addict Behav.</i> Oct 12 2021;125:107150. doi:10.1016/j.addbeh.2021.107150</p>	<p>We added this reference to Question 3 in the Limitations section where we discuss enforcement and compliance.</p>
<p>71. Shang, C., Nonnemaker, J., Sterling, K., Sobolewski, J. and Weaver, S.R., 2021. Impact of Little Cigars and Cigarillos Packaging Features on Product Preference. <i>International Journal of Environmental Research and Public Health</i>, 18(21), p.11443.</p>	<p>We added this to the section on the appeal of flavor-related packaging characteristics under Question 1.</p>
<p>72. Simuzingili M, Hoetger C, Garner W, et al. What influences demand for cigars among African American adult cigar smokers? Results from a hypothetical purchase task. <i>Exp Clin Psychopharmacol.</i> Jun 10 2021;doi:10.1037/pha0000491</p>	<p>This study used a hypothetical purchasing task to examine demand for cigars. Given that the study did not specifically examine flavoring as a factor influencing demand, nor were there any other patterns in the results that were not consistent with what is already included in the Scientific Assessment, we opted to not add this reference to the Scientific Assessment.</p>

<p>73. Stanton CA, Keith DR, Gaalema DE, et al. Trends in tobacco use among US adults with chronic health conditions: National Survey on Drug Use and Health 2005-2013. <i>Prev Med</i>. Nov 2016;92:160-168. doi:10.1016/j.ypmed.2016.04.008</p>	<p>We added this reference to the “Disparities in Cigar Use Among Adults” subsection of the Prevalence section.</p>
<p>74. Sterling KL, Fryer CS, Nix M, Fagan P. Appeal and Impact of Characterizing Flavors on Young Adult Small Cigar Use. <i>Tob Regul Sci</i>. Apr 2015;1:42-53. doi:10.18001/TRS.1.1.5</p>	<p>This article was already cited in the Scientific Assessment. We also included it in new content related to concept flavors (Question 3) and flavor appeal (Question 1).</p>
<p>75. Sterling KL, Jones DM, Majeed B, Nyman AL, Weaver SR. Affect Predicts Small Cigar Use in a National Sample of US Young Adults. <i>Tob Regul Sci</i>. May 2019;5(3):253-263. doi:10.18001/TRS.5.3.4</p>	<p>We added this reference to the appeal section in Question 1.</p>
<p>76. Sterling KL, Vishwakarma M, Ababseh K, Henriksen L. Flavors and Implied Reduced-Risk Descriptors in Cigar Ads at Stores Near Schools. <i>Nicotine Tob Res</i>. Oct 7 2021;23(11):1895-1901. doi:10.1093/ntr/ntab136</p>	<p>We added this reference to the concept flavor sections in Question 3.</p>
<p>77. Sterling, K.L., Fryer, C.S., Pagano, I. and Fagan, P., 2017. Flavored cigar misperceptions and uncertainty: identifying at-risk smokers. <i>Tobacco Regulatory Science</i>, 3(2), pp.17-30.</p>	<p>We added this reference to the Adult Prevalence section and the new Harm Perceptions (Question 1) section.</p>
<p>78. Stokes, A.C., Wilson, A.E., Lundberg, D.J., Xie, W., Berry, K.M., Fetterman, J.L., Harlow, A.F., Cozier, Y.C., Barrington-Trimis, J.L., Sterling, K.L. and Benjamin, E.J., 2021. Racial/Ethnic Differences in Associations of Non-cigarette Tobacco Product Use With Subsequent Initiation of Cigarettes in US Youths. <i>Nicotine and Tobacco Research</i>, 23(6), pp.900-908.</p>	<p>This article was already cited in the Scientific Assessment (“Disparities in Cigar Use Among Adults” subsection of the Prevalence section).</p>
<p>79. Timberlake DS, Rhee J, Silver LD, et al. Impact of California's tobacco and cannabis policies on the retail availability of little cigars/cigarillos and blunt wraps. <i>Drug Alcohol Depend</i>. Sep 24 2021;228:109064. doi:10.1016/j.drugalcdep.2021.109064</p>	<p>We added this reference to Question 3 in the “Local and National Policy Evaluation Study Summary and Limitations” section.</p>
<p>80. Villanti AC, Johnson AL, Ambrose BK, et al. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). <i>Am J Prev Med</i>. Aug 2017;53(2):139-151. doi:10.1016/j.amepre.2017.01.026</p>	<p>We added this reference to the “Appeal of Flavors in Tobacco Products” subsection of Question 1.</p>

<p>81. Yingst JM, Bordner CR, Hobkirk AL, et al. Response to Flavored Cartridge/Pod-Based Product Ban among Adult JUUL Users: "You Get Nicotine However You Can Get It". <i>Int J Environ Res Public Health</i>. Dec 30 2020;18(1)doi:10.3390/ijerph18010207</p>	<p>This study evaluated adults' ENDS use behavior before and after JUUL stopped selling most of its flavored pods. We opted to not include this article because the focus was exclusively on e-cigarettes and JUUL in particular.</p>
<p>82. Zhu, Y., Pasch, K.E., Loukas, A., Sterling, K.L. and Perry, C.L., 2021. Exposure to cigar Point-of-Sale marketing and use of cigars and cigarettes among young adults. <i>Addictive Behaviors</i>, 116, p.106821.</p>	<p>This study examined the relationship between exposure to cigar marketing and cigar use. Given that there were no results specific to the marketing of flavored products, the focus of this manuscript is beyond the scope of the Scientific Assessment and we opted to not add it.</p>