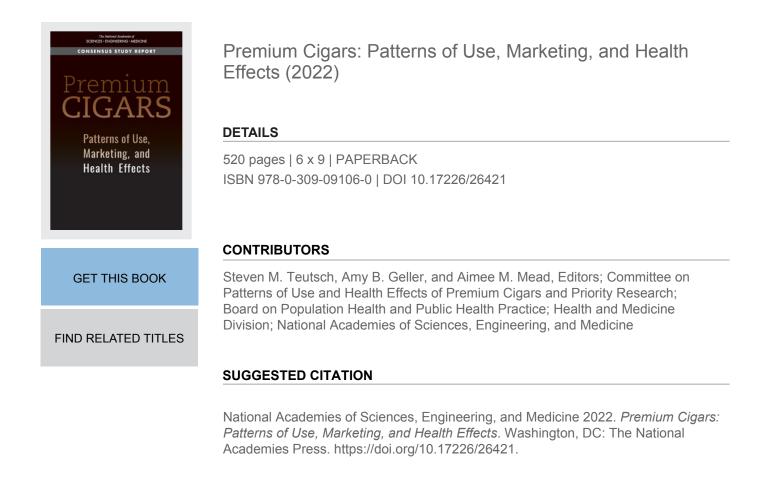
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# Premium CIGARS

## Patterns of Use, Marketing, and Health Effects

Steven M. Teutsch, Amy B. Geller, and Aimee M. Mead, Editors

Committee on Patterns of Use and Health Effects of "Premium Cigars" and Priority Research

Board on Population Health and Public Health Practice

Health and Medicine Division

A Consensus Study Report of

The National Academies of SCIENCES • ENGINEERING • MEDICINE

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **Linda C**. **Degutis**, Yale School of Public Health, and **David A. Savitz**, Brown University. They responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

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## Acronyms and Abbreviations

AOR	adjusted odds ratio
APA	Administrative Procedure Act
BaP	benzo[a]pyrene
BC	bladder cancer
CAL	clinical attachment loss
CEJ	cemento-enamel junction
CIR	Canadian intense regimen
CO	carbon monoxide
COPD	chronic obstructive pulmonary disease
CPS	Current Population Survey
CTP	Center for Tobacco Products
CVD	cardiovascular disease
DTC	direct-to-consumer
ENDS	electronic nicotine delivery systems
EPIC	European Prospective Investigation into Cancer and
	Nutrition
ETS	environmental tobacco smoke
FDA	Food and Drug Administration
FEV1/FVC	forced vital capacity
FTC	Federal Trade Commission
GC-MS	gas chromatography-mass spectrometry
GEE	general estimating equation
HPHCs	harmful and potentially harmful constituents
HR	hazard ratio

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IARC	International Agency for Research on Cancer
IRR	incidence rate ratio
ISO/FTC	International Organization for Standardization/U.S. Fed- eral Trade Commission
LC-MS	liquid chromatography-mass spectrometry
LGB	lesbian, gay, and bisexual
MDE	major depressive episode
MRTP	modified risk tobacco product
NATS	National Adult Tobacco Survey
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NHL	non-Hodgkin's lymphoma
NIH	National Institutes of Health
NLMS	National Longitudinal Mortality Study
NNAL	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone
NNN	N'-nitrosonornicotine
NSDUH	National Survey on Drug Use and Health
OR	odds ratio
PAH	polycyclic aromatic hydrocarbons
PATH	Population Assessment of Tobacco and Health Study
PCA	Premium Cigar Association
RR	relative risk
RYO	roll-your-own
SES	socioeconomic status
SHS	secondhand tobacco smoke
SPD	serious psychological distress
TDS	tobacco dependence score
TTB	Alcohol and Tobacco Tax and Trade Bureau
TUS	Tobacco Use Supplement
TUS-CPS	Tobacco Use Supplement to the Current Population Survey
UADT	upper aerodigestive tract

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## Abstract

At the request of the Food and Drug Administration (FDA) and the National Institutes of Health, the National Academies of Sciences, Engineering, and Medicine (NASEM) convened an expert committee to examine four premium cigar topics: product characteristics, patterns of use, marketing and perceptions, and health effects. The resulting report includes 13 findings, 24 conclusions, and nine priority research recommendations for federal support.

Since the late 1990s, overall cigar<sup>1</sup> consumption has increased every year, with a total increase of 145 percent from 1998 to 2020. However, the committee found that premium cigars are consistently a small percent of the U.S. cigar market. Data from the Alcohol and Tobacco Tax and Trade Bureau suggest that the percentage of the cigar market that may be premium was 1.5–3.0 percent between 2010 and 2020. In addition, the committee found that one percent of the adult population uses premium cigars.

In 2016, FDA broadened its regulatory authority to include cigars. In 2018, FDA issued a call for additional information and comments on several aspects of premium cigars specifically, including the definition, patterns of use, and public health impacts, to further inform its regulatory actions. Since 2016, various cigar associations have filed several lawsuits

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<sup>&</sup>lt;sup>1</sup>When the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

against FDA regarding how it regulates cigars in general and premium cigars specifically; some are still ongoing. Members of Congress in both chambers have introduced legislation several times to exclude premium cigars from FDA regulation, most recently in June 2021.

There is not a single, consistent definition of premium cigars accepted by FDA, industry, courts, and the public. Consequently, there is no clear distinction between premium and large nonpremium cigars or even with other cigar types (e.g., filtered/little cigars and cigarillos). For the purposes of its work, the committee developed a working definition of premium cigars. The committee defined a premium cigar as having all of the following characteristics: 1) handmade, 2) filler composed of at least 50 percent natural long-leaf filler tobacco, 3) wrapped in whole leaf tobacco (i.e., not reconstituted tobacco), 4) weight of at least 6 pounds per 1,000 units, 5) no filters or tips, and 6) no characterizing flavor other than tobacco. The committee was not tasked with recommending a regulatory definition of a premium cigar. While other stakeholders may adopt or adapt the committee's definition for other purposes, additional factors that the committee did not emphasize would need to be considered. For example, the tobacco industry has altered its products so that the products no longer fit existing regulatory definitions (or now meet the definition of a different tobacco product), and this factor was not a major consideration for the committee.

After reviewing the definitions of premium cigars used by different entities, the committee identified no material difference between products typically considered premium and other cigar types in terms of harmful or potentially harmful constituents. However, a meaningful difference currently exists in how products typically considered premium are used (e.g., frequency of use, depth of inhalation). The committee notes that tobacco products are inherently harmful, but their patterns of use are mutable, including how and by whom they are used, which ultimately determines their health effects.

The committee conducted a comprehensive literature search to identify publications on premium cigars. The literature on premium cigars specifically is limited, and most publications do not distinguish premium from other large cigars. With no agreed-upon definition of premium cigars, there is a lack of consistency regarding which brands are considered premium. In addition, study designs varied considerably (e.g., surveys and laboratory, epidemiologic, and toxicological studies). Because of the paucity of literature on premium cigars, studies of large, traditional cigars, cigars overall (including filtered cigars/little cigars and cigarillos), and other combustible tobacco products were included based on committee members' assessment of the relevance and the potential generalizability of those studies' findings to premium cigars. The com-

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#### ABSTRACT

mittee also relied heavily on biological mechanisms and plausibility in its framework, as well as threats to validity, particularly for the assessment of health effects. In addition, the committee commissioned several analyses to further inform its work.

The committee's priority research recommendations for federal agencies include the following:

- Development of formal categories and definitions for all cigar types to be used for research to ensure consistency among studies;
- Implementation of a strategic plan to regularly monitor patterns of use, product characteristics, consumer knowledge and perceptions, and collection of sales and marketing data, among other data points;
- Improvement of survey data collection, such as measuring cigar ever use, ever regular use, and past 12-month use to better capture lifetime use of cigar products, and collecting data on selfreported inhalation patterns and how and when the cigars are smoked; and
- Research to assess specific aspects of premium cigars for:
  - Cigar characteristics,
  - Health effects (including priority populations),
  - Addiction potential, and
  - Marketing practices and consumer perceptions and knowledge.

If implemented, these recommendations will considerably advance the knowledge base of premium cigars and cigars in general and better inform policy and regulatory decisions. Premium Cigars: Patterns of Use, Marketing, and Health Effects

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### Summary

The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) asked the National Academies of Sciences, Engineering, and Medicine (the National Academies) to examine the evidence on the patterns of use and health effects of "premium"<sup>1</sup> cigars compared to other tobacco products, identify research needs, and make prioritized recommendations for future federally funded research on premium cigars (see Box 1-2 in Chapter 1 for the full statement of task). The committee also addressed research questions provided by FDA, NIH, and other stakeholders, including examining the state of marketing and perceptions of premium cigars (see Appendix A).

#### INTRODUCTION AND DEFINITIONS

The early to mid-1990s saw a large surge in U.S. cigar consumption: 5 billion cigars in 1997. Premium cigar consumption increased approximately 250 percent from 1993 to 1997 and 90 percent from 1996 to 1997. These trends did not apply to all tobacco products, as cigarette consump-

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<sup>&</sup>lt;sup>1</sup>Note that quotations are used at first occurrence of the term "premium" in each chapter, as there is no formally agreed-upon definition of what constitutes a premium cigar, and different entities might use this term differently. See later in this Summary and Chapter 1 for more information. In addition, when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/ traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

#### 2 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS

tion decreased 2 percent in 1993–1997. Premium cigars, however, make up a small percent of the total U.S. cigar market. With these dramatic increases in cigar smoking, the National Cancer Institute (NCI) undertook a comprehensive review of available knowledge about cigars in 1998 the only one to date. The resulting monograph (*Cigars: Health Effects and Trends*) made several recommendations for research; however, they have largely not been addressed, and many of the identified information gaps persist. This report provides a comprehensive update to that report for health effects, marketing, and perceptions of premium cigars, and patterns of use for all cigar types.

There is no single, consistent definition of premium cigars accepted by FDA, industry, courts, and the public. Consequently, there is no clear distinction between premium and large nonpremium cigars or even among other cigar types. The lack of a formal, accepted definition makes research challenging, and few published studies specifically focus on premium cigars. The marketplace is diverse, with many different types of cigars, including little/filtered cigars, cigarillos, large cigars, and premium cigars. Box S-1 provides what are largely considered common characteristics of the different cigar types, and Figure S-1 provides examples of what these products generally look like.

Premium cigars do have a different pattern of use than other cigar products and, therefore, different resulting health effects. However, they are not inherently less risky than other cigar products. All cigars contain harmful and potentially harmful constituents,<sup>2</sup> and the extent to which they negatively affect health largely depends on how they are used (e.g., frequency and duration of use, pattern of inhalation).

#### CONTEXT

The Family Smoking Prevention and Tobacco Control Act<sup>3</sup> (commonly known as the Tobacco Control Act) of 2009 established FDA as the principal federal regulatory authority for the manufacture, distribution, and marketing of tobacco products. This authority was applied to cigarettes and to cigarette tobacco, roll-your-own, and smokeless tobacco. The statute permitted FDA to issue regulations "deeming" other types of tobacco products subject to restrictions and regulation under the Federal Food, Drug, and Cosmetic Act.<sup>4</sup> In 2014, FDA proposed two alternatives

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<sup>&</sup>lt;sup>2</sup> Harmful or potentially harmful constituents is the FDA regulatory term for chemicals or chemical compounds in tobacco products or tobacco smoke that cause or could cause harm to smokers and nonsmokers.

<sup>&</sup>lt;sup>3</sup> Public Law 111–31.

<sup>&</sup>lt;sup>4</sup> 21 U.S.C. 301.

SUMMARY

#### BOX S-1 Common Characteristics of Cigar Types

A cigar is a tobacco product that is not a cigarette and is a roll of tobacco wrapped in leaf tobacco or a substance containing tobacco. The common types and characteristics of cigars are listed below. Note that no regulatory or formal definition of any cigar type exists (other than the categories of small and large cigars for federal tax purposes).

**Filtered cigar/little cigar:** cigars that are usually brown and have a filter like a cigarette; are made on the same machines as cigarettes; and are similar in size and shape as cigarettes. Little cigars weigh less than 3 pounds per thousand cigars or 1.36 g per stick, whereas filtered cigars weigh slightly more and so are technically taxed as large cigars.

**Cigarillo:** medium-sized machine-made cigars that sometimes come with plastic or wood tips. These cigars weigh more than 3 pounds per thousand cigars or 1.36 g per stick.

**Other traditional/large cigars:** nontipped, machine-made cigars that tend to be larger than cigarillos and weigh more than 3 pounds per thousand cigars or 1.36 g per stick.

**Premium cigars:** For this report, a premium cigar is defined as having all six of these characteristics (see Chapter 1 for more information on how the committee came to this definition\*):

- 1. Handmade
- 2. Filler composed of at least 50 percent natural long-leaf filler tobacco
- 3. Wrapped in whole leaf tobacco (i.e., not reconstituted tobacco)
- 4. Weight of at least 6 pounds per 1,000 units (i.e., 2.72 g per stick)\*\*
- 5. No filters or tips
- 6. No characterizing flavor other than tobacco

\* The committee was not tasked with providing a recommendation for a regulatory definition of a premium cigar. The definition that it used is for the purpose of this report only—to allow for a systematic review of the literature. While other stake-holders may adopt or adapt this definition for other purposes, additional factors might need to be considered (see Chapter 1 for additional discussion).

\*\* Most premium cigars currently on the market weigh much more than this threshold, and cigars in other categories sometimes weigh this much as well (see Appendix F).

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FIGURE S-1 Types of cigars compared to a cigarette.

NOTES: From left to right: premium cigar (Arturo Fuente Curly Head), premium cigar (Rocky Patel 1990), traditional cigar (Phillies Blunt), cigarillo (Backwoods Honey Berry), cigarillo (Swisher Sweets Blueberry), filtered/little cigar (Djarum), filtered/little cigar (Cheyenne), and cigarette (Marlboro). Picture taken as part of commissioned work; see Appendix F. Brand names included for identification only.

for the scope of the deeming provisions: Option 1 (all products meeting the statutory definition of "tobacco product" would be deemed) and Option 2 (same as Option 1, but excluding premium cigars). In 2016, FDA adopted Option 1 and finalized a rule to broaden its regulatory authority to include all products meeting the statutory definition of a tobacco

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#### SUMMARY

product,<sup>5</sup> including cigars. FDA concluded that this option would more comprehensively protect the public's health, as it noted that the evidence was insufficient to justify excluding premium cigars from the final deeming rule and therefore regulation.

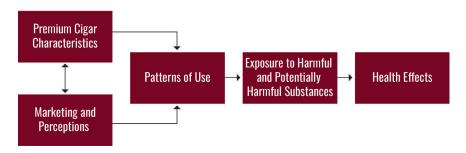
However, in March 2018, FDA issued a call for additional information and comments not previously submitted for consideration for the deeming rule. This advanced notice of proposed rulemaking sought information on the definition, use patterns, and public health effects of premium cigars to further inform FDA's regulatory actions on such cigars. In August 2020, FDA stated that the comments received did not provide sufficient evidence to answer questions about how premium cigar characteristics and patterns of use affect health outcomes and if they do so differently than other tobacco products. Premium cigars have been the subject of legal and regulatory efforts for the past decade. In June 2021, FDA withdrew its entry for information request on premium cigars from the Unified Agenda of Regulatory and Deregulatory Actions, pending review of this report. Several court cases are ongoing regarding cigars and premium cigars involving FDA. Members of Congress in both chambers have introduced legislation since 2011 to exclude premium cigars from FDA regulation; none of the bills have passed the chamber of Congress in which they were introduced.

#### STUDY PROCESS

The committee organized its work in four focus areas: characteristics of cigars, patterns of use, marketing and perceptions, and health effects (see Figure S-2). Figure S-2 highlights how patterns of premium cigar use are influenced by cigar characteristics (e.g., nicotine level, pH, addiction potential), marketing, and user perceptions. Premium cigar marketing is impacted by characteristics of the product itself and how the product is described (e.g., handmade, artisanal, premium) and, in turn, how consumers perceive the product, which directly influences how they intend to use it. Consumers' reactions to marketing campaigns and/or their perceptions about premium cigars may influence how premium cigar companies characterize their products. The resulting patterns of use lead to varying levels of toxic exposures from smoking premium cigars (or being exposed to secondhand smoke) based on use, ending with health outcomes.

<sup>&</sup>lt;sup>5</sup> Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

6 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS



**FIGURE S-2** Simplified illustration of potential causal pathways by which premium cigars could affect health.

Given the heterogeneity of the research and the varied topics that the committee was tasked with reviewing, it adapted its approach to reviewing the literature and assessing the evidence for each focus area. Box S-2 describes its evidence framework to assess the strength of the evidence throughout the report.

A systematic literature search was conducted (see Appendix B) to identify publications on premium cigars. Because the term "premium" has not been used systematically, searches considered cigars more generally. The committee's approach was informed by published guidelines for conducting systematic reviews and approaches taken by prior National Academies committees.

Early in its work, the committee noted the very limited literature available on premium cigars specifically. With no agreed-upon definition of premium cigars, the literature is inconsistent regarding which brands are considered premium, and many publications do not distinguish premium from other large cigars. To guide its work, the committee developed a working definition of premium cigars (see Box S-1 and Chapter 1).

Because of the paucity of literature on premium cigars, studies of large/traditional cigars (which include premium), cigars overall (including filtered cigars/little cigars and cigarillos), and other combustible tobacco products were included based on committee members' assessment of the relevance and potential generalizability of the findings to premium cigars. The committee also relied heavily on biological mechanisms and plausibility in its framework, particularly to assess health effects. The committee extrapolated data from other tobacco products when the data was strong and in the absence of any important threats to validity. In addition, the committee commissioned several analyses to further inform its work (see Appendixes C, D, F, and G).

SUMMARY

#### **Evidence Framework**

Based on previous reviews, the committee developed standardized language to categorize the strength of the evidence. Box S-2 presents the categories and describes the types of evidence that correspond to the committee's confidence in each conclusion category. Conclusive evidence implies that observed associations between premium cigar use and a given outcome are very unlikely to change in the face of new evidence, whereas other categories progressively represent less available (or conflicting) evidence. Conclusive, strongly suggestive, and moderately suggestive evidence describe a direction of effect (e.g., increased or decreased risk of a health outcome), whereas topics with insufficient or no available evidence do not imply a direction. The level of evidence does not indicate the magnitude or importance of the effect. The committee used the framework as a guide and included expert judgment in evaluating individual studies and in the bodies of evidence. The report provides findings<sup>6</sup> on patterns of use, and conclusions on product characteristics, marketing and perceptions, and health effects.

#### FINDINGS AND CONCLUSIONS

#### **Characteristics of Cigars**

Vast amounts of data, much of it recent, exist on toxic and carcinogenic constituents of cigar tobacco and smoke demonstrating that all analyzed toxicant levels are similar or higher than those found in cigarette tobacco and smoke, compared per unit of tobacco. These data clearly demonstrate that cigars could be as dangerous as or more dangerous than cigarettes, with respect to toxicant and carcinogen exposure per unit consumed. Despite only limited data on premium cigars, it is reasonable to expect that the results of analyses of tobacco and smoke would not substantially differ from other cigar types because premium cigars' tobacco and pyrolysis conditions are similar. Based on laboratory studies using validated analytical methods and a variety of smoking conditions, including human smoking topography conditions, the available data demonstrate that exposure of premium cigar users to toxic and carcinogenic constituents of smoke will be qualitatively similar to the exposure of users to constituents of other combustible tobacco products. The relationship between tobacco pH and smoke pH remains unclear, and smoke analysis in general can be challenging. However, two laboratory studies have shown cigar smoke

<sup>&</sup>lt;sup>6</sup> A finding is a statement of the evidence, whereas a conclusion is an inference, interpretation, or generalization drawn from the evidence.

8 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS

BOX S-2 Evidence Framework		
Level of Confidence	<ul> <li>Description*</li> <li>Conclusive evidence implies that observed associations between premium cigar use and a given outcome are very unlikely to change with new evidence, whereas other categories provide progressively less evidence.</li> <li>The categorizations for each conclusion are based on the committee's overall assessment of the body of evidence.</li> </ul>	
Conclusive evidence	The available evidence (including biologic plausibility when appropriate here and in the categories below) usually includes consistent results from well-designed, well-conducted studies in representative relevant settings and/or populations. These studies assess the effects on relevant outcomes. <i>The conclu- sion is therefore unlikely to be strongly affected by the</i> <i>results of future studies.</i>	
Strongly suggestive evidence	<ul> <li>The available evidence is sufficient to determine the effects on relevant outcomes, but confidence in the <i>estimate is constrained</i> by such factors as:</li> <li>The number, size, or quality of individual studies;</li> <li>Inconsistency of findings across individual studies;</li> <li>Limited generalizability of findings to routine practice/ populations; and/or</li> <li>Lack of coherence in the chain of evidence.</li> <li>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</li> </ul>	

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SUMMARY

Moderately suggestive evidence	<ul> <li>The available evidence is sufficient to determine the effects on relevant outcomes, but confidence in the <i>estimate is significantly constrained</i> by such factors as:</li> <li>The number, size, or quality of individual studies;</li> <li>Inconsistency of findings across individual studies;</li> <li>Limited generalizability of findings to routine practice/ populations; and/or</li> <li>Lack of coherence in the chain of evidence.</li> <li>As more information becomes available, the magnitude or direction of the observed effect could change, which could alter the conclusion.</li> </ul>
Insufficient/ No available evidence	<ul> <li>The available evidence is insufficient to assess effects on relevant outcomes. Evidence is insufficient because of: <ul> <li>The limited number or size of studies;</li> <li>Important flaws in study design or methods;</li> <li>Inconsistency of findings across individual studies;</li> <li>Gaps in the chain of evidence;</li> <li>Findings not generalizable to the general population; and/or</li> <li>Lack of information on important outcomes.</li> </ul> </li> </ul>

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pH becoming more alkaline from early to last puffs, which would result in more unprotonated nicotine and therefore more oral nicotine absorption.

Conclusion 2-1: There is **conclusive evidence** that the addictive, toxic, and carcinogenic **constituents of cigar tobacco in general** are the same as those present in cigarette tobacco. There is **strongly suggestive evidence** that **constituents of premium cigar tobacco** are similar to constituents of other cigars because all tobacco contains nicotine, carcinogenic tobaccospecific nitrosamines, metals, and precursors to toxic and carcinogenic compounds formed during the combustion process.

Conclusion 2-2: There is **conclusive evidence** that the **toxicants and carcinogens in cigar smoke in general** are qualitatively the same as those in cigarette smoke. There is no reason to believe that **toxicants and carcinogens in premium cigar smoke** are any different from those in other types of cigars. Additionally, it is likely that the total toxic and carcinogenic constituent yields will increase with the mass of tobacco filler in the cigar.

Conclusion 2-3: There is **strongly suggestive evidence** that there is a wide variety of **pH levels of tobacco used in cigars overall**; however, higher pH has been noted in premium cigar tobacco than for other cigar types. While there is **insufficient evidence** on the **pH of premium cigar smoke**, the **pH of large cigar smoke** is generally higher than cigarette smoke, which can decrease depth of inhalation and increase nicotine absorption through the oral mucosa. There is **insufficient evidence** on the relationship between the pH of premium cigar tobacco and smoke.

Based on the measurement of urinary biomarkers of nicotine and toxicants and carcinogens in the large NHANES and PATH studies and several smaller controlled clinical studies examining different products, such as small and large cigars, cigar users are exposed to significant amounts of nicotine and harmful and potentially harmful constituents. While levels of some urinary biomarkers were higher in every day exclusive cigarette smokers, the PATH study found that, for other biomarkers, concentrations in every day exclusive traditional cigar smokers were comparable to those of every day exclusive cigarette smokers. This indicates similar exposure and uptake of nicotine, toxicants, and carcinogens. Concentrations of biomarkers were also higher than in never-tobacco users.

*Conclusion* 2-4: *There is conclusive evidence that cigar smokers in general are exposed to significant amounts of nicotine and numerous harmful and potentially harmful constituents.* 

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#### SUMMARY

Inhalation patterns and the resulting exposure to nicotine and harmful and potentially harmful smoke constituents have not been studied directly in premium cigar users. However, based on the measurement of inhalation patterns among users of large cigars and studies that examined the effect of inhalation patterns on exposure to nicotine and toxicants from conventional cigarettes, the available data strongly suggest that inhalation patterns will be important determinants of exposure in premium cigar users, too. Although data from experimental studies that objectively measured puffing patterns in large cigar users who also smoke conventional cigarettes (dual users) are limited, they are consistent with self-reported inhalation patterns of cigar smokers who used to smoke cigarettes. The body of evidence suggests that, compared to those who only smoke cigars, dual users of cigars and cigarettes are more prone to smoking cigars with a greater intensity and therefore, inhaling the smoke more deeply.

Conclusion 2-5: There is **strongly suggestive evidence** that the **inhalation patterns of cigar smokers in general** significantly affect their exposure to nicotine and harmful and potentially harmful constituents. At present, the extent to which **premium cigar users who do not inhale** have systemic exposure to nicotine and harmful and potentially harmful constituents remains unknown. It is likely that **smokers of premium cigars who concurrently smoke cigarettes or smoked cigarettes in the past** inhale more smoke compared to exclusive users of premium cigars.

#### PATTERNS OF USE

Despite a paucity of data on the patterns of use of premium cigars specifically, based on the available published literature and work commissioned by the committee (see Appendixes C and D), the committee identified the following key findings:<sup>7</sup>

Finding 3-1: Large, machine-produced cigars have been the dominant cigar type for much of the last century. Total cigar consumption began declining in the mid-1970s and reached its lowest level in 1993, when promotion of premium cigars reversed overall consumption trends for all cigar types. Since the release of the NCI's 1998 monograph on cigars, overall cigar consumption has increased every year, with a total increase of 145 percent from 1998 to 2020.

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<sup>&</sup>lt;sup>7</sup> In findings 3-1 through 3-10 "premium cigar user(s)" are those reporting use for at least one of the past 30 days.

#### 12 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS

Finding 3-2: Premium cigars are consistently a small, stable percent of the U.S. cigar market.

Finding 3-3: About 1 percent of the U.S. adult population smokes premium cigars, a frequency that has remained stable over time.

Finding 3-4: Cigarettes remain the most commonly used combustible tobacco product among adults in the United States. The prevalence of cigarette smoking among adults in 2018–2019 was 16.4 percent compared to 0.7 percent for premium cigars, 0.5 percent for nonpremium cigars, 1.4 percent for cigarillos, and 0.8 percent for filtered cigars.

Finding 3-5: The majority of premium cigar users are male, white, with higher income and education levels compared to those who smoke cigarillos, little filtered cigars, or cigarettes. Premium cigar users are on average 7–10 years older than those who smoke cigarillos or little filtered cigars. Premium cigar use is less common among youth, and only 0.6 percent of those who reported smoking a premium cigar use is also less common among women, non-Hispanic Black people, and people with less than a high school education.

Finding 3-6: The frequency and intensity of smoking is lower for premium cigars compared to other types of cigars and cigarettes. Only about 5 percent of premium cigar users smoke these daily, whereas 22 percent of nonpremium cigar users, 19 percent of cigarillo users, 40 percent of filtered cigar users, and 76 percent of cigarette users smoke those products daily. The median number of cigars or cigarettes smoked per day is about 0.1 for premium cigars, 0.2 for nonpremium cigars, 0.3 for cigarillos, 1.0 for filtered cigars, and 10 for cigarettes.<sup>8</sup>

Finding 3-7: Premium cigar users are less likely to smoke cigarettes or other cigar types concurrently than other cigar type users. Dual use with cigarettes was highest for filtered cigar users (~70 percent), followed by cigarillo users (~60 percent) and nonpremium cigar users (~50 percent), and lowest for premium cigar users (~26 percent).

<sup>8</sup> The median was calculated consistent with the methods used by Corey et al. (2018): respondents reporting smoking less than one cigar per day on the days smoked were assigned as 0.5 cigars per day.

#### SUMMARY

Finding 3-8: Premium cigar users are more likely to be never or former cigarette smokers than users of other cigar products. They are also more likely than the general population to smoke cigarettes.

Finding 3-9: The prevalence of alcohol dependence among those who smoke premium cigars is similar to those who smoke nonpremium cigars or cigarettes. The prevalence of cannabis and illicit drug dependence among those who smoke premium cigars is lower than those who smoke nonpremium cigars or cigarettes. However, the prevalence of alcohol, cannabis, and illicit drug dependence among those who smoke premium cigars is higher than for those who do not use any tobacco products.

Finding 3-10: Population Assessment of Tobacco and Health Study analyses suggest that about three-quarters of exclusive premium cigar users continued smoking premium cigars in the following year. Among exclusive premium cigar users in Wave 1 (2013–2014), slightly more than half remained as exclusive premium cigar users in Wave 5 (2018–2019). About 35 percent discontinued use of cigars and cigarettes by Wave 5. Less than 5 percent became cigarette smokers (exclusive or dual with premium or nonpremium cigars) by Wave 5. Additionally, exclusive premium cigar users who smoked infrequently (i.e., less than 6 days in the past 30 days) were more likely to discontinue use within a year compared to those who smoked more frequently.

#### MARKETING AND PERCEPTIONS

*Cigar Aficionado*, the first magazine to specifically promote premium cigars as a lifestyle, was associated with the rapid increase in premium cigar sales and consumption in the early 1990s. Along with other cigar lifestyle magazines, it continues to promote premium cigars. Despite the 1998 NCI monograph's recommendations, data on overall cigar marketing expenditures have been limited, as are published data on marketing expenditures of premium cigars through traditional channels (e.g., direct mail, e-mail). Although the committee found it difficult to access marketing data (for both branded and non-branded marketing) and found few published studies, marketing of premium cigars still occurs. Based on the committee's primary data collection, it is evident that cigars are marketed on the Internet and social media platforms, but only one published study reported the extent to which premium cigars are marketed in these ways. Evidence indicates that premium cigars are marketed through direct mail advertisements, although the magnitude of this type of marketing is

unknown because tracking data are not readily accessible. Based on its review, the committee concludes:

Conclusion 4-1: Based on the committee's primary data collection, there is conclusive evidence that third-party cigar retailers use direct-to-consumer methods to market premium cigars using similar strategies as the nonpremium cigar industry.

Conclusion 4-2: Based on the committee's primary data collection, there is **conclusive evidence** that **premium cigar** companies use lifestyle magazines and festivals to promote premium cigars. Some of these marketing strategies, such as sponsoring music festivals and promoting their products with an urban lifestyle and hip-hop and rock music, may appeal to young people.

Conclusion 4-3: Based on the committee's primary data collection, there is **conclusive evidence** that **premium cigar** companies have online and social media presences not captured by traditional methods of tracking marketing expenditures.

Conclusion 4-4: Based on the 1998 NCI monograph on cigars, subsequent publications, the committee's primary data collection, and consistent with research on the "premiumization" of tobacco products that purport better quality and less harm, there is **conclusive evidence** that **premium cigars** are advertised and promoted as less harmful than other tobacco products and as having benefits that outweigh their adverse health effects. Premium cigars are also marketed as an integral component of a successful, luxurious lifestyle, used at upscale social events, and by influential celebrities and individuals.

Conclusion 4-5: There is **strongly suggestive evidence** from survey data that consumers of **premium cigars** who buy in person typically purchase their cigars from cigar bars or smoke/tobacco specialty shops or outlet stores, whereas **nonpremium large traditional cigar** users typically purchase their cigars at convenience stores/gas stations. A lower proportion of premium cigar users buy their cigars in person than nonpremium large traditional cigar users. Data from online cigar retailers shows that a large proportion of premium cigar sales occur online, though this is not directly captured in current surveys of cigar users.

Conclusion 4-6: There is **no research** that examines whether consumers distinguish **premium cigars** from large cigars or other cigar types, consumers' knowledge of premium cigars, or what defines premium cigars.

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Conclusion 4-7: There is **strongly suggestive evidence** that the U.S. population perceives **cigar products overall** to be harmful and addictive. However, there is **no research** that examines the knowledge of the specific health effects of **premium cigars**.

Conclusion 4-8: There is **strongly suggestive evidence** from prospective studies that lower perceived harm and addictiveness of **cigars in general** is associated with cigar use behavior, including current use in adults and initiation in youth.

#### HEALTH EFFECTS

The potential adverse health effects of premium cigars need to be viewed in the context of the harms of smoking combusted tobacco broadly. Cigarette smoking is the most common form of combusted tobacco use, and its health effects are well established, including increased overall mortality, cardiovascular disease, chronic obstructive lung disease, cancers, susceptibility to respiratory infection, periodontal disease, and other diseases. The toxicants generated by burning tobacco are generally similar across tobacco types. The extent of inhalation and frequency and duration of use are major factors in determining whether tobacco smoking will cause disease.

Assessing the health effects of premium cigars (including secondhand smoke) included reviewing biological plausibility; reviewing the chemical nature of the tobacco leaf and emissions from premium cigars and how these compare to other combusted tobacco products; reviewing the evidence for extent of inhalation of premium cigar smoke, including biomarkers of exposure that might establish levels of systemic exposure; and researching the epidemiology of particular diseases in relation to cigar use. Because the epidemiology on premium cigar use is quite limited, the committee examined cigar use in general, with a particular focus on inhalation, frequency, and duration. These data were considered as a whole to assess specific disease risks from premium cigar use. The committee was unable to compare risks among various cigar types.

Conclusions 5-1 and 5-2 are based on the known chemical characteristics of combustible tobacco products, including cigars, and biological mechanisms by which constituents of combustible tobacco products are processed (in animals and humans). While studies on cigars may include premium cigars, they do not distinguish premium from other cigar types. However, given the conclusive data on tobacco products, including cigars in general, and the absence of any important threats to validity, the committee extrapolated these findings to premium cigars.

Conclusion 5-1: There is **conclusive evidence** that **smoke** from **cigars in general, including premium cigar smoke,** contains many hazardous and potentially hazardous constituents, capable of causing cardiovascular disease, lung disease, cancer, and multiple other negative health effects.

Conclusion 5-2: There is **conclusive evidence** that the chemical nature of emissions from **cigars in general**, **including premium cigars**, are similar to those of cigarette smoke. There is strong biological plausibility that exposure to these chemicals will cause disease. Thus, if cigar smoke is inhaled and cigars are smoked regularly, the risks are likely to be qualitatively similar to those of cigarette smoking.

Tobacco smoking is associated with increased risk of mortality, CVD, respiratory disease, cancer, and other adverse health outcomes. Health risk associated with tobacco use, including use of premium cigars, may be determined by smoking behaviors, including frequency, intensity, duration, and depth of inhalation. No epidemiologic studies have examined the association of premium cigars with health outcomes; however, several have examined the health effects of cigar use in general, which may include premium cigars. Based on the findings from epidemiologic studies evaluating the health effects of cigar use in general, biological plausibility, the absence of any important threats to validity, generalizability of study inferences, and the smoking behaviors of premium cigar users, the committee concludes:

Conclusion 5-3: There is **strongly suggestive evidence** that the health risks of **premium cigar use** (overall mortality; cardiovascular disease; lung, bladder, and head/neck cancer; chronic obstructive pulmonary disease; and periodontal disease) depend on frequency, intensity, duration of use, and depth of inhalation.

Conclusion 5-4: There is **insufficient evidence** to determine if occasional or **nondaily exclusive cigar use in general** is associated with increased health risks.

Conclusion 5-5: There is **strongly suggestive evidence** that health consequences of **premium cigar smoking overall** are likely to be less than those smoking other types of cigars because the majority of premium cigar smokers are nondaily or occasional users and because they are less likely to inhale the smoke.

Conclusion 5-6: There is **strongly suggestive evidence** that many of the health risks of **daily exclusive cigar use in general** (overall mortality; cardiovascular disease; lung, bladder, and head/neck cancer; chronic obstructive

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#### SUMMARY

pulmonary disease; and periodontal disease) are significantly higher than those of never-smokers and lower than those of daily cigarette smokers.

Conclusion 5-7: There is **moderately suggestive evidence** that the health risks among **primary cigar users in general** (those who were never established cigarette users) are generally lower than among secondary cigar users (those who were former users of cigarettes) because secondary cigar users may be more likely to inhale the smoke. Likewise, **concurrent users of premium cigars** and other combustible tobacco products would experience greater health risks than those smoking only premium cigars.

*Conclusion 5-8: There is insufficient evidence to draw conclusions on the health effects of premium cigars on* 

- Youth or young adults,
- Racialized and ethnic populations,
- Pregnancy,
- Those with underlying medical conditions,
- People with occupational exposures to premium cigars (e.g., cigar lounges, manufacturing), and
- Health effects compared to other cigar types.

Despite a lack of direct evidence on the potential health effects of flavored premium cigars (as added flavors are excluded in most definitions of premium cigars), based on the extensive literature on the effects of flavors on other types of cigars and other tobacco products, evidence suggests that adding characterizing flavors (not inherent to the tobacco itself) would have important implications for premium cigars' impact on public health. Based on the findings from flavored cigars in general and other flavored tobacco products, and biological plausibility, no important threats to validity, and generalizability of study inferences, the committee concludes:

Conclusion 5-9: Based on the extensive literature on the effects of flavors on cigars and other tobacco products, there is **moderately suggestive evidence** that **adding characterizing flavors** (that is, flavors added to the product that are not inherent to the tobacco itself) **to premium cigars** could result in a greater appeal to nonusers and lead to more frequent use with potentially increased nicotine intake, increased addiction potential, and increased exposure to harmful and potentially harmful constituents present in premium cigar smoke.

Studies are limited on premium cigar secondhand smoke; nonetheless, it seems clear that concentrations of secondhand cigar smoke in general can be similar to or greater than that from cigarettes. The emission

rates appear to be lower for cigars, but cigars are smoked for much longer periods. It is likely that the health effects of indoor premium cigar and cigarette smoking would be similar for a similar duration and intensity of exposure. Evidence is lacking about the extent of secondhand exposure to premium cigar smoke.

Conclusion 5-10: There is **sufficient evidence** that **premium cigars** generate considerable levels of secondhand smoke; however, there are **insufficient data** on the health risks associated specifically with exposure to **premium cigar secondhand smoke**. It is plausible that since the constituents emitted from premium cigars are similar to constituents from other tobacco products, the health risk might be the same, but the extent of secondhand premium cigar exposure is unknown.

Premium cigars, like other cigar products, provide the sensations and stimuli shown to be important to the dependence potential of tobacco products (e.g., hand-to-mouth movements, taste, smells, airway sensations). Per this report's definition, they lack characterizing flavors, which are known to increase the addictiveness of other tobacco products. Some research indicates that nonpremium cigars, particularly large cigars that are similar in size and other characteristics (no filter), might have nicotine levels similar to other cigar products and potentially conventional cigarettes. A strong biological plausibility exists that premium cigars possess the features (i.e., rate/amount of nicotine delivery, pleasant stimuli) liable to make them as addictive as other tobacco products with known addiction potential (e.g., smokeless tobacco).

Conclusion 5-11: There is **moderately suggestive evidence** to support the biological plausibility that **regular cigar smoking in general** can be addictive. It is likely that this is also true for **premium cigar** smoking, based on nicotine delivery characteristics, abuse liability studies, and epidemiological data. The magnitude of **premium cigar** dependence appears to be less than that of cigarette smoking and smokeless tobacco use dependence. The extent of addiction is likely to depend on the patterns of use.

# PRIORITY RESEARCH

After reviewing the varied definitions of premium cigars used by different entities and the chemical constituents of cigar products, the committee concluded that there is no material difference between products typically considered premium cigars and other cigar types in terms of harmful or potentially harmful constituents. Based on available data, however, a meaningful difference does exist in how products typically

#### SUMMARY

considered premium are currently used (e.g., how often they are smoked, depth of inhalation, user demographics). The committee notes that there is a difference between a tobacco product being inherently harmful due to its constituent makeup, which generally stays consistent, and patterns of use, which change over time. However, the committee was not tasked with providing guidance on whether premium cigars should be considered separately from other cigar types for research or for regulatory purposes.

Premium cigars comprise a small share of the market compared to other cigar types. Evidence suggests that they are less likely to be used by youth, and most users smoke them only occasionally. However, it is important to continue to monitor premium cigar use, as these patterns could change. For example, changes in regulation that could affect one or more tobacco categories, shifts in consumer awareness or perceptions, changes in prices or taxes of one or more tobacco products, or social shifts could result in a preference for premium cigars and influence patterns of premium cigar use. Therefore, it is important to have a greater understanding of premium cigars' physical characteristics, patterns of use, user perceptions, tobacco industry marketing strategies, and health effects, over time, to inform regulatory decisions.

The committee identified nine priority recommendations that the federal government should support to advance the field. Chapter 6 describes the criteria that the committee considered to specify its research recommendations.

#### **High-Priority Recommendations**

#### Definition of Premium Cigars and Other Cigar Types

This report repeatedly points to the lack of formal definitions for not only premium cigars but also other cigar types, which has significantly hindered cigar research.

# Recommendation 1: The Food and Drug Administration, in consultation with other federal agencies, should develop formal categories and definitions for cigars to be used for research to ensure consistency among studies.

These definitions could likely also be used for regulatory purposes. It should be noted that many cigars considered premium weigh considerably more than 6 pounds per 1,000 units. Since this weight threshold is used in many definitions of premium cigars, the weight criterion merits re-examination, as it might need to be increased to be consistent with the

current marketplace (for example, other cigar types also commonly meet this weight threshold). Experience with other tobacco products (e.g., e-cigarettes) has demonstrated that as definitions are delineated, new products arise that no longer fit into existing definitions. In addition, tobacco products are also sometimes altered to meet the definition or category of another product. Therefore, in addition to standardizing definitions for research, product design criteria (e.g., length, weight, circumference, tobacco weight, tobacco type, flavors, filters) should also be identified and reported consistently in all research studies so that as products evolve, they can still be characterized and compared.

# Strategic Planning and Data Collection

The 1998 NCI monograph identified significant gaps in data on cigar use and evaluation and made recommendations for improvement. No coordinated federal surveillance and evaluation infrastructure has since been established to support regular monitoring and tracking related to different cigar types. To conduct research on premium cigars and compare among cigar types, infrastructure to gather relevant data for cigars overall is needed.

Recommendation 2: The Department of Health and Human Services, in partnership with the Alcohol and Tobacco Tax and Trade Bureau and the Federal Trade Commission (FTC), should implement a strategic plan to develop surveillance and evaluation systems that regularly monitor patterns of use, product characteristics, and related knowledge and perceptions by cigar type. These systems should also measure exposure to cigar smoke; track health outcomes; monitor tobacco industry marketing and promotion strategies; track sales and marketing expenditures; track cigar prices by cigar type; make data available; and define other indicators of monitoring to inform public health research and practice. These efforts should include but are not limited to

- a. Agreed-upon definitions of each cigar type (see Recommendation 1), and
- b. Development of annual FTC sales and marketing expenditure reports on all cigar product types, as is done for cigarettes, smokeless tobacco, and electronic cigarettes.

This recommendation will likely require funding from Congress. A similar infrastructure is already in place for cigarettes. Parts of this recom-

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#### SUMMARY

mendation could be implemented in the short term—for example, item b, which calls for annual FTC sales and marketing expenditure reports.

Available data to classify study participants based on type of cigar use has been on relatively recent use (e.g., past 30 days), which may underestimate the total number of users. Collecting data on the environments in which premium cigars are smoked (e.g., homes, cigar lounges, outdoors), including by whom and smoking duration, will allow researchers to determine the real-life exposures to secondhand smoke, an area with a paucity of data. Given the potential seasonal and geographic variation in premium cigar use, including paradata (administrative data about the survey) in publicly available datasets could facilitate a better understanding of such variations and their implications for interpreting prevalence estimates.

Recommendation 3: The Department of Health and Human Services should ensure that the tobacco research it supports, including surveys such as the Population Assessment of Tobacco and Health Study, the Tobacco Use Supplement to the Current Population Survey, and the National Survey on Drug Use and Health:

- a. Measures ever use, ever regular use, and past 12-month use to better capture lifetime use of each type of cigar product.
- b. Asks participants about use of premium cigars, employing commonly used terminology (e.g., "Have you ever smoked premium cigars?") in addition to asking about brands used.
- c. Asks participants about self-reported inhalation patterns, how cigars are typically smoked (e.g., in one session or partial/relighting), and where cigars are smoked (e.g., indoors at home) to assess secondhand smoke exposure.
- d. Includes paradata (administrative data about the survey), such as survey date and geographic location in publicly available datasets to improve understanding of patterns of use and/or exposure.

### Health Effects

Most studies on health effects do not distinguish premium from nonpremium cigars. Cigar use in these studies may include premium cigars and other large cigars, little cigars, or cigarillos. Studies that distinguish premium from nonpremium cigar use would better isolate the health effects of premium cigar smoking. In addition, data on premium cigar use shows that co-use with alcohol is more likely than any other substance (for example, co-use of cannabis was low). Co-use of alcohol with tobacco products is directly related to cancer risk. Recommendation 4: The Food and Drug Administration (FDA), the National Institutes of Health, and other federal agencies should ensure that the research they support on the associations between cigar, including premium cigar, use and health effects

- a. Reports the frequency of use, duration, intensity, cumulative exposure, pattern of inhalation, and the number of years smoking cigars to inform potential dose-response relationship and modifying factors (e.g., co-use of alcohol, cannabis, and other substances);
- b. Distinguishes primary, secondary, and dual use cigar smokers;
- c. Examines co-use of alcohol and premium cigars;
- d. Estimate the associations between cigar use and specific lung cancer histological types;
- e. Includes questions on the type of cigar, including premium cigars, separated from large cigars and other cigar types; and
- f. Uses the definitions of cigar types provided by FDA (see Recommendation 1).

# Additional Priority Recommendations

# Product Characteristics

Methods are available to analyze harmful and potentially harmful constituents in premium cigar tobacco, but developing standardized conditions for quantifying the components of premium cigar smoke and executing studies on these components are a research priority.

Recommendation 5: To improve knowledge of premium cigar characteristics, the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and other federal agencies should support

- a. The development of reproducible methods for machine smoking of premium cigars;
- b. Laboratory studies to measure nicotine, toxicants, and carcinogens in tobacco and smoke emitted from premium cigars;
- c. Studies to assess how the pH of premium cigar smoke affects puff topography and extent of inhalation;
- d. Comparative biomarker studies, both of toxicant exposure and of potential harm, in smokers of premium, large, and other cigar type smokers;

#### SUMMARY

- f. Studies that systematically evaluate how various premium cigar characteristics (e.g., size, shape, type of tobacco, added flavoring, sugar content, moisture, smoke pH) affect puffing topography; and
- g. Observational studies to assess patterns and intensity of secondhand smoke exposure to premium cigar smoke.

#### Marketing and Risk Perceptions

Because promotional activities can increase cigar consumption, normalize cigar use, and decrease barriers to cigar use among new users (including youth and young adults, women, racialized and ethnic populations, and sexual and gender minority groups), and given the lack of research in this area for premium cigars, the committee recommends:

Recommendation 6: The Food and Drug Administration (FDA), the National Institutes of Health (NIH), and other federal agencies should conduct or fund research to determine the unique type of marketing, advertising, and promotional practices used by companies that manufacture, distribute, and sell premium cigars. FDA, NIH, and other federal agencies should also identify strategies for tracking these activities, especially those that may appeal to youth.

See Chapter 6 for specific related research needs—for example, studies on various environmental (e.g., print and online media and social media platforms, social events, bars, lounges) and interpersonal channels (e.g., industry representatives, peers, online users) used to promote premium cigars.

#### Addiction Potential

Little is known about the addiction potential of premium cigars and how it compares to other cigar types. Premium cigars may have nicotine levels similar to (or higher than) other cigar products and conventional cigarettes because they contain more tobacco. In addition, premium cigar and non-flavored cigar products may have similar sensorimotor characteristics that contribute to addiction potential (see Chapter 5). For these reasons, the conceptual and biological plausibility that premium cigars can be addiction-promoting products cannot be ruled out, given a sufficient level of exposure. However, more research is needed.

Recommendation 7: The Food and Drug Administration (FDA), the National Institutes of Health, and other federal agencies should support research that

- a. Provides data on the level of dependence in relation to patterns of premium and other cigar type use;
- b. Measures dependence on cigars and other tobacco products in dual and/or poly-tobacco users;
- c. Compares dependence on large cigars with flavors to dependence on premium cigars (which, by definition in this report, do not include flavors); and
- d. Studies the impact on dependence of reduced nicotine content in cigars, per proposed FDA policy to reduce nicotine to 0.4 mg/g for all cigarettes, to make them minimally addictive.

Regarding item d, FDA has issued an advance notice of proposed rulemaking that would require tobacco companies to lower the nicotine content in all cigarettes sold to levels at which they are no longer addictive. If this regulation progresses and all cigars are excluded, or other cigar types are included but premium cigars are excluded, premium cigars would provide an alternative source of nicotine for cigarette and cigar smokers.

# Priority Populations

The literature has significant gaps about the health effects of large and premium cigars on specific populations; however, additional research is a high priority in certain areas.

Recommendation 8: The Food and Drug Administration, the National Institutes of Health, and other federal agencies should support research on the comparative health effects of cigar types, including premium cigars, in priority populations (as needed based on prevalence and trends), including

- a. Women, racialized and ethnic populations, sexual and gender minority groups, adolescents/young adults, and during pregnancy, including studies on the impact on nondaily users of cigars;
- b. People with vascular disease, including assessments of their cardiovascular risk, as this population would be especially vulnerable to the adverse effects of acute short-term smoke exposure;

#### SUMMARY

- c. People with respiratory diseases, such as chronic obstructive pulmonary disease and asthma;
- d. Cancer survivors; and
- e. People with occupational exposures to premium cigars (e.g., in cigar lounges, manufacturing).

#### Consumer Perceptions and Knowledge

Beliefs such as risk perceptions are central to numerous health behavior theories and have been the focus of decades of tobacco research. Risk perceptions are also often the targets of interventions to prevent and reduce tobacco use, such as required health warning labels on tobacco packaging/marketing and mass media campaigns designed to raise awareness. However, no research examines whether consumers distinguish premium cigars from large cigars or other cigar types, consumers' knowledge of what premium cigars are, what defines premium cigars, or knowledge on the health effects of premium cigars specifically.

Recommendation 9: The Food and Drug Administration, the National Institutes of Health, and other federal agencies should support research to assess consumer knowledge and awareness of premium cigars in the U.S. population. Specifically, these studies should

- a. Develop and implement specific measures that capture awareness of premium cigars as a tobacco product category, perceived risks and benefits of using premium cigars, and knowledge of the risks of premium cigar use; and
- b. Gather data regarding consumer knowledge about different cigar types and how, why, and where people start, continue, and discontinue using premium cigars (including perceived benefits and harms).

#### CONCLUDING REMARKS

While research on premium cigars is largely lacking, the committee drew conclusions in many areas based on studies on other cigar types, biological plausibility, and the absence of important threats to validity. Therefore, the committee identified nine research priorities directed to federal agencies to expand the evidence base for premium cigars and cigars in general. If implemented, the committee's recommendations will result in a better understanding of premium cigar use, marketing practices, and health effects over time. Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# I

# **Context and Methods**

#### **BACKGROUND AND LANDSCAPE**

The early to mid-1990s saw a large surge in U.S. cigar<sup>1</sup> consumption; 5 billion cigars were consumed in 1997 (NCI, 1998). "Premium"<sup>2</sup> cigar consumption increased 90 percent from 1996 to 1997 and approximately 250 percent from 1993 to 1997. These trends did not apply to all tobacco products, as cigarette consumption decreased 2 percent in 1993–1997. Premium cigars, however, make up a small percent of the total U.S. cigar market. With these dramatic increases in cigar smoking, the National Cancer Institute (NCI) undertook a comprehensive review of available knowledge about cigars in 1998 (*Cigars: Health Effects and Trends*). The resulting monograph made several recommendations for research that have largely not been addressed, and many of the information gaps that it

<sup>&</sup>lt;sup>1</sup> Note that when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

<sup>&</sup>lt;sup>2</sup> Note that quotations are used at the first occurrence of the term "premium" in each chapter, as there is no formally agreed-upon definition of what constitutes a premium cigar, and different entities might use this term differently. See later in this chapter for more information.

identified still exist today.<sup>3</sup> This report provides a comprehensive update to that report for health effects, marketing, and perceptions of premium cigars and patterns of use for all cigar types.

A premium cigar is typically considered to be handmade, large in size, filled with at least 50 percent natural long-leaf filler tobacco, wrapped in whole leaf tobacco, and with no filters or tips, among other characteristics. However, there is neither a formal regulatory definition of a premium cigar nor a single, consistent definition accepted by the Food and Drug Administration (FDA), the cigar industry, courts, and the public (see below for a discussion of cigar definitions). This lack of a formal definition makes research challenging, and few published studies specifically focused on premium cigars. The cigar marketplace is diverse, including little/filtered cigars, cigarillos, large cigars, and premium cigars (see Chapter 2). Despite no formal definitions of these cigar types, Box 1-1 provides what are largely considered common characteristics (see the definitions section later in this chapter for more on premium cigars and Chapter 2 for a detailed description of cigar types).

# **Regulatory Context**

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is responsible for regulating tobacco products. The Family Smoking Prevention and Tobacco Control Act<sup>4</sup> (commonly known as the "Tobacco Control Act") of 2009 established FDA as the principal federal regulatory authority for the manufacture, distribution, and marketing of tobacco products. This regulatory authority was applied to cigarettes and to cigarette tobacco, roll-your-own, and smokeless tobaccos (Apelberg, 2021). The statute permitted FDA to issue regulations "deeming" other types of tobacco products subject to restrictions and regulation under the Federal Food, Drug, and Cosmetic Act.<sup>5</sup>

In 2014, FDA proposed two alternatives for the scope of the deeming provisions: Option 1 (all products meeting the statutory definition of "tobacco product" would be deemed) and Option 2 (same as Option 1, except premium cigars would be excluded) (FDA, 2016). In 2016, FDA adopted Option 1 after concluding that deeming all cigars would more comprehensively protect the public's health. FDA noted that the evidence

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<sup>&</sup>lt;sup>3</sup> For example, the report recommended that questions on cigar use be included in surveys designed to measure tobacco use, questions about cigar use be standardized for uniformity of data collection, and standard definitions for cigars be developed. While many surveys now include some questions on cigar use, they are not standardized, and no standard definitions exists (NCI, 1998).

<sup>&</sup>lt;sup>4</sup> Public Law 111-31.

<sup>&</sup>lt;sup>5</sup>21 U.S.C. 301.

# **BOX 1-1 Common Characteristics of Cigar Types** A cigar is a tobacco product that is not a cigarette and is a roll of tobacco wrapped in leaf tobacco or a substance containing tobacco. The common types and characteristics of cigars are listed below. Note that no regulatory or formal definition of any cigar type exists (other than the categories of small and large cigars for federal tax purposes). Filtered cigar/little cigar: cigars that are usually brown, and have a filter like a cigarette; are made on the same machines as cigarettes; and are similar in size and shape to cigarettes. Little cigars weigh less than 3 pounds per thousand cigars or 1.36 g per stick, whereas filtered cigars weigh slightly more and so are technically taxed as large cigars. Cigarillo: medium-sized machine-made cigars that sometimes come with plastic or wood tips. These cigars weigh more than 3 pounds per thousand cigars or 1.36 g per stick. · Other traditional/large cigars: nontipped, machine-made cigars that tend to be larger than cigarillos and weigh more than 3 pounds per thousand cigars or 1.36 g per stick. "Premium" cigars: For this report, a premium cigar is defined as having all of the following six characteristics: handmade, filler composed of at least 50 percent natural long-leaf filler tobacco, wrapped in whole leaf tobacco (i.e., not reconstituted tobacco), weighs at least 6 pounds per 1,000 units (i.e., 2.72 g per stick), no filters or tips, no characterizing flavor other than tobacco (see definitions section later in this chapter). SOURCES: Apelberg, 2021; FDA, 2018; NCI, 1998.

was insufficient to justify excluding premium cigars from the final deeming rule and therefore regulation. The finalized rule broadened FDA's regulatory authority to include all products meeting the statutory definition of a tobacco product,<sup>6</sup> including cigars (FDA, 2016)<sup>7</sup> and established restrictions on newly deemed tobacco products for the protection

nition of a tobacco product,<sup>6</sup> including cigars (FDA, 2016)<sup>7</sup> and established restrictions on newly deemed tobacco products for the protection of public health, including requiring health warnings on packaging and in advertisements.

<sup>&</sup>lt;sup>6</sup> Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

<sup>&</sup>lt;sup>7</sup> A cigar is "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco" (26 USC Sec. 5702a).

However, in March 2018, FDA issued a call for additional information and comments not previously submitted for consideration for the deeming rule (FDA, 2018). This advanced notice of proposed rulemaking sought information on the definition, use patterns, and public health effects of premium cigars to further inform FDA's regulatory actions on them. In August 2020, FDA stated that the comments received did not provide sufficient evidence to answer questions about how premium cigar characteristics and patterns of use affect health outcomes and if they do so differently than do other tobacco products (FDA, 2021). As described later in this chapter, in early 2021, FDA and the National Institutes of Health (NIH) asked the National Academies of Sciences, Engineering, and Medicine (National Academies) to form a committee to explore the available literature on the health effects and patterns of use of premium cigars. In June 2021, FDA withdrew its entry for information request on premium cigars from the Unified Agenda of Regulatory and Deregulatory Actions, pending review of this report (FDA, 2021).

# Litigation

In 2016, the Cigar Association of America, International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America (trade associations and advocates for premium cigar manufacturers, retailers, and consumers) filed a lawsuit<sup>8</sup> against FDA, contesting the deeming rule and its application to cigars and pipe tobacco (i.e., Option 1 in the deeming rule). The lawsuit alleged that the enforcement of premarket review of premium cigars would be costly, making FDA's issuance of the deeming rule "arbitrary and capricious" in violation of the Administrative Procedure Act (APA); requiring industry to pay "user fees" is an illegal tax, also in violation of APA; imposing user fees on cigar manufacturers but not e-cigarette manufacturers is "contrary to [the] constitutional right" to due process protected by the Fifth Amendment, a violation of APA; FDA's cost analysis did not properly quantify the rule's costs or identify significantly less costly alternatives to the rule, a violation of the Regulatory Flexibility Act; and FDA's decision to regulate all cigars rather than exempting premium cigars is also "arbitrary and capricious" (PHLC, n.d.).

Litigation is ongoing. For example, in August 2020, a ruling from the U.S. District Court for the District of Columbia prohibited FDA from enforcing the premarket authorization requirement for premium cigars (part of the Tobacco Control Act) until it develops a streamlined substan-

<sup>&</sup>lt;sup>8</sup> Cigar Association of America et al. v. U.S. Food and Drug Administration (2016). Docket No. 1:16-cv-1460 (D.D.C.); Appeal #1: Docket No. 18-05195 (D.C. Cir. 2018); Appeal #2: Docket No. 20-05266 (D.C. Cir. Aug 31, 2020).

tial equivalence process for premium cigars (FDA, 2020; PHLC, n.d.). Requirements for warnings on cigar packages have also been suspended (FDA, 2020; PHLC, n.d.).

In July 2021, the Washington, DC Court of Appeals rejected an appeal filed in May 2021 by three cigar trade organizations challenging a previous decision made by the DC District Court, which legally validates FDA's requirements for substantial equivalence and upholds the 2007 predicate date for cigars.<sup>9</sup>

#### **Congressional Bills**

Members of Congress in both chambers have introduced legislation several times to exclude premium cigars from FDA regulation. Most recently, a bill sponsored by Rep. Kathy Castor (D-FL-14), with both Democratic and Republican cosponsors, was introduced in June 2021 to exclude "traditional and premium cigars" from FDA regulation.<sup>10</sup> A similar version of the bill sponsored by Senator Marco Rubio (R-FL) was introduced in February 2021.<sup>11</sup> Members of Congress have introduced previous iterations of the same bill since 2011, none of which have passed the chamber of Congress in which they were introduced (Nagy, 2016).

#### Cigar Use in the United States

Historically, premium cigars in the United States are imported (NCI, 1998). Nicaragua, the Dominican Republic, and Honduras are currently the three largest producers (Savona, 2021). Recent data suggests that premium cigar use may be increasing, given that the United States imported more than 171 million premium cigars from January to May 2021, which is a 73 percent increase from the same months in 2020. However, as noted, premium cigars make up a small percent of the U.S. cigar market. Alcohol and Tobacco Tax and Trade Bureau data suggest that the percentage of the cigar market sales that may be premium ranged from 1.5 to 3.0 percent between 2010 and 2020 (see Chapters 3 and 4).

Robust data on premium cigar use is scarce, given the lack of a single, consistent definition, absence of survey questions that assess premium cigar use, and lack of studies directly measuring consumer perceptions

<sup>&</sup>lt;sup>9</sup>Cigar Association of America v. United States Food and Drug Administration. No. 1:16cv-01460. https://www.cadc.uscourts.gov/internet/opinions.nsf/027EF724C43DBA848525 871800512412/\$file/20-5266-1906982.pdf (accessed November 10, 2021).

<sup>&</sup>lt;sup>10</sup> H.R.3982—Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2021

<sup>&</sup>lt;sup>11</sup> S.438—Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2021

(see Chapter 4). However, some information about prevalence of premium cigar use has been published with data from the Population Assessment of Tobacco and Health (PATH)<sup>12</sup> Study and the National Survey on Drug Use and Health (NSDUH);<sup>13</sup> the committee commissioned additional analyses of these datasets (see Appendixes C and D). In 2019, 3.6 percent of adults in the United States smoked at least one type of cigar; the majority of cigar users are men (CDC, 2020; Jeon and Mok, 2022). A 2021 analysis of PATH data shows that the majority of adult premium cigar users were non-Hispanic White people (Jeon and Mok, 2022). Additionally, premium cigar users tend to be older, male, and more affluent than users of other tobacco products. An analysis of PATH Wave 1 data found the past-30 day prevalence of premium cigars to be 0.7 percent among adults in 2013-2014 (Corey et al., 2018); the prevalence of current established premium cigar users was also 0.7 percent in a commissioned analysis of PATH Wave 4 (2016-2017) data (Jeon and Mok, 2022). The authors also found a median of 1.7 days of cigar smoking in the last 30 days among premium cigar users (Corey et al., 2018). See Chapter 3 and Appendixes C and D for more information on premium cigar patterns of use and demographics.

Although data on premium cigar use in youth is sparse, cigar smoking overall in this group declined significantly from 2011 to 2018. However, cigars were the most common combustible tobacco product in 2020 (3.5 percent of middle and high school youth reported smoking cigars in the past 30 days, exceeding levels of past 30-day cigarette smoking) (Gentzke et al., 2019; Gentzke et al., 2020). Cigar use was higher in Black middle and high school students in 2020 than for any other tobacco product (Gentzke et al., 2019). Additionally, data from the 2020 Monitoring the Future survey<sup>14</sup> show that 1.5 and 1.2 percent of eighth and tenth grade students, respectively, reported smoking large cigars in the past 30 days (Gentzke et al., 2019). Past-month cigar use in the 2019 NSDUH was higher among people aged 18–25 (7.7 percent) than 12–17 (1.4 percent) and 26+ (4.0 percent) (Miech et al., 2021; SAMHSA, 2020). Past 30-day use

<sup>&</sup>lt;sup>12</sup> Led by FDA and NIH, PATH is a nationally representative longitudinal study examining tobacco use and health effects among U.S. people aged 12+ (see https://pathstudyinfo.nih. gov [accessed November 10, 2021]).

<sup>&</sup>lt;sup>13</sup> The Substance Abuse and Mental Health Services Administration directs NSDUH. The study produces national and state-level data on tobacco, alcohol, and illicit drug use, as well as mental health, among those aged 12+ in the United States (see https://nsduhweb.rti.org/respweb/about\_nsduh.html [accessed November 10, 2021]).

<sup>&</sup>lt;sup>14</sup> The Monitoring the Future survey is funded by the National Institute on Drug Abuse. It is a nationally representative survey measuring drug and alcohol use among adolescent students in the United States (see https://www.drugabuse.gov/drug-topics/trends-statistics/monitoring-future [accessed November 10, 2021]).

#### **Health Effects**

Studies have shown that cigar smoking and inhalation of cigar smoke are associated with a variety of negative health outcomes, including coronary heart disease, certain forms of cancer (e.g., of the oral cavity, esophagus, larynx, and lungs), and all-cause mortality (Apelberg, 2021; Chang et al., 2015; Manderski et al., 2022; NCI, 1998; Rostron et al., 2019). An estimated 9,000 deaths per year among U.S. adults ages 35+ are attributed to regular cigar smoking (Nonnemaker et al., 2014). The physical characteristics of cigars affect users' interactions with them and subsequently influence their health effects. For example, most cigars contain more tobacco than cigarettes and can be smoked for longer (NCI, 1998). Due to the incomplete combustion of tobacco in cigars, the smoke is composed of many of the same carcinogenic compounds found in cigarette smoke (NCI, 1998). The pH of premium cigars may affect inhalation patterns, which in turn affects exposure to cigar tobacco and smoke constituents and influence health outcomes. Premium cigar pH is generally more alkaline than that of cigarette smoke, hindering but not preventing inhalation when smoking cigars (NCI, 1998). In an alkaline pH, more nicotine is in the unprotonated form, which is readily absorbed by the oral mucosa but also results in harsher smoke, which is more difficult to inhale (see Chapters 2 and 5).

#### THE COMMITTEE'S CHARGE

FDA and NIH asked the Health and Medicine Division of the National Academies to examine the available evidence on the patterns of use and health effects of premium cigars compared to other tobacco products and to identify research needs and make prioritized recommendations for future federally funded research on premium cigars. Box 1-2 contains the full statement of task. To respond to this task, the ad hoc Committee on Patterns of Use and Health Effects of "Premium Cigars" and Priority Research was formed. FDA and NIH also provided a list of preliminary research questions to inform the committee's literature review and report; the committee received public input on these research questions and developed a final list (see Appendix A for that final list). While marketing and perceptions of premium cigars is not detailed in the statement of task, these topics are included in the research questions because they have a direct impact on patterns of use (see Figure 1-1). The committee

#### BOX 1-2

#### Committee on Patterns of Use and Health Effects of "Premium Cigars" and Priority Research: Statement of Task

The National Academies of Sciences, Engineering, and Medicine (National Academies) will convene an ad hoc committee to evaluate the available evidence of the health effects related to the use of "premium" cigars and identify future federally funded research needs regarding "premium" cigars. FDA has established an initial list of research objectives and questions guiding the requested literature review. This list is subject to further input from stakeholders.

National Academies shall conduct a comprehensive and systematic assessment and review of the scientific literature and provide a final report of the study results.

The literature review shall first describe patterns of use for "premium" cigars and how those may differ among cigar subtypes and other tobacco products as well as by different populations (types of tobacco users, age, and other demographics).

The literature review shall also include analysis of data on both short- and longterm health effects of "premium" cigars, including but not limited to

- a description of health effects associated with the use of "premium" cigars and how that compares to use of 1) other cigar subtypes and 2) other tobacco products, particularly among vulnerable populations (e.g., youth) and those with underlying medical conditions
- how variations in the patterns of use for "premium" cigars and other cigar subtypes may impact health outcomes
- exposure to harmful and potentially harmful constituents in the tobacco and smoke and associated toxicity, among cigar users and nonusers
- · abuse liability and dependence
- a description of populations who use "premium" cigars versus 1) those who use other cigar subtypes, and 2) those who use other tobacco products (including demographic characteristics, tobacco use status, and factors that influence potential use)

Based on the literature review and information National Academies and FDA have collected on premium cigars, the multidisciplinary committee convened by National Academies will make prioritized recommendations for future federally funded research on premium cigars.

undertook a comprehensive literature review guided by the research questions (see the following section and Appendix B). The report identifies research gaps and measurement needs and prioritizes these for future federally funded research on premium cigars. While the committee also was not tasked with providing policy recommendations, FDA may use its research recommendations to inform and evaluate policy and regulatory options for premium cigars. The committee was not asked to recommend a definition to be used to regulate premium cigars, but it did define premium cigars for its own work.

# STUDY CONTEXT AND APPROACH

#### "Premium Cigar" Definition for the Purposes of This Report

Federal regulations define a cigar as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco."<sup>15</sup> Cigars come in many different types, including large traditional cigars (premium and nonpremium), cigarillos, and little cigars;<sup>16</sup> products vary widely in size, shape, components (e.g., filters, flavors), cost, and packaging. Despite the wide variety, no universally accepted classification system exists, which creates challenges for research, policy, and regulation. For federal tax purposes, a distinction is made between large and small cigars.<sup>17</sup> The Department of Treasury defines small cigars as weighing no more than 3 pounds per thousand cigars (less than or equal to 1.36 grams per cigar) and large cigars as weighing more than this amount. Additionally, for taxation purposes, large cigars, which include a wide array of sizes, including cigarillos, are reported in two groups: those with a pretax value below \$763.222 per thousand and those above; these groupings correspond with federal excise tax structures. Prior to 2003, these two groups were referred to as Class A–G and Class H cigars, respectively. While these designations are no longer used, it is important to note that the cigar industry has referred to premium cigars as "Class H," although all Class H cigars may not be premium under some definitions (i.e., they could be machine made) (Hoyt, 2008). In the NCI Monograph on Cigars, Hoffman and Hoffman (1998) classify cigars into four groups (see Table 1-1). This classification system is useful because it illustrates the extent of the cigar marketplace. Compared to "small" or "little" cigars, premium cigars are larger and heavier, are handmade, and do not use filters or tips.

The lack of standardization in the cigar market, combined with the wide range of products, presents challenges for operationally defining premium cigars. Existing definitions do have commonalities, such as the wrapper composition and filler type (see the Chapter 1 Annex, which lists various definitions). Consequently, different definitions have been used by state agencies, federal entities, the tobacco industry and associated organizations, courts, and researchers. The seven most common premium cigar attributes are listed in Box 1-3.

With the exception of price, the first six attributes are consistent with the definition used in FDA's 2014 advance notice of proposed rulemaking for deeming tobacco products and in the August 2020 U.S. District

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<sup>15 26</sup> USC Sec. 5702a.

<sup>&</sup>lt;sup>16</sup> There is no formal definition from FDA for these cigar types (see Box 1-1).

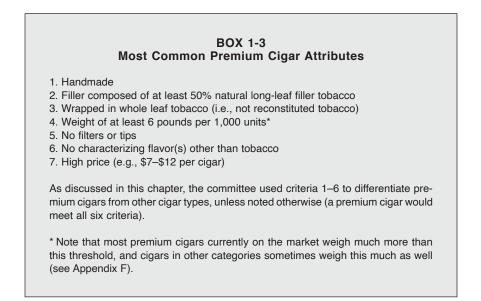
<sup>&</sup>lt;sup>17</sup>See https://www.federalregister.gov/documents/2006/10/25/06-8835/tax-classification-of-cigars-and-cigarettes-2006r-276p (accessed January 12, 2022).

Tax classification	Cigar type	Weight in grams*	Length in mm	Description
Small	Little	<1.36	70–100	Shaped like cigarette with spongy filter
	Cigarillo	1.36–2.5	70–120	Small cigar—some with wood/ plastic tip
Large	Regular	5–17	110–150	Rolled to a tip, banded, machine made
	Premium	5–22	127–214	Most hand rolled

TABLE 1-1 Cigar types by weight, length and description

SOURCE: Adapted from NCI (1998).

NOTE: \*Despite a gap in the weight range from 2.5–5 grams in the 1998 report, the cigar marketplace today includes many cigarillos and large cigars in this range.



Court ruling, so the cigar industry and FDA (FDA, 2016, 2020) generally accept this definition. None of these characteristics by themselves are a sufficient attribute for defining a premium cigar; all need to be considered together. The first three attributes (handmade, filler type, and wrapper composition) are nearly universally accepted, dating back to the NCI Monograph (and likely further), as features that distinguish premium and nonpremium cigars. While weight is not as commonly referred to in definitions and not intrinsic to being premium, the cut point of 6 pounds

per 1,000 is the weight most commonly used, including by FDA. Therefore, it is part of the definition in this report so as to include a minimum weight threshold; however, the majority of premium cigars weigh moresometimes double this weight or more (see Chapter 2 and Appendix F). Filters or tips and flavoring are quite common in the mass-produced cigar marketplace but rare in the premium market; these attributes also assist in differentiation. Lastly, price is important to consider for a few reasons. First, as noted, it is relevant for taxation, and the industry has historically considered premium cigars to fall into the now defunct Class H. Second, the committee acknowledges consumers' understanding of "premium" may vary (marketing experts define "premium" products as those that cost more, with at least 20 percent more than the average given as an example) (NielsenIQ, 2016). Third, researchers have used price (i.e., \$2) to discriminate between large and premium cigars in the absence of other information (Corey et al., 2018). Last, and perhaps most importantly, price likely serves as a proxy for the first three attributes (handmade, filler type, and wrapper composition) in Box 1-3; a handmade cigar with longleaf filler and a whole leaf wrap is more expensive to produce. Setting a threshold for price is challenging, as it can be impacted by local, state, and federal taxation and manipulated by the industry. Therefore, price is not formally considered as part of the committee's definition but may be useful when information is lacking on the other six attributes.

For the literature review and this report, the committee is referring to the six attributes in Box 1-3 to define "premium cigars," unless noted otherwise. As stated, the committee was not tasked with providing a recommendation for a regulatory definition of a premium cigar, and therefore the definition of premium cigars used by the committee is for the purpose of this report only. While other stakeholders may adopt or adapt this definition for other purposes, additional factors might need to be considered. For example, the tobacco industry has altered its products so that they no longer fit existing regulatory definitions (or now meet the definition of a different tobacco product), and this factor was not a major consideration for the committee. As noted, the price of tobacco products can also be manipulated by the tobacco industry. See Recommendation 1 in Chapter 6 for additional considerations on this topic, including considerations of the weight criterion used in many definitions and the need to potentially increase the weight threshold.

### THE COMMITTEE'S APPROACH

#### **Study Process**

The 1998 NCI monograph is the only comprehensive review on of cigars (all types)—it included a review of product characteristic, marketing, health effects, and research needs (NCI, 1998). While several review articles have examined specific aspects of cigar use since then, these look at just one aspect (e.g., a specific health effect) or review just one type of cigar (e.g., marketing of cigarillos). Therefore, the committee used the 1998 NCI report as a starting point for its review and has updated many aspects of it.

To conduct its review, the committee gathered information in a variety of ways. It held four information-gathering sessions between March and May 2021 (agendas are available in Appendix H; all meetings were virtual) on a range of topics, including tobacco science, tobacco control policy, cigar industry perspectives, health effects of cigars, and tobacco data. In addition, the committee held a public comment session to solicit feedback on the preliminary research questions provided to the committee by FDA and NIH (see next paragraph). It held deliberative meetings and received public submissions of materials for its consideration throughout the course of the study.<sup>18</sup> Its online activity page also provided information to the public about its work and facilitated communication with the public.<sup>19</sup>

As noted, FDA and NIH provided a list of preliminary research questions and asked that the committee solicit input from stakeholders on the preliminary list to guide its literature review. The final determination of specific questions to be answered was the responsibility of the committee, which took into account the preliminary list and feedback received via public meetings and written comments. That final list is available in Appendix J.

Given the paucity of data available on premium cigars, the committee commissioned several analyses to further inform its work: two papers on the patterns of use of premium and other cigars, one with 10 years of NSDUH data (2010–2019) and one with PATH data from Waves 1–5 (2013–2019; see Appendixes C and D), a paper with data on cigar weight, length, and nicotine content from a convenience sample of different brands and cigar types (see Appendix F), and a paper with geographic information system mapping analysis to map the locations of premium cigar retailers and overlay retailer density with demographic measures

<sup>&</sup>lt;sup>18</sup> Public access materials can be requested from PARO@nas.edu.

<sup>&</sup>lt;sup>19</sup>See https://www.nationalacademies.org/our-work/health-effects-and-patterns-of-use-of-premium-cigars (accessed September 24, 2021).

by census tract using data provided by the Premium Cigar Association (to gain a better sense of where premium cigar retailers and lounges are located; see Appendix G). The committee also conducted a social media environmental scan and a content analysis of three popular cigar lifestyle magazines; social media and magazine content were examined to understand marketing content (see Chapter 4).

Four work groups were formed to refine the research questions, incorporate public comments, and undertake the literature reviews. These work groups were organized by the topics of product characteristics, patterns of use, psychosocial factors, and health effects. Committee members reviewed each article identified through the literature search (see Appendix B) to assess the content, relevance, study methodology, and quality. The overall body of literature for each research question was assessed, and research gaps and measurement issues were identified. The committee then prioritized the research and measurement needs and provided recommendations for future research (see Chapter 6).

#### **Evidence Review**

The statement of task charges the committee with conducting a "comprehensive and systematic assessment and review of the scientific literature" of the health effects related to the use of premium cigars (see Box 1-2). It was also asked to review patterns of use and other factors related to premium cigars (see Appendix A for the research questions). Given the heterogeneity of the research and varied topics that the committee had to review, it created a formalized framework to assess the strength of the evidence (see the sections later in this chapter).

A systematic literature search was conducted (see Appendix B for search terms, years, databases, and journals) to identify publications on premium cigars. Because "premium" has not been used systematically, searches considered cigars more generally. Reviews were identified for all combustible tobacco products for comparison to premium cigars (whereas individual articles were summarized for large/traditional and premium cigars and other cigar types as needed). The committee's approach was informed by published guidelines for conducting systematic reviews and the approaches taken by prior National Academies committees (CRD, 2009; Higgins, 2021; IOM, 2011, 2012, 2016; NASEM, 2017, 2018; NRC, 2014; OHAT, 2019; Whiting et al., 2016). However, early in its work, the committee noted the very limited literature available on premium cigars specifically and lack of agreed-upon definition, no agreement by consumers on the nature of the product they use, and therefore of consistency regarding which brands are considered "premium" in the literature. Moreover, many publications do not distinguish "premium" from other

large cigars.<sup>20</sup> For many of its conclusions, the committee extrapolated data from other tobacco products, cigars in general, or large/traditional cigars overall (which include premium) when the data was strong and there were no important threats to validity. In addition, the study types varied considerably (e.g., laboratory, epidemiologic and toxicologic studies, and surveys). The committee adjusted its approach and framework accordingly. Notably, its approach incorporated major attributes of systematic reviews. It systematically located, screened, and selected studies (including using multiple databases and systematically collecting data); evaluated individual studies for strengths and limitations; and synthesized findings into an assessment of the overall body of literature. Note that for patterns of use, the committee included only findings (no conclusions).<sup>21</sup>

Because of the paucity of literature on premium cigars specifically, studies of large, traditional cigars, cigars overall, and occasionally other combustible tobacco products were included based on committee members' assessment of the relevance and potential generalizability of those studies' findings to premium cigars.

Given the limited data, the committee relied heavily on biological mechanisms and plausibility in its framework, particularly for health effects. As noted in Chapter 2, despite differences between premium cigars and traditional large cigars, many similarities also exist, and therefore information from large traditional cigars and sometimes other types of cigars can be relevant. This section includes an overview of the committee's methods for identifying, reviewing, and assessing the literature, which is followed by its approach to assessing causality and integrating data from human, animal, in vitro, and laboratory studies and the framework developed to describe the strength of the evidence informing its conclusions.

<sup>&</sup>lt;sup>20</sup> When cigar brands were reported in the studies reviewed, the committee used the designation from two commissioned papers to determine if the brands were premium (see Appendix E). Three expert coders independently and manually coded brands from NSDUH and PATH data using the committee's definition of a premium cigar (Jeon and Mok, 2022; Manderski et al., 2022). If the brand in a study was not included in the commissioned papers, the committee applied the criteria in Box 1-3 to classify the brand (when enough information about the brand's cigar(s) was available to do so).

<sup>&</sup>lt;sup>21</sup> A finding is a statement of the evidence, whereas a conclusion is an inference, interpretation, or generalization drawn from the evidence. Per the committee statement of task and the research questions (see Box 1-2 and Appendix A), the committee was asked only to describe the patterns of use, whereas for product characteristics, marketing and perceptions, and health effects, the committee was asked to provide analysis and interpretation.

#### Health Effects Literature

The process for assessing the health effects literature is based on that used for the 2018 National Academies report Public Health Consequences of E-Cigarettes. For the assessment of studies on disease end points, in general, one committee member conducted an initial review of all literature identified pertaining to a set of outcomes. In its assessment of study strengths and limitations, the committee considered study design, elements of the design (e.g., sample size, setting, study population, exposure variables and methods of assessment, relevant controls or comparison groups, statistical methods, and outcome measures assessed), other potential sources of conflict of interest or bias,<sup>22</sup> quality of study execution, applicability to premium cigars, and study results. After the initial review by the work group, a full committee discussion evaluated each study and the overall body of evidence, with particular attention to the studies' strengths and weaknesses. The committee searched for data on the study population (and its characteristics when available), exposure (including dose and other characteristics), and conditions of the adverse outcome. However, as noted later in this section, no studies of the health effects of premium cigars specifically were identified, so the committee relied on health effects and toxicology studies of other cigar types (including overall and large/traditional cigars, which could include premium cigars) and biologic plausibility.

The committee also used a modified approach to assess laboratory, in vivo animal, and in vitro studies based on known similarities between large cigars and other cigar types. It considered research design, conduct, analysis, representativeness (external validity), and other sources of bias when assessing strengths and weaknesses, as it did for human studies.

#### Causality

Little to no direct empirical evidence exists evaluating the health effects of premium cigars specifically. Despite a general consensus that high-quality epidemiological studies supported by strong toxicology and

<sup>&</sup>lt;sup>22</sup> The committee recognizes a range of nonscientific influences on research, including the research sponsorship and source of employment, and particular concerns in literature on the health effects of tobacco products due to the tobacco industry's involvement in manipulating evidence to support its interests. For completeness, the committee documented the source of research sponsorship, noting whether each study was funded by industry, a federal research agency, or other (e.g., university or foundation), or an unstated source, as well as other industry participation in a table available as an online supplement.

other mechanistic biological evidence provide the strongest basis for firm inferences regarding causality, these studies do not exist for premium cigars in isolation (and, in large part, studies also do not differentiate between large/traditional cigars and other types). With only a few exceptions, the epidemiological literature is extremely limited, and even where it is stronger, it does not address the etiology of chronic diseases. In other cases, there is simply no credible epidemiological research on premium or large cigars.

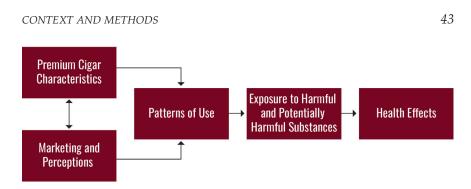
Given this challenge, the committee drew upon knowledge of the health effects of some constituents of the emissions from cigars and other combustible tobacco products, as this provides one relevant line of indirect evidence. Another important source of evidence is toxicology studies with implications for the biological mechanisms of premium cigars. The certainty, magnitude, and health relevance of these pathways bear on their value for making causal inferences (NASEM, 2018). For example, in vivo animal evidence may be more pertinent to inferences regarding human health effects than in vitro findings are. Nevertheless, the toxicological and mechanistic literature provides evidence supporting the plausibility of various mechanisms by which premium cigar exposure influences health (NASEM, 2018).

As noted in NASEM (2018), "tying these diverse threads of indirectly relevant evidence together to draw a summary conclusion is necessarily somewhat subjective, bringing together the knowledge and judgment of the committee as a whole to reach consensus." To provide comparable inferences across the full array of health concerns, the committee reviewed and modified approaches used in other National Academies reports and published guidelines on evidence synthesis (e.g., IOM, 2012; NASEM, 2017, 2018; NRC, 2007, 2014) to reach conclusions based on human evidence, animal evidence, laboratory studies, and their integration.

### **Causal Pathways**

Figure 1-1 presents a simplified schematic of the pathway from premium cigars to health outcomes. Individual health effects are, of course, based on individual level (frequency, duration, etc.) of use. Patterns of premium cigar use are impacted by cigar characteristics (e.g., nicotine level, pH, addiction potential), its marketing, and the user's risk and benefit perceptions. Marketing is also impacted by characteristics of the product itself and how the product is described (e.g., handmade, artisanal, premium; see Chapter 4 for more on this topic) and, in turn, the way that consumers perceive the product, which directly influences how they intend to use it. Product perceptions are informed by both the marketing of and trial with the product. Consumers' reactions to marketing

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**FIGURE 1-1** Simplified illustration of potential causal pathways by which premium cigars could affect health.

campaigns and/or their perceptions about premium cigars may influence how premium cigar companies characterize their products (e.g. addictive potential, the role of pH on users' smoking experience). Although the committee's statement of task does not specifically request a review of marketing and perceptions, they are inextricably linked to patterns of use (these topics are also included in the research questions). The resulting patterns of use lead to varying levels of toxic exposures from smoking premium cigars (or from secondhand smoke), ending with health outcomes. Note that other factors could be included in this framework (e.g., social factors such as social networks); however, the framework focuses on the factors described in this report. Because the committee primarily focused on distal health outcomes, evidence on the effects of premium cigars for these outcomes is most relevant to assessing premium cigar health effects. In the absence of high-quality epidemiological evidence on these outcomes, the committee drew upon biologic and mechanistic evidence, which have documented and well-known health effects.

### **Evidence Synthesis—Health Effects**

The committee's assessment of data aimed to establish causation between premium cigars and a given health end point, not merely a statistical association. However, in the absence of high-quality epidemiological studies of the health effects of premium cigar use specifically, the committee took into account several considerations to draw causal inferences from the evidence available (as was done in NASEM, 2018). These considerations rely on criteria typically used to interpret and establish causation based on epidemiological data and are adapted from the approach taken in the 2014 Surgeon General's report on smoking and health (e.g., strength of the association, consistency, specificity, biological gradient) (HHS, 2014;

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Hill, 1965). Evidence from multiple epidemiological studies would provide the strongest evidence of a consistent effect (NASEM, 2018).

The committee looked for coherence across the body of evidence. For example, the committee draws analogies from other combustible tobacco products, such as other cigars and cigarettes. The committee also uses animal, in vitro, and laboratory data and evidence on intermediate outcomes to establish the biological plausibility of a hypothesized disease pathway.

#### Conclusions

Informed by reports of previous Institute of Medicine and National Academies committees (IOM, 2012, 2016; NASEM, 2017, 2018) and the U.S. Preventive Services Task Force (USPSTF, 2018), the committee developed standardized language to categorize the strength of the evidence described in its conclusions. Box 1-4 presents the categories and describes the types of evidence that correspond to the committee's confidence in each category. Conclusive evidence implies that observed associations between premium cigar use and a given outcome are very unlikely to change with new evidence, whereas other categories provide progressively less evidence. Conclusive, strongly suggestive, and moderately suggestive evidence describe a direction of effect (e.g., increased or decreased risk of a health outcome); topics with insufficient or no available evidence cannot imply a direction. The level of evidence does not indicate the effect's size, magnitude, or importance. The framework is a guide, and expert judgment—in the evaluation of individual studies and in bodies of evidence-was involved.

#### **REPORT OVERVIEW**

The committee provides background and analysis in four areas: premium cigar product characteristics (Chapter 2), patterns of use of premium cigars and other cigar types (Chapter 3), marketing and perceptions of cigar products (Chapter 4), and health effects of premium cigars (including secondhand smoke) (Chapter 5). The committee was tasked with providing recommendations for federally funded research on premium cigars. Each chapter identifies research and measurement gaps, and Chapter 6 provides the recommended priority research areas. The appendixes provide additional background and analyses used to inform the committee's deliberations.

BOX 1-4 Evidence Framework		
Level of Confidence	<ul> <li>Description*</li> <li>Conclusive evidence implies that observed associations between premium cigar use and a given outcome are very unlikely to change with new evidence, whereas other categories provide progressively less evidence.</li> <li>The categorizations for each conclusion are based on the committee's overall assessment of the body of evidence.</li> </ul>	
Conclusive evidence	The available evidence (including biologic plausibility when appropriate here and in the next categories) usually includes consistent results from well-designed, well-conducted studies in representative relevant settings and/or populations. These studies assess the effects on relevant outcomes. <i>The con- clusion is therefore unlikely to be strongly affected by the results of future studies.</i>	
Strongly suggestive evidence	<ul> <li>The available evidence is sufficient to determine the effects on relevant outcomes, but confidence in the <i>estimate is constrained</i> by such factors as: <ul> <li>The number, size, or quality of individual studies;</li> <li>Inconsistency of findings across individual studies;</li> <li>Limited generalizability of findings to routine practice/ populations; and</li> <li>Lack of coherence in the chain of evidence.</li> </ul> </li> <li>As more information becomes available, the magnitude or direction of the observed effect could change, and this change might be large enough to alter the conclusion.</li> </ul>	
<i>Moderately suggestive evidence</i>	<ul> <li>The available evidence is sufficient to determine the effects on relevant outcomes, but confidence in the estimate is significantly constrained by such factors as: <ul> <li>The number, size, or quality of individual studies;</li> <li>Inconsistency of findings across individual studies;</li> <li>Limited generalizability of findings to routine practice/ populations; and</li> <li>Lack of coherence in the chain of evidence.</li> </ul> </li> <li>As more information becomes available, the magnitude or direction of the observed effect could change, which could alter the conclusion.</li> </ul>	

continued

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	Continued The available evidence is insufficient to assess effects on relevant outcomes. Evidence is insufficient because of: • The limited number or size of studies;
Insufficient/ No Available Evidence	<ul> <li>Important flaws in study design or methods;</li> <li>Inconsistency of findings across individual studies;</li> <li>Gaps in the chain of evidence;</li> <li>Findings not generalizable to the general population; and/or</li> <li>Lack of information on important outcomes.</li> </ul>
nonpremium ci	ries, the evidence includes, when appropriate, literature on gars. pted from USPSTF, 2021, pg. 45.

# CONCLUDING OBSERVATIONS

After reviewing the varied definitions of premium cigars used by different entities (for various purposes-marketing, regulation, taxation, research, and litigation) and their chemical constituents, the committee identified no material difference between products typically considered premium cigars and other cigar types in terms of harmful or potentially harmful constituents (see Chapter 2). However, based on available data, a meaningful difference exists in how products typically considered premium are used (e.g., frequency, depth of inhalation, demographics). The committee notes the difference between a tobacco product being inherently harmful due to its constituent makeup (which generally stays consistent) or its patterns of use, which can change and include how it is used and by whom. However, the committee was not tasked with providing guidance on whether premium cigars should be considered separate from other types. Therefore, as discussed, it identified the most commonly cited differences between what would be considered premium and nonpremium cigars and applied this definition throughout the report. Based on this definition and the literature review, the report provides conclusions on product characteristics, patterns of use, and marketing and perceptions for premium cigars. From its assessment of the evidence, the committee offers conclusions on the health effects of premium cigars-for both the product itself and the current patterns of use.

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# **Chapter I Annex**

# **Premium Cigar Definitions**

As described in Chapter 1, there is no formally agreed-upon definition of what constitutes a "premium" cigar, and different entities might use this term differently. Although the committee was not tasked with developing such a formal definition, it did examine existing definitions and developed a working definition for its own efforts (see Chapter 1). The tables in this annex present existing definitions of premium cigars and a comparison of the characteristics that the committee used to inform its working definition. Table 1A-1 shows existing definitions sorted by source. Table 1A-2 shows the same definitions sorted by the categories of defining characteristics as listed in the Food and Drug Administration (FDA) advanced notice of proposed rulemaking (ANPRM) on regulation of premium cigars (FDA, 2018). The tables are not intended as an exhaustive list of all existing definitions.

#	Source	Definition
		Wrapped in whole tobacco leaf
		Contains a 100% leaf tobacco binder
	August 2020 court	Contains at least 50% (of the filler by weight) long filler tobacco (whole tobacco leaves that run the length of the cigar)
1	ruling prohibit- ing enforcement of premarket authoriza- tion requirements	Is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling)
	for premium cigars	Has no filter, nontobacco tip, or nontobacco mouthpiece
	(FDA, 2020)	Does not have a characterizing flavor other than tobacco
		Contains only tobacco, water, and vegetable gum with no other ingredients or additives
		Weighs more than 6 pounds per 1,000 units
		Diameters ranging from 12 to 23 mm and lengths between 12.7 and 21.4 cm
	NCI Tobacco Control Monograph No. 9:	Carry bands with an imprint of their brand name and/or manufacturer's name or logo
2	Cigars: Health Effects and Trends <sup>23</sup> (NCI, 1998)	Leaves are primed and hung individually on strings in sheds or barns for air-curing
		Do not contain reconstituted tobacco as binder, wrapper, or both
		Can measure more than 7 inches in length
	NCL website <sup>24</sup> (NCL	Typically contain between 5 and 20 grams of tobacco
3	NCI website <sup>24</sup> (NCI, 2010)	Some contain the tobacco equivalent of an entire pack of cigarettes
		Can take between 1 and 2 hours to smoke
		Consist of more expensive tobacco varieties and compo- nents, such as whole tobacco leaf wrapper and binder
4	Corey et al., 2018	May be assembled by hand
		Usual price <sup>25</sup> paid per stick of ≥\$2
		Does not have a filter or tip
5	Corey et al., 2014	Described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper

## TABLE 1A-1 Premium Cigar Definitions—Sorted by Definition

<sup>&</sup>lt;sup>23</sup> Also for "many regular cigars."

<sup>&</sup>lt;sup>24</sup> Unclear distinction between large and premium cigars.

<sup>&</sup>lt;sup>25</sup> "Price per cigar was calculated as the usual price the participant reported paying divided by the number of cigars sold in the usual unit purchased" (Corey et al., 2018).

# TABLE 1A-1 Continued

#	Source	Definition
6	Arkansas Depart- ment of Finance and Administration, n.d.	Invoice price <sup>26</sup> (before discounts) equal to or greater than \$0.7576 per cigar
		Is wrapped in 100% leaf tobacco
		Is bunched with 100% tobacco filler
		Does not contain a filter, tip, or nontobacco mouthpiece
	SB18-126: Traditional And Large Premium	Weighs at least six pounds per one thousand
7	Cigars Tax Defini- tion <sup>27</sup> (Colorado General Assembly, 2018)	Has a 100% leaf tobacco binder and is hand rolled; has a 100% leaf tobacco binder made using human hands to lay the tobacco leaf wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or has a homogenized tobacco leaf binder and is made in the United States using human hands to lay 100% leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar
		Are made entirely by hand of all natural tobacco leaf
8	New Hampshire De-	Are hand constructed and hand wrapped
0	partment of Revenue Administration, 2020	Weigh more than 3 pounds per 1,000 cigars
		Are kept in a humidor
9	Cigar Advisor (Korb, 2011)	Made entirely by hand with long leaf tobaccos, although some mixed filler (long and short leaf) handmade cigars would qualify
		Made entirely by hand
		Are harvested, cured, and fermented the same way as nonpremium cigars
10	Frontline Cigars, n.d.	Only use tobacco
		Are not chemically treated to alter the color and taste of the product (i.e., the color, taste and flavor profile are all achieved through the curing and fermentation process)

NOTE: NCI=National Cancer Institute.

<sup>&</sup>lt;sup>26</sup> "Invoice price means the price that a wholesaler or retailer of tobacco products pays to a manufacturer, importer, or distributor for tobacco products that the wholesaler or retailer subsequently sells in the state" (Arkansas Department of Finance and Administration, n.d.).

<sup>&</sup>lt;sup>27</sup> "Traditional large and premium cigar."

# **TABLE 1A-2** Premium Cigar Definitions—Sorted by FDA ANPRMCategory of Defining Characteristic

FDA ANPRM category of defining characteristic <sup>28</sup>	Part of definition relevant to category of defining characteristic	#
Size (e.g., length, ring gauge, total weight)	Diameters ranging from 12 to 23 mm and lengths between 12.7 and 21.4 cm	2
weight)	Can measure more than 7 inches in length	3 <sup>29</sup>
Tobacco filler type and minimum	Contains at least 50% (of the filler by weight) long filler tobacco (whole tobacco leaves that run the length of the cigar)	1
required percentages of each filler per cigar	Made entirely by hand with long leaf tobaccos, although some mixed filler (long and short leaf) handmade cigars would qualify	9
	Is bunched with 100% tobacco filler	7 <sup>30</sup>
Fermentation type	Leaves are primed and hung indi- vidually on strings in sheds or barns for air-curing	2 <sup>31</sup>
	Are harvested, cured, and fermented the same way as nonpremium cigars	10
	Wrapped in whole tobacco leaf	1
	Contains a 100% leaf tobacco binder	1
	Do not contain reconstituted tobacco as binder, wrapper, or both	2
Wrapper and binder composition (e.g., whole leaf, reconstituted or homogenized tobacco leaf)	Consist of more expensive tobacco varieties and components, such as whole tobacco leaf wrapper and binder	4
	Described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrap- per	5
	Is wrapped in 100% leaf tobacco	7 <sup>32</sup>
	Only use tobacco	10

 $<sup>^{28}</sup>$  See https://www.federal register.gov/documents/2018/03/26/2018-06047/regulation-of-premium-cigars

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<sup>&</sup>lt;sup>29</sup> Unclear distinction between large and premium cigars.

<sup>&</sup>lt;sup>30</sup> "Traditional large and premium cigar."

<sup>&</sup>lt;sup>31</sup> Also for "many regular cigars."

<sup>32 &</sup>quot;Traditional large and premium cigar."

# TABLE 1A-2 Continued

FDA ANPRM category of defining characteristic <sup>28</sup>	Part of definition relevant to category of defining characteristic	#
Where the tobacco used for pre- mium cigar filler or wrappers is grown, and whether differences in growing practices for that tobacco, as compared to tobacco used in other cigars, result in different health impacts		
	Has no filter, nontobacco tip, or non- tobacco mouthpiece	1
Presence or absence of a filter	Does not have a filter or tip	4
	Does not contain a filter, tip, or non- tobacco mouthpiece	7 <sup>33</sup>
Presence or absence of a mouth-	Has no filter, nontobacco tip, or non- tobacco mouthpiece	1
piece	Does not contain a filter, tip, or non- tobacco mouthpiece	7

<sup>&</sup>lt;sup>33</sup> "Traditional large and premium cigar."

# TABLE 1A-2 Continued

FDA ANPRM category of defining characteristic <sup>28</sup>	Part of definition relevant to category of defining characteristic	#
	Is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling)	1
	May be assembled by hand	4
Manufacturing and assembly pro- cess (e.g., including any production by hand or by machine)	Has a 100% leaf tobacco binder and is hand rolled; has a 100% leaf tobacco binder made using human hands to lay the tobacco leaf wrapper or binder onto only one machine that bunches, wraps, and caps each indi- vidual cigar; or has a homogenized tobacco leaf binder and is made in the United States using human hands to lay 100% leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar	7 <sup>34</sup>
	Are made entirely by hand of all natural tobacco leaf	8
	Are hand constructed and hand wrapped	8
	Made entirely by hand with long leaf tobaccos, although some mixed filler (long and short leaf) handmade cigars would qualify	9
	Made entirely by hand	10
Rate of production (e.g., "produced at no more than [insert number] units per minute")		
Durante en el como el decom	Does not have a characterizing flavor other than tobacco	1
Presence or absence of flavor imparting compounds, flavor addi- tives, or characterizing flavors other than tobacco	Are not chemically treated to alter the color and taste of the product (i.e., the color, taste and flavor profile are all achieved through the curing and fermentation process)	10
Presence or absence of any addi- tives other than cigar glue	Contains only tobacco, water, and vegetable gum with no other ingredi- ents or additives	1

<sup>&</sup>lt;sup>34</sup> "Traditional large and premium cigar."

## TABLE 1A-2 Continued

FDA ANPRM category of defining characteristic <sup>28</sup>	Part of definition relevant to category of defining characteristic	#
Nicotine content	Typically contain between 5 and 20 grams of tobacco	3 <sup>35</sup>
Nicoline content	Some contain the tobacco equivalent of an entire pack of cigarettes	3 <sup>36</sup>
Tar delivery amounts (and how this should be defined and measured)		
Carbon monoxide delivery amounts (and how this should be defined and measured)		
	Usual price <sup>37</sup> paid per stick of ≥\$2	4
Retail price	Invoice price <sup>38</sup> (before discounts) equal to or greater than \$0.7576 per cigar	6
Frequency with which price chang- es are initiated by particular levels in the distribution chain (retailers, manufacturers, importers, and/or distributors)		
Packaging quantity and size		
Any action directed to consumers, by a retailer or manufacturer, such as through labeling, advertising, or marketing, which would reasonably be expected to result in consumers believing that the tobacco product is a premium cigar	Carry bands with an imprint of their brand name and/or manufacturer's name or logo	2
	Weighs more than 6 pounds per 1,000 units	1
Weight <sup>39</sup>	Weighs at least six pounds per one thousand	$7^{40}$
	Weigh more than 3 pounds per 1,000 cigars	8

<sup>&</sup>lt;sup>35</sup> Unclear distinction between large and premium cigars.

<sup>&</sup>lt;sup>36</sup> Unclear distinction between large and premium cigars.

<sup>&</sup>lt;sup>37</sup> "Price per cigar was calculated as the usual price the participant reported paying divided by the number of cigars sold in the usual unit purchased" (Corey et al., 2014).

<sup>&</sup>lt;sup>38</sup> "Invoice price means the price that a wholesaler or retailer of tobacco products pays to a manufacturer, importer, or distributor for tobacco products that the wholesaler or retailer subsequently sells in the state" (Arkansas Department of Finance and Administration, n.d.).

<sup>&</sup>lt;sup>39</sup>Not included in the categories listed in FDA's ANPRM on regulation of premium cigars. <sup>40</sup> "Traditional large and premium cigar."

#### TABLE 1A-2 Continued

FDA ANPRM category of defining characteristic <sup>28</sup>	Part of definition relevant to category of defining characteristic	#
Other <sup>41</sup>	Can take between 1 and 2 hours to smoke	3 <sup>42</sup>
	Are kept in a humidor	8

NOTE: ANPRM: advanced notice of proposed rulemaking; FDA: Food and Drug Administration.

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<sup>&</sup>lt;sup>41</sup>Not included in the categories listed in FDA's ANPRM on regulation of premium cigars.

<sup>&</sup>lt;sup>42</sup> Unclear distinction between large and premium cigars.

Premium Cigars: Patterns of Use, Marketing, and Health Effects

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2

# **Characteristics of Cigars**

As explained in Chapter 1, many types of cigars<sup>1</sup> are available to U.S. consumers. This chapter describes the physical characteristics of various types, including "premium cigars";<sup>2</sup> reviews what is known about the chemistry of cigar tobacco and smoke; discusses biomarkers of product use; considers inhalation patterns of cigar users; and briefly examines flavorings. See Chapter 5 for information on secondhand emissions from premium cigars. As illustrated in the report's framework (see Figure 1-1 in Chapter 1), these characteristics of premium cigars influence both patterns of use and marketing and risk perceptions. Published data on premium cigars specifically is lacking in many areas; in those cases, the committee relied on studies of large cigars when possible, on the 1998 NCI monograph on cigars (which, as noted in Chapter 1, is the only comprehensive review of all cigar types), and on committee expertise when extrapolating results and implications to premium cigars. This chapter was guided by research questions from FDA and National Institutes of Health (NIH) about cigar manufacturing processes, chemical constituents of tobacco and smoke, and smoking topography; see Appendix A for the full listing

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<sup>&</sup>lt;sup>1</sup> Note that when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

<sup>&</sup>lt;sup>2</sup> Note that quotations are used at the first occurrence of the term "premium" in each chapter, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information.

of research questions. Conclusions are provided throughout the chapter; a listing of all conclusions by chapter is available in the Summary.

#### PHYSICAL CHARACTERISTICS OF CIGARS

As noted in Chapter 1, federal regulations define a cigar as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco."<sup>3</sup> At the most basic level, the major regulatory difference between cigars and cigarettes is the wrapper; while a cigar uses a tobacco leaf or material containing tobacco (often referred to as "reconstituted tobacco" or "homogenized tobacco leaf"<sup>4</sup>), a cigarette has paper or a material that does not contain tobacco. Mass-produced cigarettes usually have filters, whereas most cigars do not, with a few notable exceptions like filtered cigars. Additionally, cigar filler, binder, and wrappers are predominantly air-cured and fermented tobacco, in contrast to cigarettes, which commonly use a blend of Virginia tobacco (also known as "Bright" tobacco; flue-cured), Burley tobacco (air-cured), and Turkish/oriental tobacco (sun-cured); expanded and reconstituted tobacco are also used in cigarettes (NCI, 1998; Philip Morris International, n.d.). Exceptions to this are some little cigars, which tend to use some flue-cured and/or Turkish tobacco, presumably to be more appealing to cigarette users (Delnevo and Hrywna, 2007). Cigar tobacco undergoes fermentation, which can be a multistep process that lasts months or even years for premium cigars. These differences in the manufacturing process (e.g., the fermentation process) typically result in higher nitrate levels in the tobacco and a higher (alkaline) pH of cigar smoke than cigarette smoke, which has important implications for nicotine absorption orally and by inhaling. At an alkaline pH, some of the nicotine in cigar smoke is unprotonated; this form of nicotine is readily absorbed by the oral mucosa. Alkaline smoke is also harsh and more difficult to inhale, affecting patterns of smoke inhalation into the lungs (Henningfield et al., 1999; NCI, 1998). The form of nicotine present in acidic smoke, as generally found in cigarettes, is not easily absorbed by oral mucosa, and inhalation is required for efficient nicotine absorption; it is also generally less noxious to inhale. The relationship between tobacco pH and smoke pH is complex and not fully understood, especially for premium cigars. Few studies address the pH of cigar smoke, and it can be difficult to measure. Smoke pH measurements can be affected by the measurement method and by relative humidity and

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<sup>&</sup>lt;sup>3</sup>26 USC Sec. 5702a.

<sup>&</sup>lt;sup>4</sup> Reconstituted tobacco or homogenized tobacco leaf is a mixture of an adhesive with the ground remnants of tobacco that remain after manufacture. The malleable sheets of "recycled" tobacco can then be used in various tobacco products (Cigar Aficionado, n.d).

smoke density and velocity, for example (Henningfield et al., 1999; NCI, 1998). See the sections on chemistry and inhalation patterns later in this chapter for more information.

The cigar marketplace is highly diverse, including little/filtered cigars, cigarillos, large nonpremium cigars, and premium cigars (see Figure 2-1). Despite the wide variety of products, as noted in Chapter 1, no universally accepted classification system exists. The 1998 NCI monograph used four groups (see Table 1-1 in Chapter 1), which is useful because it illustrates the wide variety in the cigar marketplace. Each of these categories is described briefly below.



FIGURE 2-1 Types of cigars compared to a cigarette.

NOTES: From left to right: premium cigar (Arturo Fuente Curly Head), premium cigar (Rocky Patel 1990), traditional cigar (Phillies Blunt), cigarillo (Backwoods Honey Berry), cigarillo (Swisher Sweets Blueberry), filtered/little cigar (Djarum), filtered/little cigar (Cheyenne), cigarette (Marlboro). Picture taken as part of commissioned work; brand names are included for identification purposes only. PHOTO CREDIT: Sundos Yassin, 2021; taken as part of commissioned work for Appendix F.

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## Little/Filtered Cigars

Little cigars are filtered, frequently sold in packs of 20, and weigh less than 3 pounds per thousand cigars, or 1.36 g per stick (TTB, 2017). They are made on the same machines as cigarettes and are similar in size and shape. The main difference is the wrapper. Whereas cigarettes are wrapped in paper, little cigars are almost always wrapped in reconstituted tobacco. The amount of tobacco in that wrapper has been observed by some, including the tobacco industry, to be minimal in most cases (Delnevo and Hrywna, 2007). Since the early 1970s, little cigars have been marketed to cigarette users as substitutes for cigarettes (Delnevo and Hrywna, 2007; Delnevo et al., 2017b). In 2009, in response to changes in federal tobacco excise tax, many little cigar manufacturers modified their products and made them slightly longer and heavier to meet the large cigar tax classification and the lower federal excise tax (CDC, 2012; Delnevo et al., 2017b). A recent evaluation of several common little and large filtered cigars found many similarities between filtered cigars and cigarettes and minor (but statistically significant) difference in weight between little cigars and large filtered cigars (Caruso et al., 2015). For this reason, they are discussed as one grouping of cigars, consistent with prior research (Corey et al., 2018; Corey et al., 2014).

Given their similarities to cigarettes, it is not surprising that the pH levels of little/filtered cigars are likewise similar. Henningfield and colleagues (1999) tested four little cigars and found the pH of the tobacco filler ranged from 5.7 to 6.1; they concluded that these products closely resembled typical cigarettes. Lawler and colleagues (2017) tested over 100 cigarettes, little cigars, cigarillos, and cigars (the committee identified 13 large cigars and 2 cigarillos as premium based on brand name and committee definition)<sup>5</sup> and found the mean pH for cigarette tobacco in aqueous solution was 5.46, whereas it was 5.72 for the little/filtered cigar tobacco. Moreover, of the 14 little/filtered cigars tested, the pH ranged from 5.24 to 6.11 and all but one brand had a pH below 6.0 (Lawler et al., 2017).

Flavorings in cigarettes are banned, but filtered cigars may be flavored. When the Tobacco Control Act was signed in 2009, one brand of clove cigarettes, Djarum, changed its wrapper and rebranded its product as a filtered cigar to circumvent the flavor ban on cigarettes (Delnevo and Hrywna, 2015). Some of the most popular brands of little or filtered cigars in the United States are Cheyenne, Swisher Sweets, Primetime, and Djarum (Corey et al., 2018; Delnevo et al., 2017a; Delnevo et al., 2021).

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<sup>&</sup>lt;sup>5</sup> The authors' cigar classification was based on product labeling.

#### Cigarillos

As with the other cigar types, the term "cigarillo" has no formal definition, but these products are commonly understood by consumers and researchers to be medium-sized, machine-made cigars that may have plastic or wood tips. The wrapper is often reconstituted tobacco, but rough "natural leaf" wrappers have recently become a popular characteristic, driving sales (Vonder Haar, 2021). The 1998 NCI monograph describes these cigars as weighing 1.3–2.5 grams (NCI, 1998), but more recent measurements suggest a wider and higher weight range. For example, Henningfield and colleagues (1999) reported the weight of three cigarillos in their sample: 2.26-3.37 grams. Koszowski and colleagues (2018) tested 10 popular cigarillos, which were 1.64–4.24 grams, with a mean weight of 2.86 grams. Likewise, recent testing commissioned by this committee of 23 popular cigarillos, representing five brands (Black & Mild, Swisher Sweets, Backwoods, Dutch Masters, and Garcia y Vega) were 2.1–3.2 grams, with a mean weight of 2.8 grams (Yassin et al., 2021); see Appendix F for more information. The typical weight likely falls more closely between 2.5 and 3.5 grams (see Appendix F). Notably, 2.72 grams translates to 6 pounds per thousand, a threshold that has been proposed for a premium cigar product.

Small samples from Henningfield and colleagues (1999) (3 cigarillos) and Koszowski and colleagues (2018) (10 cigarillos) found a mean pH for cigarillo tobacco filler of 6.1 and 6.39, respectively. Lawler and colleagues (2017) measured 21 cigarillos (including what they refer to as "mini" cigarillos) and reported a mean pH of tobacco in aqueous solution of 5.7; the two cigarillos with the highest pH were determined by the committee to be premium cigars. The authors noted that cigars made with pipe tobacco had the lowest pH (5.05) (Lawler et al., 2017). The bestselling cigarillo brand in the United States, Black & Mild, is made exclusively with pipe tobacco. Koszowski and colleagues (2018) also found a low pH for this brand.

Cigarillo products tend to be flavored, with fruity, sweet, and alcoholic beverage flavors being the most common (Delnevo et al., 2017a; Delnevo et al., 2021; Lawyer et al., 2019). Moreover, wood tip cigarillos are growing in popularity; the tip itself can be sweetened and flavored (Erythropel et al., 2018). The two most popular brands of cigarillos are Black & Mild and Swisher Sweets, which have for decades held the majority of the market; other popular brands are White Owl, Garcia y Vega/ Game, and Backwoods (Corey et al., 2018; Delnevo et al., 2017a; Delnevo et al., 2021; NCI, 1998).

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#### Large Nonpremium Cigars

Large cigars are, for tax purposes, those that weigh more than 1.36 grams (TTB, 2017). This broad weight category includes filtered cigars and cigarillos. Despite the similar lack of formal definition, the term is commonly understood as nontipped, machine-made cigars that tend to be larger than cigarillos. Large cigars typically have three components: wrapper, binder, and filler. The wrapper is often made from reconstituted tobacco leaf. The 1998 NCI monograph describes these as weighing 5–17 grams and measuring 110–150 mm (NCI, 1998). Koszowski and colleagues (2018) tested large cigars and found the mean weight was 7.16 grams, which was notably greater than the cigarillos they assessed (2.86 grams). Additionally, the large cigars were longer (mean length = 140 mm) than the cigarillos (110 mm). However, they potentially misclassified some conventional cigarillos as large cigars, as their classification was based on product labeling.

Koszowski and colleagues (2018) found a mean pH for large cigar tobacco filler of 6.53, which did not notably differ from the cigarillos. While Lawler and colleagues (2017) measured 27 "large cigars," Koszowski and colleagues (2018) relied on product labeling. Many products measured by Lawler and colleagues would be conventionally classified as filtered cigars (e.g., Santa Fe Filtered Cigars in a 20 pack) or cigarillos (e.g., Backwoods Wild Rum). Several of the remaining "large cigars" were premium cigar brands and matched the committee's definition of a premium cigar. The lowest-pH "large cigars" as measured by Lawler and colleagues (2017) were filtered cigars or cigarillos.

Like cigarillo products, machine-made large cigars also tend to be flavored (Delnevo et al., 2017a; Delnevo et al., 2021). The most popular brands of large cigars are Black & Mild<sup>6</sup>, Swisher Sweets, White Owl, Garcia y Vega, and Dutch Masters (Corey et al., 2018; Delnevo et al., 2017a; Delnevo et al., 2021; NCI, 1998). Size and the presence or absence of wood or plastic tips tend to be arbitrary dividing lines between cigarillos and large cigars; some research has combined machine-made cigarillos and large cigars (Corey et al., 2014).

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<sup>&</sup>lt;sup>6</sup> Consumers and researchers may refer to Black & Mild products as cigarillos and/or filtered cigars, but they are large cigars for federal tax purposes. As Chapter 1 notes, no formal definitions exist for any cigar types (other than the large and small cigar taxation categories); therefore, the industry can name products without restriction, and consumers may have different ideas of product classification. Consequently, there is overlap in the popular brands listed for each type of cigar described in this chapter.

#### **Premium Cigars**

This report employed a definition that provides a dividing line between premium cigars and the machine-made filtered cigars, cigarillos, and large cigars described previously. In comparison to other cigars, premium cigars are handmade; consist of 100 percent tobacco leaf wrapper; contain long filler tobacco; do not use a filter, tip, or mouthpiece; and are larger and heavier. While flavors are common in the machine-made cigar marketplace, additives and flavors are rare in the premium market, with exceptions (Corey et al., 2018). The committee definition of premium cigars does not allow for flavors or additives; however, particular premium cigars brands do have distinctive aromas and tastes that are partially attributed to the fermenting, blending, and aging of the tobacco (see the section on flavors later in this chapter for more information).

While weight is not as commonly referred to in definitions and is not intrinsic to a cigar being premium, the cut point of 6 pounds per 1,000 units is the weight most commonly used, as noted in Chapter 1. Premium cigars have been described as 5-22 grams (Henningfield et al., 1999; NCI, 1998). The research literature rarely refers to the cigars being tested as premium. Therefore, the summary provided here relies on the premium cigar brands noted throughout this report. Henningfield and colleagues' (1999) study included three cigar brands that are considered premium: Cuesta Rey, Macanudo, and Nat Sherman. With the exception of the Cuesta Rey Cameo (described in the paper as a "cigarillo"), their weight was considerably higher than the cigars types previously described; two of them were more than 20 grams. In the Koszowski and colleagues (2018) study, one of the large cigars was premium: a Romeo y Julieta 1875 Churchill, which weighed 17.60 grams. Recent testing commissioned by the committee of 66 premium cigars from several top premium cigar brands highlights that these products are quite large and considerably exceed 6 pounds per 1,000 (Yassin et al., 2021), indicating that this weight criterion commonly used in definitions of premium cigars may need to be re-examined, and possibly increased, to be consistent with the current marketplace (see Table 2-1 and Appendix F for more information). The most popular brands of premium cigars are Cohiba, Macanudo, Arturo Fuente, and Montecristo (Corey et al., 2018); other popular brands are detailed in Table 2-1.

Finding 2-1: There is a wide variety of cigar products overall, and within the category of premium, on the market, which differ with respect to size and weight. Many of the cigars considered premium weigh considerably more than 6 pounds per 1,000 units.

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	Number of Cigars Measured	Mean Weight (g)	Mean Length (mm)	Mean Diam- eter (mm)	Mean Pounds per Thousand
Arturo Fuente	6	10.0	137.2	16.9	21.9
Ashton	3	13.3	144.4	20.3	29.4
CAO	3	17.9	139.9	19.5	39.5
Cohiba	5	13.8	135.5	19.5	30.4
Davidoff	4	16.2	134.4	19.8	35.6
K. Hansotia Gurkha	4	17.2	151.8	20.7	37.9
La Gloria Cubana	5	14.8	137.0	19.0	32.7
Macanudo	5	11.7	135.0	17.0	25.8
Montecristo	3	18.0	147.9	18.9	39.8
My Father	5	15.1	142.6	20.4	33.4
Padron	5	12.7	140.5	18.7	28.0
Partagas	4	13.6	123.1	19.9	30.0
Punch	4	12.4	145.7	18.2	27.3
Rocky Patel	6	13.7	133.1	18.9	30.2
Romeo y Julieta	4	15.1	133.0	19.8	33.2
Mean		14.1	138.2	19.1	31.0
Range		6.6–25.8	99.4–178.2	14.1–24.2	14.6–56.9

**TABLE 2-1** Summary of Characteristics of a Sample of Premium Cigars

NOTE: *N* = 66. g = gram; mm = millimeter. SOURCE: Yassin et al., 2021.

#### CIGAR CHEMISTRY

#### Introduction

*All* cigar tobaccos, like *all* cigarette and smokeless tobaccos, contain the highly addictive compound nicotine and carcinogenic tobacco-specific nitrosamines (NCI, 1998). When tobacco is burned during smoking, the tobacco-specific nitrosamines are transferred to the smoke and a plethora of new carcinogens and toxicants, including polycyclic aromatic hydrocarbons (PAH), such as benzo[*a*]pyrene (BaP), and volatiles, such as formaldehyde, acrolein, and 1,3-butadiene, are formed. The user is exposed to this carcinogenic mixture.

It is difficult to quantify constituents of cigar smoke because of the lack of standardization of measurement conditions. This is particularly true for large cigars, including premium cigars. As discussed in Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA, a tobacco industry association) documents and in presentations to the committee, the varying sizes and shapes of cigars, as well as their sometimes uneven combustion properties, makes smoke measurements challenging (CORESTA, 2021; Lindegaard, 2021; Watson, 2021).

However, these challenges do not exist for the uncombusted tobacco; well-standardized procedures exist for tobacco analysis involving isotopically labeled internal standards, extraction with suitable solvents, partial purification and enrichment of analytes, and quantitation by gas chromatography-mass spectrometry (GC-MS) or liquid chromatographymass spectrometry (LC-MS), and related well-established and validated analytical chemistry techniques. Thus, highly reliable analytical data on constituents of cigar tobacco are available. These are partially transferred to smoke during smoking and are also the substrates for pyrosynthesis of new toxicants.

This section begins with a retrospective overview of the comprehensive NIH-sponsored review of the health effects of cigars (NCI, 1998), then proceeds to the relevant literature published since. The committee's literature search identified 243 references that could have been related to this topic. Each reference was considered, and the conclusions of the relevant studies are described here.

# Overview of Chemistry and Toxicology Findings from 1998 NCI Monograph on Cigars

Chapter 3 of the 1998 NCI monograph, on chemistry and toxicology, compared selected components of cigar tobacco (including some premium cigars) and types of cigarette tobacco; relevant data are discussed here.

The report compared levels of certain constituents in cigar tobacco to four types of cigarette tobacco: Burley, Maryland, Bright (Virginia), and Oriental (data expressed as percent dry weight of tobacco). The constituents included nicotine, nitrate, total polyphenols, paraffins, reducing sugars, neophytadiene, phytosterols, and oxalic, maleic, and citric acids. Nicotine concentrations were similar in the different tobacco types. Some constituent differences were noted, and these were believed to be related to the long aging and fermentation process used in cigar manufacturing. Cigar tobacco contained much lower levels of polyphenols and somewhat lower levels of phytosterols but higher levels of nitrate than the cigarette tobacco types other than Burley (which is a main constituent of cigars). Reducing sugars were higher in Bright tobacco than in cigar tobacco and

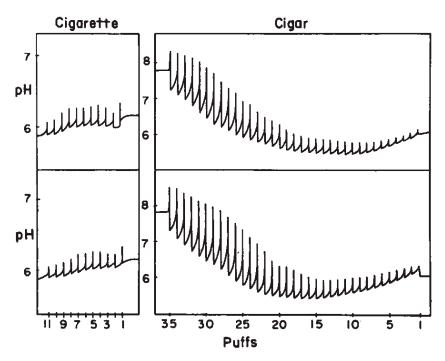
the other cigarette tobacco types. The pH of cigar tobacco (6.9–7.8) was higher than that of the cigarette tobacco types (4.4–7.5).

Further comparisons focused on nitrate and tobacco-specific nitrosamines. Tobacco nitrate is the precursor to nitrite in tobacco, and the latter reacts with tobacco alkaloids during curing and processing to produce tobacco-specific nitrosamines, arguably the most carcinogenic constituents occurring in relatively high quantities in unburned tobacco, including cigar tobacco. The most carcinogenic compounds among the tobacco-specific nitrosamines, based on extensive laboratory testing in animals, are N'-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and these are considered "carcinogenic to humans" by the International Agency for Research on Cancer (IARC, 2007). NNN in particular is highly relevant to the health effects of cigars because it is a powerful oral cavity and esophageal carcinogen in rats when given in drinking water, while a mixture of NNN and NNK also produced oral and lung cancers in rats when applied in the oral cavity (Balbo et al., 2013; Hecht et al., 1986). Similar concentrations of NNN and total tobacco-specific nitrosamines (NNN, NNK, N'-nitrosoanatabine and N'-nitrosoanabasine) have been found in all tobacco types of little cigars, nonfilter cigars, filter cigarettes, and nonfilter cigarettes (NCI, 1998).

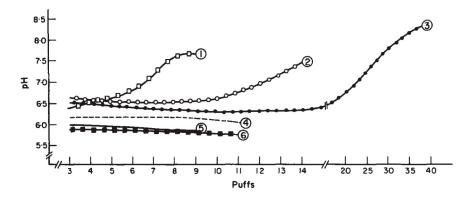
Further comparisons explored the comparative smoke profiles of cigarettes and cigars, including premium cigars. Premium and other cigar smoke have been found to deliver amounts of tar, carbon monoxide (CO), nitrogen oxides, nicotine, NNN, NNK, acrolein, acetaldehyde, benzene, isoprene, BaP and other PAH, hydrogen cyanide, metals, nitrogen oxides, and other potentially toxic constituents generally comparable to or greater than cigarettes (when expressed per gram of tobacco smoked) (NCI, 1998). However, these comparisons are complex because of the different physical characteristics of cigarettes and cigars and the different machine smoking conditions used. Additionally, smoke pH changes differentially over time for different tobacco products (see Figures 2-2 and 2-3) (Brunnemann and Hoffmann, 1974; Henningfield et al., 1999; NCI, 1998). For example, one study found that the smoke pH of cigarettes decreased from 6.0 at the third puff to 5.7 at the last. In contrast, little cigar smoke pH changed from 6.5 to 7.4 from third to last puff, and cigar smoke pH increased from 6.5 at the third puff to 8.0 at the last (Brunnemann and Hoffmann, 1974; NCI, 1998). As described, these changes are important because tobacco smoke above pH 6.0, as is generally observed in cigars, contains greater proportions of unprotonated nicotine, which affects puffing topography (the pattern of inhalation by a user) and increases oropharyngeal nicotine absorption (Henningfield et al., 1999; NCI, 1998).

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**FIGURE 2-2** Variation of pH with individual puffs of cigarettes or cigars. SOURCE: Brunnemann and Hoffmann, 1974.



**FIGURE 2-3** pH of total mainstream smoke of various tobacco products. NOTE: 1 = little cigar I; 2 = little cigar II; 3 = cigar; 4 = Kentucky reference cigarette; 5 = blended filter-tipped cigarette (85 mm); 6 = blended cigarette without filter (85 mm).

SOURCE: Brunnemann and Hoffmann, 1974.

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The NCI monograph (1998, p. 97) chapter concluded

- 1. "Cigar smoke contains the same toxic and carcinogenic compounds identified in cigarette smoke.
- 2. When examined in animal studies, cigar smoke tar appears to be at least as carcinogenic as cigarette smoke tar.
- 3. The differences in risk between cigarette smoking and cigar smoking appear to be related to the differences in patterns of use of those two tobacco products, principally nondaily use and less inhalation among cigar smokers, rather than a difference in the composition of the smoke.
- 4. The amount of nicotine available as free, unprotonated nicotine is generally higher in cigars than in cigarettes due to the higher pH of cigar smoke. This free nicotine is readily absorbed across the oral mucosa, and may explain why cigar smokers are less likely to inhale than cigarette smokers."

No new evidence in the current literature would significantly alter these conclusions.

# Studies Published After the 1998 NCI Monograph on Cigars

## Constituents of Cigar Tobacco

The studies reported here investigated constituents of cigar tobacco. Only a few of the studies mentioned premium cigars, specified countries of origin, or listed brand names that might identify some of the products as premium cigars.

As mentioned, Henningfield and colleagues (1999) studied nicotine concentration and smoke pH of various cigar brands, including "large premium cigar brands." The tobacco content of the cigars ranged from 0.53–21.50 g, and the aqueous pH of the tobacco varied widely, from 5.7 to 7.9. The range of aqueous pH of the tobacco of the smaller cigars was 5.7–7.6, while that of the large cigars was 6.7–7.9. There was no clear relationship between tobacco pH and smoke pH overall. However, the smoke pH of smaller cigars became acidic after the first third of the cigar was consumed and remained acidic, while the larger cigars' smoke pH, presumably including the premium cigars', became acidic during the first third and then alkaline during the last third (Henningfield et al., 1999). Thus, nicotine and other constituents would be more readily absorbed through the buccal mucosa in the users of the large cigars, and not necessarily inhaled, particularly in the later puffs. This could relate to the

risk of oral cavity cancer in users of large cigars (see Chapter 5 for more information).

Ng and colleagues (2001) developed a GC-MS method to characterize nonvolatile organic acids in cigar tobacco, quantifying them in aqueous tobacco extracts by capture on strong anion exchange disks, followed by silylation and analysis. This method was applied to analyze 18 cigars from Cuba and 31 from other countries. Their identity as premium cigars was not specified. Principal component analysis of the acid profiles of all cigars showed separation of the two groups, indicating that acid profiles, including nicotinic, succinic, malic, citric, and pyroglutamic acids, are potentially useful in authenticating Cuban cigars.

In another study of cigar tobacco constituents, levels of free plus conjugated phytosterols in (unspecified) cigar tobacco were compared to flue-cured, Oriental, Burley, and Maryland tobacco. Phytosterols are potential precursors to PAH in smoke. Total phytosterols, the sum of stigmasterol, campesterol, and -sitotsterol and their conjugates, were similar in Burley, Maryland, and cigar tobaccos, with higher levels in flue-cured and Oriental tobaccos (Liu et al., 2008).

Pappas and colleagues (2015) developed a new analytical method to determine concentrations of 10 toxic metals in little cigar tobacco using triple quadrupole inductively coupled plasma mass spectrometry: arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, nickel, selenium, and uranium. The results indicated no significant differences in analyte levels in little cigar versus cigarette tobacco, with the exception of nickel, which was lower in little cigar tobacco.

Fresquez and colleagues (2015) developed a validated method for the high-throughput determination of mercury in tobacco and mainstream smoke from little cigars. The method used a platinum trap and direct release for analysis by heating the trap in a mercury analyzer. The tobacco mercury levels were 17.9–24.9 ng/g tobacco.

Limited data are available on the pH of premium cigar tobacco. As described above, Lawler and colleagues (2017) compared pH values and levels of nicotine in cigarette and cigar filler, including in cigars determined by the committee to be premium cigars. The range of mean pH of the large cigar filler in aqueous solution was 5.40–6.83; the range of mean filler pH of large cigars determined to be premium was 6.12–6.83. In this analysis, 73 percent (55 out of 75 brands) of the products had filler pH levels lower than 6.0. Of the 20 cigar tobacco products with the highest filler pH levels (mean pH >6), 85 percent (17) were large cigars, and 15 were determined to be premium cigars. In fact, all premium cigars had mean filler pH levels greater than 6.0. As described earlier in this chapter, alkaline pH results in more unprotonated nicotine and greater oral absorption of nicotine. However, the relationship between tobacco pH,

which is more easily measured, and smoke pH, which is more difficult to measure, is unclear (Henningfield et al., 1999; NCI, 1998). The authors found large cigars and cigarillos to have the highest mean nicotine concentrations when compared to little cigars, pipe tobacco cigars, and minicigarillos. The range of mean nicotine values in large cigars was 9.2–24.8 mg/g tobacco; the range of mean nicotine in those determined by the committee to be premium was 13.2–24.8 mg/g tobacco (Lawler et al., 2017). The nicotine values can be compared to the value given in the 1998 NCI monograph, 6.0–17.0 mg/g—in the same general range and extending beyond (NCI, 1998).

The committee commissioned an analysis of tobacco nicotine content in a convenience sample of premium cigars (see Appendix F). Nicotine in tobacco was analyzed using gas chromatography with nitrogen-phosphorous detector, using a modification of the CORESTA 62 method for determination of nicotine in tobacco and tobacco products by gas chromatographic analysis (CORESTA, 2020). A summary of findings is presented in Table 2-2.<sup>7</sup> Overall, the analysis reveals that the average nicotine concentration was 19.91 milligrams per gram of tobacco and varied from 8.51 to 33.26 milligrams (Yassin et al., 2021). Total nicotine content in the sample of premium cigars was 297.89 milligrams per cigar (varying from 98.62 to 629.26) (Yassin et al., 2021).

Finally, researchers quantified the levels of the tobacco-specific nitrosamines NNN and NNK in the tobacco of 60 commercial brands of little cigars (Edwards et al., 2021). The values were 1,440–12,100 ng/g tobacco for NNN and 26–2,950 ng/g tobacco for NNK. The NNN values are in the same range as that given in the 1998 NIH monograph, 2,940 ng/g. The relatively high levels of NNN and NNK are consistent with the high concentrations found in Burley tobacco, which is used in these products (Ding et al., 2008).

Although premium cigars were not the main focus of most of these studies, there is no reason to believe that the chemical profile of premium cigars would differ in important ways from those of other cigar types. They are all made from cigar tobacco (with the exception of little cigars, which can include cigarette tobacco blends (Delnevo and Hrywna, 2007); the main concern is the tobacco and the resulting combustion, not the design of the cigar.

<sup>&</sup>lt;sup>7</sup> A complete summary of the methods and analysis is available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

	Number of Cigars Mea- sured	Mean Weight (g)	Mean Nicotine Concentration (mg/g tobacco)	Total Nicotine per Premium Cigar (mg/stick)
Arturo Fuente	3	9.63	17.76	170.43
Ashton	3	13.33	18.47	245.41
CAO	2	17.90	16.53	296.71
Cohiba	3	15.03	22.76	353.82
Davidoff	3	16.37	26.57	438.06
K. Hansotia Gurkha	2	16.40	24.14	397.45
La Gloria Cubana	3	15.60	22.83	363.24
Macanudo	3	12.80	13.65	173.69
Montecristo	3	18.00	22.92	427.46
My Father	3	14.97	15.96	240.53
Padron	3	12.70	19.70	252.53
Partagas	3	14.50	20.61	299.21
Punch	3	11.47	17.77	217.15
Rocky Patel	4	13.85	18.25	265.64
Romeo y Julieta	3	15.67	21.51	370.56
Mean		14.42	19.91	297.89
Range		6.60-25.80	8.51-33.26	98.62-629.26

**TABLE 2-2** Tobacco Nicotine Content in a Sample of Premium

 Cigars

73

NOTE: *N* = 44. g = gram; mm = milligram. SOURCE: Yassin et al., 2021.

#### Constituents of Cigar Smoke

As noted, Fresquez and colleagues (2015) developed a validated method to determine mercury in tobacco and mainstream smoke from little cigars. Mercury levels in little cigar smoke under International Organization for Standardization/U.S. Federal Trade Commission (ISO/FTC) smoking conditions<sup>8</sup> were 2.6–7.5 ng/cigar.

<sup>&</sup>lt;sup>8</sup> There are two smoking conditions/methods used by studies in this chapter. The Canadian Intense Regimen (CIR) includes 2-second puff duration, 55 mL puff volume, and 30-second interval (Minister of Justice, 2019), while the International Organization for Standardization/US Federal Trade Commission (ISO/FTC) regimen includes 2-second puff duration, 35 mL puff volume, and 60-second interval (ISO, 2012).

Klupinski and colleagues (2016) used two-dimensional gas chromatography-time of flight mass spectrometry to compare little cigar mainstream smoke with cigarette mainstream smoke. Among more than 25,000 components detected, the tricyclic terpenoid ambrox was unique to little cigars, and 3-methylbutanenitrile and 4-methylimidazole were more abundant in little cigar mainstream smoke, at levels of 0.4, 0.7, and 12  $\mu$ g/rod, respectively, than in cigarette smoke.

Hamad and colleagues (2017) compared levels of nicotine and certain harmful and potentially harmful constituents in mainstream, standard 3R4F reference cigarette smoke with those in the mainstream smoke of four popular little cigars under standardized smoking conditions. Under the Canadian Intense Regimen (CIR), nicotine levels in the smoke of the cigarette were higher than in the little cigars, while levels of NNK, NNN, and BaP were higher in little cigar than cigarette smoke, when expressed per mass of total particulate matter.

Cecil and colleagues (2017) quantified acrolein in mainstream smoke from sheet-wrapped cigars, also known as little cigars, versus commercial cigarettes. Of 15 sheet-wrapped cigars, the measured acrolein yields were  $34.3-105 \ \mu g/product$  under the CIR, whereas yields in the smoke of 35 commercial cigarettes were  $139-213 \ \mu g/product$ .

In a study of cigar burning under different smoking intensities and the effects of smoking conditions on emissions, researchers concluded that complex phenomena occur during cigar smoking that make emission data challenging to interpret and potentially misleading (Dethloff et al., 2017). This was attributed to the use of natural leaf, which is less processed and blended, and to physical variations of large cigars. They concluded that analysis of tobacco and physical parameters are a more sound foundation for product comparison than emission yields.

Reilly and colleagues (2018) quantified levels of seven carbonyls (formaldehyde, acrolein, propionaldehyde, crotonaldehyde, methyl ethyl ketone, acetaldehyde, and acetone) in the smoke of little cigars, filtered cigars (which the authors noted can be heavier and longer than little cigars), and cigarettes under the ISO/FTC and CIR methods of smoke generation. Per puff, levels of five of these were higher from little cigars than filtered cigars and cigarettes. Per unit, most carbonyl levels were higher from little cigars and filtered cigars than cigarettes using the ISO/FTC method, but only filtered cigars were higher using the CIR method.

Pickworth and colleagues (2018) compared mainstream smoke emissions from cigarillos and little cigars under human smoking topography conditions and found wide variability in these smoking patterns across subjects using both types of products. Toxicants measured included nicotine, NNK, NNN, BaP, 1,3-butadiene, acetaldehyde, and benzene. When adjusting for nicotine content, cigarillo mainstream smoke contained

more of all toxicants compared to little cigars; both product types delivered substantial levels of the measured toxicants.

Goel and colleagues (2018) quantified nicotine yields in the smoke of little cigars and filtered cigars (collectively called "small cigars" because of the lack of standard definitions and inconsistent classification of both products) and compared them to cigarettes. Nicotine yields in small cigars were higher under both ISO/FTC and CIR regimens than in cigarettes, but yields per puff were similar. The two types of small cigars did not differ.

In another study of carbonyls, levels of formaldehyde, acetaldehyde, acrolein, and crotonaldehyde delivery from 12 mass-market cigars were compared to those from 3R4F cigarettes (Jablonski et al., 2019). Per product, levels of acetaldehyde, acrolein, and crotonaldehyde were greater from cigar smoke than from mainstream cigarette smoke, but levels of formaldehyde were similar from both products.

Vu and colleagues (2021) determined the mainstream smoke yields of five volatile organic compounds—1,3-butadiene, acrylonitrile, benzene, isoprene, and toluene—in 60 commercial U.S. little cigars under the ISO/ FTC and CIR smoking conditions. Higher yields were found under the CIR conditions. Little cigars produced higher mainstream smoke yields than cigarettes under both smoking regimens, and little cigar smoke contained higher amounts of these compounds than cigarette smoke when amounts were adjusted for the mass of tobacco.

Edwards and colleagues (2021) quantified levels of the tobacco-specific nitrosamines NNK and NNN in the smoke of 60 commercial little cigars using the ISO/FTC and CIR smoking conditions. NNK and NNN by the ISO nonintense smoking regimen were 89–879 and 200–1,540 ng/ cigar, respectively, and 138–1570 and 445–2780 ng/cigar under the CI regimen. The average transfer of NNN from tobacco filler to mainstream smoke of little cigars was 10–18 percent, depending on the regimen, while that of NNK was 37–51 percent. Mainstream smoke yields of NNK and NNN from little cigars were 3–5 times higher than in commercial cigarettes.

#### Summary and Conclusions

In summary, vast amounts of data, much of it recent, exist on toxic and carcinogenic constituents of cigar tobacco and smoke demonstrating that all analyzed toxicant levels are similar or higher than those found in cigarette tobacco and smoke, when compared per unit of tobacco. These data clearly demonstrate that cigars could be as dangerous as or more dangerous than cigarettes, with respect to toxicant and carcinogen exposure per unit consumed. Despite only limited data on premium cigars, it is reasonable to expect that the results of analyses of tobacco and smoke

would not substantially differ from those of the products presented here because premium cigars' tobacco and pyrolysis conditions are similar to those of other cigars. Thus, based on laboratory studies using validated analytical methods and a variety of smoking conditions, including human smoking topography conditions, the available data demonstrate that exposure of premium cigar users to toxic and carcinogenic constituents of smoke will be qualitatively similar to the exposure of users to constituents of other combustible tobacco products. The relationship between tobacco pH and smoke pH remains unclear, and smoke analysis in general can be challenging. However, two laboratory studies have shown cigar smoke pH becoming more alkaline from early to last puffs, which would result in more unprotonated nicotine and therefore more oral nicotine absorption.

Conclusion 2-1: There is **conclusive evidence** that the addictive, toxic, and carcinogenic **constituents of cigar tobacco in general** are the same as those present in cigarette tobacco. There is **strongly suggestive evidence** that **constituents of premium cigar tobacco** are similar to constituents of other cigars because all tobacco contains nicotine, carcinogenic tobaccospecific nitrosamines, metals, and precursors to toxic and carcinogenic compounds formed during the combustion process.

Conclusion 2-2: There is **conclusive evidence** that the **toxicants and carcinogens in cigar smoke in general** are qualitatively the same as those in cigarette smoke. There is no reason to believe that **toxicants and carcinogens in premium cigar smoke** are any different from those in other types of cigars. Additionally, it is likely that the total toxic and carcinogenic constituent yields will increase with the mass of tobacco filler in the cigar.

Conclusion 2-3: There is **strongly suggestive evidence** that there is a wide variety of **pH levels of tobacco used in cigars overall**; however, higher pH has been noted in premium cigar tobacco than for other cigar types. While there is **insufficient evidence** on the **pH of premium cigar smoke**, the **pH of large cigar smoke** is generally higher than cigarette smoke, which can decrease depth of inhalation and increase nicotine absorption through the oral mucosa. There is **insufficient evidence** on the relationship between the pH of premium cigar tobacco and smoke.

#### BIOMARKERS

The previous section reviewed recent studies on potentially toxic and carcinogenic substances in cigar tobacco filler and smoke. The smoke concentrations were determined by machine measurements, which can be technically difficult, particularly for large cigars. Biomarkers of exposure,

substances detected in the urine, blood, saliva, and other body fluids, can potentially provide important information on human uptake and exposure under realistic conditions of product use. The following studies quantified various biomarkers in cigar users.

The tobacco alkaloids nicotine, anabasine, anatabine, nornicotine, and cotinine were quantified in the urine of subjects who smoked small cigars (Jacob et al., 1999). Levels were compared to those in the urine of users of cigarettes, smokeless tobacco, and pipes. The eight cigar users in the study used an average of five small cigars daily and excreted the lowest levels of all alkaloids except nornicotine. This was apparently the first report of systemic nicotine intake from regular cigar smoking. Cotinine levels were 1,740  $\mu$ g/24 h in the cigar users compared to 3,360  $\mu$ g/24 h in cigarette and 2,050  $\mu$ g/24 h in smokeless tobacco users.

McDonald and colleagues (2002) measured inhalation of smoke from a "standard-sized" cigar using <sup>99m</sup>Tc-labeled sulfur colloid particles. There were 24 male volunteers; all had smoked cigars previously, and half were current or past regular cigarette users, while the other half had no history of cigarette smoking. Researchers devised a cigar holder allowing the smoke drawn from a standard-sized cigar to mix with the <sup>99m</sup>Tc-sulfur colloid aerosol particles along a plastic tube. A designed mouthpiece allowed each participant to inhale the mixed aerosol and smoke; imaging was performed after each subject smoked in the usual way for approximately 2 minutes in conjunction with the aerosol. Lung ventilation scanning was performed to assess inhalation. All subjects inhaled the cigar smoke to varying degrees, independent of whether they were also current or past cigarette users or exclusive cigar users.

The 1999–2012 National Health and Nutrition Examination Survey (NHANES) reported biomarkers of exposure among U.S. cigar users (Chen et al., 2014). After adjustment for age, sex, race and ethnicity, education, and body mass index, primary cigar users (those who smoked less than 100 cigarettes in their lives) had 138 times higher serum cotinine concentrations (6.2 ng/mL versus 0.045 ng/mL) and 18.9 times higher urinary NNAL concentrations (19.1 pg/mg creatinine versus 1.01 pg/mg creatinine) than nontobacco users. Cotinine is the main metabolite of nicotine, and NNAL is a metabolite of the tobacco-specific lung carcinogen NNK. This group also had higher blood cadmium and lead concentrations than nontobacco users. Similar results for serum cotinine, urinary NNAL, and blood cadmium and lead concentrations were observed in comparing secondary cigar users (who had smoked more than 100 cigarettes in their lifetime but were not currently doing so) to nontobacco users. Primary and secondary cigar users had significantly lower serum cotinine (geometric mean cotinine concentrations: 6.2 ng/mL and 24.2 ng/mL for primary and secondary cigar users and 131.4 ng/mL for current cigarette-

only users) and urinary NNAL concentrations than current cigarette-only users (19.1 pg/mg creatinine, 78.6 pg/mg creatinine, and 215.4 pg/mg creatinine, respectively).

Rosenberry and colleagues (2018) examined levels of plasma nicotine and exhaled CO in dual users who were randomized to smoke their own brand of cigarettes or a study-provided large cigar (Phillies Blunt; not a premium cigar). Both products significantly increased plasma nicotine and exhaled CO and significantly reduced the reported urge to smoke. They concluded that such dual users alter their smoking patterns so that they are exposed to similar levels of nicotine from both products and that the results challenge the idea that cigar smoking is less toxic than cigarette smoking.

Pickworth and colleagues (2017b) examined smoking topography and toxicant exposure (plasma nicotine and exhaled CO) in three groups of study participants who smoked both cigarettes and filtered little cigars, cigarillos, or large cigars (Phillies Blunt). All products resulted in similar plasma nicotine boost, but cigarillos and large cigars resulted in greater exhaled CO. These results indicate that biomarker data from cigar types can be quite different.

Koszowski and colleagues (2017) studied biomarkers in two groups of dual users who smoked their usual brand of cigarette and an unflavored little cigar or a cigarillo. The authors found significant differences in measures of puff topography, plasma nicotine, and exhaled CO after all three. Smoke deliveries, as determined by machine smoking under conditions that replicate human smoking, were similar for all three.

Pickworth and colleagues (2017a) studied smoking patterns and toxicant exposure after smoking a little cigar and a cigarette in dual users of these products. Plasma nicotine and exhaled CO increases were essentially identical after cigarette or little cigar smoking.

Claus and colleagues (2018) examined factors related to cigar smoking, including biomarkers of exposure in current exclusive cigar users. Adult exclusive cigar users (N = 77, aged 22–77 years, 16 female) were recruited and smoked their own brand product ad libitum for up to 1 hour; biomarkers of exposure, dependence symptoms, and smoking topography were assessed. The study design separated the groups into small (3 grams) and large (>3 grams) cigar users. The first group was subdivided into small cigars and cigarillos. Exclusive cigar users who smoked at least one cigar per week had measurable and variable urinary cotinine and total NNAL concentrations (see Table 2-3). Upon smoking a single cigar, plasma nicotine levels increased significantly overall and within each group (see Figure 2-4). Exhaled CO levels significantly increased following cigar smoking in all groups, including self-reporting noninhalers.

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<b>NBLE 2-3</b>

			Cigar Size		Cigarette Smoking History	ing History	Self-Reported Inhalation Behaviors	nhalation
	All	Small	Cigarillo	Large	Primary	Secondary	Inhaler	Noninhaler
				Screening Visit	it			
Cotinine (ng/mg creati- nine)	469.0 (SD = 802.3)	640.4 (SD = 783.8)	695.2 (SD = 1,024.6)	297.6 (SD = 639.4)	87.3 (SD = 186.9)*	787.1 (SD = 967.5)*	657.5 (SD = 924.9)	320.0 (SD = 664.2)
Total NNAL (pg/mg creati- nine)	418.3 (SD = 712.2)	859.0 (SD = 1,167.7)	552.7 (SD = 794.2)	201.1 (SD = 282.9)	84.2 (SD = 169.2)*	680.7 (SD = 856.1)*	665.2 (SD = 961.1)	213.5 (SD = 285.6)
(		_		Exposure Visit	t t			
Baseline Plasma Nicotine (no/mL)	0.7 (SD = 0.9)	0.6 (SD = 0.4)	0.8 (SD = 1.4)	0.7 (SD = 0.7)	0.5 (SD = 0.0)	0.9 (SD = 1.2)	0.9 (SD = 1.2)	0.6 (SD = 0.5)
Nicotine C <sub>max</sub> (ng/mL)	10.2 (SD = 10.5)	$5.8 (SD = 5.7)^{c}$	8.2 (SD = 7.1)	12.6 (SD = 12.5) <sup>a</sup>	8.4 (SD = 9.8)	11.7 (SD = 11.0)	13.2 (SD = 12.3)#	7.9 (SD = 8.5)#
Range	0.3-54.7	0.3-17.6	0.3-25.6	0.3-54.7	0.3-41.7	0.3-54.7	0.3-54.7	0.3-37.7
Nicotine AUC <sub>0-120</sub> (min x ng/mL)	742.3 (SD = 870.4)	343.6 (SD = 299.1) <sup>c</sup>	601.0 (SD = 559.9)	936.0 (SD = 1,055.6) <sup>a</sup>	613.1 (SD = 769.1)	848.8 (SD = 942.0)	989.7 (SD = 1,093.6)#	549.1 (SD = 591.2)#
Range	12.2-5,252.5	12.2-921.6	17.2-2044.3	27.8-5,262.5	12.2–3,367.7	17.5-5,262.5	17.2-5,262.5	12.2-2.844.2

continued

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			Cicar Size		Cicarette Smoking History	ino History	Self-Reported Inhalation Rehaviors	halation
	All	Small	Cigarillo	Large	Primary	Secondary	Inhaler	Noninhaler
I-N Nico-	0.8 (SD = 1.3)	$0.8 (SD = 1.3)  1.3 (SD = 1.3)^{c}  1.3 (SD = 2.0)^{c}  0.4 (SD = 0.4)  0.4 (SD = 0.4)^{*}  1.2 (SD = 1.7)^{*}  1.3 (SD = 1.7)^{\#}  0.5 (SD = 0.6)^{\#}  0.5 (SD = 0.6)^$	$1.3 (SD = 2.0)^{c}$	0.4 (SD = 0.4)	$0.4 (SD = 0.4)^*$	$1.2 (SD = 1.7)^*$	1.3 (SD = $1.7$ ) <sup>#</sup>	$0.5 (SD = 0.6)^{\#}$
tine C <sub>max</sub> (ng/mL)				a þ				
I-N	56.7 (SD =	75.3 (SD =	99.3 (SD =	28.7 (SD =	29.0 (SD =	79.5 (SD =	88.9 (SD =	31.4 (SD =
Nicotine	91.8)	64.0)	148.8) <sup>c</sup>	34.1) <sup>b</sup>	35.4)*	$115.6)^{*}$	$124.6)^{\#}$	$40.6)^{\#}$
AUC <sub>0-120</sub>								
(min x ng/mL)								
L-N	4.1 (SD = 6.0)	4.9 (SD = 4.7)	$6.7 (SD = 9.5)^{c}$	2.4 (SD =	$2.3 (SD = 2.2)^*$	$5.5 (SD = 7.6)^*$	$6.1 (SD = 8.1)^{\#}$	$2.4 (SD = 2.8)^{\#}$
Nicotine				2.7) <sup>b</sup>				
C <sub>max</sub>								
(C <sub>max</sub> nor-								
malized								
by the								
amount								
of tobacco								
smoked [								
i.e., ng/								
mL/g								
tobacco])								

TABLE 2-3 Continued

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$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$				Cigar Size		Cigarette Smoking History	king History	Self-Reported Inhalation Behaviors	nhalation
287.5 (SD = 285.3 (SD = 494.8 (SD = 179.3 (SD = 166.9 (SD = 386.9 (SD = 439.7 (SD = 440.3)))) $440.3) 228.7) 713.5) 713.5) 216.5) 183.9) 554.7) 599.4) 599.4)$		All	Small	Cigarillo	Large	Primary	Secondary	Inhaler	Noninhaler
440.3)     228.7)     713.5)     216.5)     183.9)     554.7)     599.4)	T-N	287.5 (SD =	285.3 (SD =	494.8 (SD =	179.3 (SD =	166.9 (SD =	386.9 (SD =	439.7 (SD =	168.6 (SD =
AUC <sub>0-120</sub> (AUC (AUC normal- ized by the amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	Nicotine	440.3)	228.7)	713.5)	216.5)	183.9)	554.7)	599.4)	193.6)
(AUČ normal- ized by the amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	AUC <sub>0-120</sub>								
normal- ized by the amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	(AUC								
ized by the amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	normal-								
by the amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	ized								
amount of tobacco smoked [ i.e., ng/ mL/g tobacco])	by the								
of tobacco smoked [ i.e., ng/ mL/g tobacco])	amount								
smoked [ i.e., ng/ mL/g tobacco])	of tobacco								
i.e., ng/ mL/g tobacco])	smoked [								
mL/g tobaccol)	i.e., ng/								
tobacco])	mL/g								
	tobacco])								

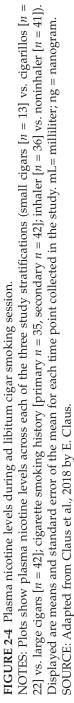
Statistically significant differences (p < .05) for cigar type are denoted with superscripts showing the relative group differences where <sup>a</sup> = small, <sup>b</sup> = cigarillo, and  $^{c}$  = large; all follow-up comparisons are corrected for multiple comparisons using Tukey's method for multiple comparisons (Tukey ences (p < .05) between self-reported inhalers and noninhalers. AUC = area under the concentration curve; AUC<sub>0.120</sub> = area under the concentration curve from 0 to 120 minutes; C<sub>max</sub> = maximum observed concentration; g = gram; I-N = nicotine intake (consumed weight of cigar [g] x nicotine concentration [mg/g]); mg = milligram; mL = milliliter; ng = nanogram; NNAL = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol; SD = standard adjusted ps < .05). \* = statistically significant difference (p < .05) between primary and secondary cigar smokers. # = statistically significant differdeviation.

SOURCE: Claus et al., 2018.

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c

Primary Secondary

¢ Δ

Cigarillo Large Small **≜**∳₿ σ

Plasma levels (ng/mL)

7.5 Plasma levels (ng/mL)

5.0

Plasma levels (ng/mL)

Levels of biomarkers of exposure among U.S. adult cigar users in PATH Wave 1 have been reported (Chang et al., 2019). Biomarker data from 5,604 adults were available; the study authors compared geometric mean concentrations among cigar-only smokers (all cigars and separately for traditional cigars, cigarillos, and filtered cigars), cigarette-only smokers, dual cigar/cigarette smokers, and never-users of any tobacco product. Only 12 every day traditional cigar smokers participated, all of whom were male. Table 2-4 presents selected data for this group and comparator groups. Every day exclusive traditional cigar smokers were comparable with every day exclusive cigarette smokers for numerous biomarkers, including total NNAL (from NNK) and cyanoethyl mercapturic acid (from acrylonitrile), and slightly lower for total nicotine equivalents, 3-hydroxypropyl mercapturic acid (from acrolein), and 1-hydroxypyrene (from pyrene), but all of these and most of the other biomarkers in this group were substantially higher than in never-tobacco users, even for some day traditional cigar users.

Based on the measurement of urinary biomarkers of nicotine and toxicants and carcinogens in the large NHANES and PATH studies and several smaller controlled clinical studies examining different products, such as small and large cigars, cigar users are exposed to significant amounts of nicotine and harmful and potentially harmful constituents. While levels of some urinary biomarkers were higher in every day exclusive cigarette smokers, the PATH study found that, for other biomarkers, concentrations in every day exclusive traditional cigar smokers were comparable to those of every day exclusive cigarette smokers. This indicates similar exposure and uptake of nicotine, toxicants, and carcinogens. Concentrations of biomarkers were also higher than in never-tobacco users.

Conclusion 2-4: There is **conclusive evidence** that **cigar smokers in general** are exposed to significant amounts of nicotine and numerous harmful and potentially harmful constituents.

#### INHALATION PATTERNS

When assessing potential health risk associated with premium cigars, it is important to understand the pattern of exposure to nicotine and harmful chemicals inhaled. Such patterns of exposure could be affected by multiple factors, including product characteristics, such as cigar size, shape, and tobacco type (see the section at the beginning of this chapter) and the behavior of individual users. That behavior is characterized by not only the number of cigars smoked per day or month (see Chapter 3) but also the way an individual cigar is smoked, including the depth of inhalation and number of puffs taken per cigar. The health risks associ-

TABLE 2-4 Cor and in Other Sn	nparison of Se nokers and Ne	TABLE 2-4       Comparison of Selected Urinary Biomarkers in Every Day Exclusive Traditional Cigar Smokers         and in Other Smokers and Never-Tobacco Users	ırkers in Every Day E	xclusive Traditional	Cigar Smokers
Urinary Biomarker	Biomarker Source	Every Day Exclusive Tra- ditional Cigar Smokers	Some Day Exclusive Tradi- Every Day Exclusive tional Cigar Smokers Cigarette Smokers	Every Day Exclusive Cigarette Smokers	Never-Tobacco Users
Total nicotine equiv- nicotine alents (µmol/g creatinine)	nicotine	24.05 (range = 12.85-45.00) 0.16 (range = 0.07-0.33)	0.16 (range = 0.07–0.33)	46.57 (range = 43.59- 49.75)	0.01 (range = 0.01-0.01)
Total NNAL (ng/g creatinine)	NNK	250.73 (range = 99.6 <del>4 -</del> 630.91)	8.68 (range = 5.23–14.41)	302.15 (range = 281.51- 324.3)	0.92 (range = 0.82–1.04)
Cyanoethyl mer- capturic acid (µg/g creatinine)	acrylonitrile	151.31 (range = 81.87– 279.66)	5.31 (range = 3.89–7.26)	177.32 (range = 166.71– 188.62)	1.27 (range = 1.2–1.36)
3-hydroxypropyl mercapturic acid (µg/g creatinine)	acrolein	666.62 (range = 455.34- 975.92)	294.21 (range = 241.87- 357.89)	1,396.05 (range = 1,313.86–1,483.37)	261.12 (range = 246.69–276.39)
1-hydroxypyrene (ng/g creatinine)	pyrene	177.78 (range = 117.63– 268.69)	133.65 (range = 112.18– 159.24)	336.44 (range = 320.03- 353.7)	127.93 (range = 120.46-135.86)
NOTE: g = gram; ng = nanogram; NNAL = 4 µg = microgram; µmol = micromole. SOURCE: Adapted from Chang et al., 2019.	= nanogram; NNA ol = micromole. rom Chang et al.,	NOTE: g = gram; ng = nanogram; NNAL = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol; NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; µg = microgram; µmol = micromole. SOURCE: Adapted from Chang et al., 2019.	-(3-pyridyl)-1-butanol; NNK	= 4-(methylnitrosamino)-1	-(3-pyridyl)-1-butanone;

Premium Cigars: Patterns of Use, Marketing, and Health Effects

ated with cigar smoke increases with frequency and intensity of smoking and the extent of inhalation (see Chapter 5).

Studies have shown that small cigars are often smoked and inhaled similarly to cigarettes (Pickworth et al., 2017a; Pickworth et al., 2017b). However, determining how users puff on premium cigars and how deeply they inhale is challenging for many reasons. Unlike cigarette consumption, in which users typically light, puff rather consistently, and finish a cigarette in a single session, cigar users puff differently, take much longer to consume the product, and may not smoke the entire cigar in a single session. If so, the cigar is relit, and more of it is consumed. Another important challenge in measuring the puffing behavior of premium cigar users is the lack of commercially available instruments that can be used in research studies (Watson, 2021). Optimally, puffing behavior would be captured in natural settings that premium cigar smokers usually frequent. Puffing topography monitors would also be portable and ideally would not change the way a smoker usually uses a premium cigar. Most off-theshelf commercial smoking topography instrumentation and hardware are designed for conventional cigarette research and need to be modified to accommodate cigars (Koszowski et al., 2017). The physical characteristics of cigarettes are consistent, unlike large cigars, which vary markedly in size and thus make standardization of measurements difficult (see the section at the beginning of this chapter and Appendix F for more information on variation in characteristics). Finally, alternative approaches to studying puffing topography, including direct observation by trained observers and video recordings, have not been commonly used to analyze inhalation patterns of premium cigar users. Although these methods minimize external influence on smoking characteristics, they cannot measure puff volume, an important index of smoke constituent intake (Blank et al., 2009).

Common measures of puffing topography include the number of puffs; the puff volume, duration, and velocity; interpuff interval; and time to smoke. Puffing topography is an index of toxicant exposure in cigarette smoking (Lee et al., 2003), making it an important measurement to understand the use behaviors of and toxicant exposure from large cigar smoking. A limited number of studies examine the smoking topography of large cigar users and the toxicant delivery from mainstream cigar smoke. The results of two clinical trials presented to the committee by Dr. Bartosz Koszowski are discussed next (Koszowski, 2021).

The first study was a published paper comparing large cigar and cigarette smoking use patterns, smoking topography, and toxicant exposure (Rosenberry et al., 2018). Dual users (n = 17, the majority of whom were men [n = 16] and African American [n = 13]) who smoked any brand of large cigar ( $\geq 1$  per week) and cigarettes ( $\geq 10/day$ ) were recruited.

In two laboratory sessions, they smoked ad libitum either their usual cigarette brand or a study-provided large cigar (Phillies Blunt). The order of tobacco products was randomized. The authors measured smoking topography in each session and collected plasma nicotine and exhaled CO before and after smoking.

Large cigars were smoked differently than cigarettes (Rosenberry et al., 2018). Participants smoked on average 1.49 grams of cigar, which was about 23 percent of the total weight. Interpuff interval was significantly shorter in large cigar smoking, while the number of puffs, puff volume, puff velocity, and time to smoke were significantly larger. According to the authors, these differences were in part due to the greater size of the large cigar than the cigarette (Rosenberry et al., 2018). However, cigar smoking had significant differences even among variables not reliant on product size (e.g., individual puff volume, puff velocity, and interpuff intervals), suggesting that the large cigars were smoked more vigorously (see Table 2-5).

Figure 2-5 illustrates an assessment of the temporal pattern of topography. The average of the first three and last three puffs found puff duration was significantly longer and interpuff interval was significantly shorter in the first three puffs for both products. Puff volume was greater

	Mean	n (SD)		
	Cigarette smoking	Large cigar smoking	Product F value	Product <i>p</i> value
Number of puffs <sup>a</sup>	12 (4)	23 (11)	54.2	<.001*
Total puff volume (mL) <sup>a</sup>	658 (215)	1,660 (1,060)	72.1	<.001*
Time to smoke (s)	252 (89)	371 (207)	8.0	.01*
Average puff volume (mL)	57.8 (20.4)	73.9 (20.0)	10.6	<.01*
Puff velocity (mL/s) <sup>a</sup>	23.6 (5.1)	34.3 (13.0)	20.6	<.001*
Puff duration (s)	2.6 (0.7)	2.5 (0.6)	0.8	.38
Interpuff interval(s) <sup>a</sup>	21.9 (9.8)	16.6 (9.6)	9.0	.01*

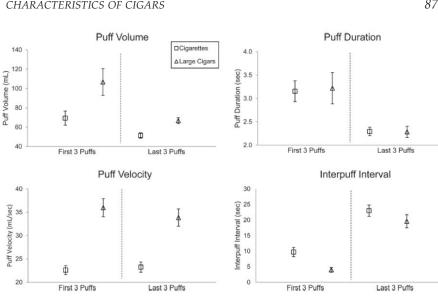
TABLE 2-5 One-way rANOVA Models of Outcomes Measures

NOTE: mL = milliliter; s = second; SD = standard deviation.

\*Denotes significance at p < .05.

<sup>*a*</sup>log-transformed variable included in rANOVA model.

SOURCE: Rosenberry et al., 2018.



**FIGURE 2-5** Temporal puff x puff analysis. SOURCE: Rosenberry et al., 2018.

in the first three puffs for large cigars but similar for cigarettes (Rosenberry et al., 2018).

The study also found that both products significantly increased plasma nicotine and CO (see Table 2-6) (Rosenberry et al., 2018); the immediate increase implies significant large cigar smoke inhalation.

Overall, the study suggests that dual users of large cigars and cigarettes adapt their puffing behavior so that they are exposed to similar levels of nicotine from both products (Rosenberry et al., 2018). A similar smoking pattern and exposure profile was also found in another study of dual users of cigarillos and cigarettes who inhaled smoke from both in the same way, thus subjecting themselves to considerable amounts of nicotine and other smoke components (Koszowski et al., 2015). The authors concluded that, among dual users of large cigars and conventional cigarettes, exposure to smoke from large cigars may lead to or sustain nicotine addiction and produce health risks similar to those of cigarette smoking (Rosenberry et al., 2018). Lung cancer studies have elaborated on arguments about the effects of inhalation intensity and pattern on cancer development (see Chapter 5) (Doll and Peto, 1976; IARC, 2004).

The second study presented to the committee (unpublished) was a single-center, randomized, single-blinded, crossover trial that included 36 adult users of small (n = 18) and large (n = 18) cigars (Koszowski, 2021). It was designed to evaluate the relationship between tobacco pH, salivary

pH, and nicotine exposure in noninhaling cigar smokers. Assignment into study groups was based on participant report of the type of cigars they smoked and confirmation of the cigar size when participants brought their product to the laboratory for the in-person screening visit. An important methodological consideration was to limit cigar smoke exposure to buccal tissue—largely the mouth and upper pharynx—so participants complied with specific instructions given before and during the directed smoking sessions not to inhale. Two brands of large cigars were used: Dutch Master's Palma (pH = 6.30) and White Owl NY Ranger (pH = 6.72). All participants in the large cigar group were male; the mean age was 46.1 years (range 22-64 years). Fifty percent of participants in the large cigar group identified as white. Large cigar participants reported using their products for a mean of 8.3 years and smoked an average of 16.5 cigars in the past 30 days. Only a few participants had measurable post-smoking nicotine concentrations in plasma. Most of the nicotine concentrations were undetectable by methods used in the study, but even when plasma nicotine could be quantified, the measured increases were small. Overall, this study suggests that exposure to nicotine among cigar users who smoked large cigars with acidic pH (<7.0) and did not inhale was minimal. This finding is consistent with a study by Gori and colleagues (1986), which found virtually no intake of nicotine through the buccal mucosa from cigarette smoke if it is kept in the mouth only and is not inhaled. It should be emphasized that the Koszowski (2021) study cited above did not include any large cigars with alkaline pH (>7.0). Since increased pH of smokeless tobacco has been shown to enhance nicotine absorption through buccal mucosa (Tomar and Henningfield, 1997), it is reasonably expected that increased alkalinity of a premium cigar could also promote oral nicotine absorption, even if emitted smoke is not inhaled.

The observation that dual users of cigars and cigarettes may be more likely to inhale deeply than exclusive users of cigars is also seen in differences in perceived level of inhalation reported by participants in the Cancer Prevention Study I of the American Cancer Society, conducted between 1959 and 1972. This was a prospective cohort study that followed more than one million individuals for 12 years (NCI, 1985, 1998). All users who participated self-reported levels of inhalation, using this subjective scale: none, slightly, moderately, or deeply. Figure 2-6 shows that individuals who inhale slightly or not at all made up the biggest portions of primary (never-cigarette user) and secondary cigar user rates. However, the study also revealed that secondary cigar users were more likely to report deep inhalation than primary cigar users (NCI, 1998).

Taken together, findings from these studies suggest that, compared to those who only smoke cigars, dual users of cigars and cigarettes are more prone to smoking cigars with a greater intensity, and therefore, inhaling

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		10 01 OULOUI	ור זאזרמסמז	20				
	Mean (SD)	(SD)	I	Product		Time	Product x ti	Product x time interaction
Outcome measure	Large ciga Cigarette smoking smoking	Large cigar smoking	F value	<i>p</i> value	<i>p</i> value <i>F</i> value	<i>p</i> value	F value	<i>p</i> value
Plasma nicotine (ng/mL)	mL)		<0.1	86.	32.2	<0.001*	0.7	0.42
Pre-smoking	18.0 (11.9)	20.7 (15.3)						
<b>Post-smoking</b>	38.8 (15.3)	36.3 (23.0)						
COex (ppm) <sup>a</sup>			4.3	.04*	36.2	<0.001*	3.2	0.08
Pre-smoking	21 (12)	22 (14)						
Post-smoking	30 (12)	47 (26)						
NOTE: COex = exhaled carbon mo *Denotes significance at <i>p</i> < .05. <sup>a</sup> log-transformed variable includ SOURCE: Rosenberry et al., 2018.	NOTE: COex = exhaled carbon monoxide; mL = milliliter; ng = nanogram; ppm = parts per million; SD = standard deviation. *Denotes significance at <i>p</i> < .05. <sup>a</sup> log-transformed variable included in rANOVA model. SOURCE: Rosenberry et al., 2018.	;; mL = milliliter; ANOVA model.	ng = nanog	ram; ppm = par'	s per million;	: SD = standar	d deviation.	

TABLE 2-6 2x2 rANOVA Models of Outcome Measures

Premium Cigars: Patterns of Use, Marketing, and Health Effects

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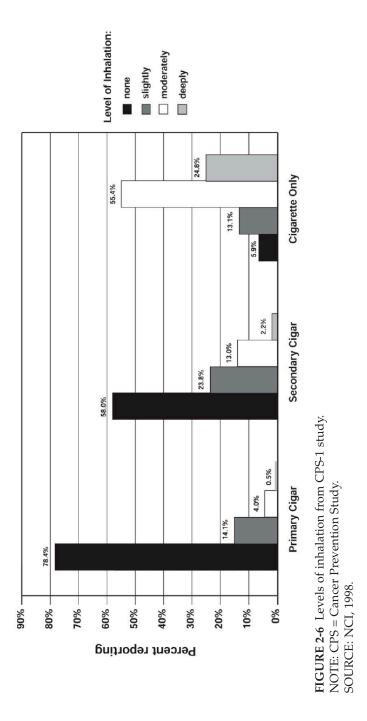
the smoke more deeply (Koszowski et al., 2015; NCI, 1998; Rosenberry et al., 2018; Rostron et al., 2016). Because of this tendency, dual use represents an especially harmful practice (Chang et al., 2015; Lee et al., 2012). This observation has important implications for a large group of premium cigar users. For example, in PATH Wave 4, only about one-third (33.7 percent) of current premium cigar users were never-cigarette users; 25.7 and 40.6 percent were current or former cigarette users, respectively (Jeon and Mok, 2022). See Chapter 3 for more information on co-use of premium cigars.

When assessing the emissions of various chemicals from premium cigars, it is important to understand how consumers are using them in natural settings (real-life conditions). In principle, mouth-level exposure to toxicants from premium cigars can be measured in laboratory settings. Tobacco smoke could be generated from via a machine that closely mimics the puffing behavior of a human smoker. Replicated human puffing measures can be used to drive machine smoking of premium cigars for post hoc analyses of mainstream smoke components. Many commercially available smoking machines can be fully programmable to closely replicate users' behavior such that cigar smoke can be generated in a laboratory setting.

The practical consequence of the wide variations in smoking behavior among cigar users renders standardized machine smoking paradigms (e.g., ISO/FTC or CIR) potentially inappropriate for the replication of cigar smoke for analysis of mainstream smoke constituents (Koszowski et al., 2017). Cigar testing puffing conditions developed originally in 1973 by the industry-formed International Committee for Cigar Smoke Studies and currently recommended by CORESTA require that large cigars be smoked for analytical purposes using a puff volume of 20 ml (adjusted for large cigars with diameter above 12 mm to achieve a constant airflow through cigar of 11.8 cm/second), a puff duration of 1.5 seconds, and frequency of puffing every 40 seconds (CORESTA, 2018). Those standardized protocols with fixed puff volumes, constant interpuff interval, and constant velocity may not be reflective of actual human smoking.

As highlighted, a major factor that may influence cigar puffing behavior appears to be a concurrent use of other combustible tobacco products, particularly cigarettes. However, other factors could also potentially influence depth of inhalation. For example, product size, density of tobacco filler, moisture of the product, and tip cutting technique may all influence airflow through the product (Watson, 2021). Restricting airflow could result in puffing harder. An increase or decrease in the cigar smoke pH may also lead to more changes in the sensory experience (Henningfield et al., 1999). Smoke that is perceived as harsh may be difficult to inhale,

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while smoke that is smooth and pleasant tasting could be easily inhaled. Finally, flavorings and sweeteners may also make cigar smoke more palatable; see the next section in this chapter for more information.

As discussed in Chapter 5, low intensity of puffing and restricted inhalation of smoke during use of premium cigars have important implications for health risks observed in these users. Some users may think of cigars as less harmful than cigarettes because of the difference in the amount smoked and the inhalation style, including perceived "no inhalation", of cigar smoke (Majeed et al., 2018). Several studies have found that beliefs that cigar users do not inhale appears to drive perceptions of less risk compared to conventional cigarettes (Bascombe et al., 2016; Cornacchione et al., 2016; Jarman et al., 2017; Jolly, 2008; Nyman et al., 2016). When asked about health risks, most participants in those studies indicated that they believed that cigars are not as risky as cigarettes. See Chapter 4 for more information on perceived risk.

In summary, inhalation patterns and the resulting exposure to nicotine and harmful and potentially harmful smoke constituents have not been studied directly in premium cigar users. However, based on the measurement of inhalation patterns among users of large cigars and studies that examined the effect of inhalation patterns on exposure to nicotine and toxicants from conventional cigarettes (Burling et al., 1985; Clark et al., 1998; Gori et al., 1986; Ingebrethsen, 2006; Tobin et al., 1982), the available data strongly suggest that inhalation patterns will be important determinants of exposure in premium cigar users, too. In particular, studies that examined the effect of inhalation patterns on exposure to nicotine and toxicants from conventional cigarettes suggest the significant effect of the depth of smoke inhalation. Although data from experimental studies that objectively measured puffing patterns in large cigar users who also smoke conventional cigarettes (dual users) are limited, they are consistent with self-reported inhalation patterns of cigar smokers who used to smoke cigarettes. Taken together, findings from these studies suggest that, compared to those who only smoke cigars, dual users of cigars and cigarettes are more prone to smoking cigars with a greater intensity and therefore inhaling the smoke more deeply.

Conclusion 2-5: There is **strongly suggestive evidence** that the **inhalation patterns of cigar smokers in general** significantly affect their exposure to nicotine and harmful and potentially harmful constituents. At present, the extent to which **premium cigar users who do not inhale** have systemic exposure to nicotine and harmful and potentially harmful constituents remains unknown. It is likely that **smokers of premium cigars who concurrently smoke cigarettes or smoked cigarettes in the past** inhale more smoke compared to exclusive users of premium cigars.

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CHARACTERISTICS OF CIGARS

#### **FLAVORS**

As explained in Chapter 1 and earlier in this chapter, the committee's definition of premium cigars excludes flavors. However, cigars otherwise matching the definition of premium used by the committee are sometimes flavored. Additionally, FDA and NIH asked the committee a research question about the potential effects of added flavors, which are an important consideration because they could influence the constituent profile and use of tobacco products like premium cigars.

#### Manufacturing of Flavored Cigars

Cigars vary by not only size but also added, characterizing flavors (Corey et al., 2014). Premium cigars can have leathery, earthy, spicy, nutty, or creamy notes, achieved by blending various strains of tobacco (Holt's Clubhouse, 2020; Savona, 2005). Many premium cigar companies also offer flavored cigars, most commonly infused with coffee or liquor (Savona, 2005). These are directly flavored with syrups, liquors, and food products. They are handmade and steeped, soaked, or infused with flavors, such as vanilla, rum, or honey (Savona, 2005). Additionally, concept-named cigars (such as "tropical") use nonspecific words that are not normally linked to specific flavors but still suggest appealing and palatable impressions.

Two common methods of adding flavors to cigars result in two types of products commonly referred to either as "flavored cigars" or "infused cigars" (Frontline Cigars, n.d.; Savona, 2005). Flavored cigars can be made by spraying a flavoring agent onto the tobacco or onto the rolled cigar or injecting a flavor solution inside a cigar. During the manufacturing of infused cigars, the absorbent tobacco or tobacco wrapper can simply sit in an area permeated by aromas, such as a room lined with botanicals, oils, and herbs (Maloney, n.d.).

#### Sensory Effects of Flavors Used in Cigars

The experience of flavor among tobacco users is a combination of olfactory, gustatory, and trigeminal effects. Flavors may influence expectancies (that is, cognitive representations of likely effects) of tobacco products, and expectations of positive sensory effects of smoking (e.g., look, feel, and taste) are predictive of smoking behavior and willingness to try a product (Ashare et al., 2007; Harrell and Juliano, 2012; Hendricks and Brandon, 2005, 2008). Much of the literature on sensory effects of flavored tobacco focuses on cigarettes, given their greater prevalence, but is nonetheless instructive for examining other tobacco products. Sensory blockade reduces urge to smoke, providing indirect evidence for the

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importance of sensory factors in maintaining behavior (Rose et al., 1985), and a body of work has attempted to dissociate the sensory and drug components of smoking (Rose, 2006; Rose et al., 1993; Rose et al., 2003; Rose et al., 1985; Westman et al., 1996).

Giovenco and colleagues (2017) conducted semistructured telephone interviews with 40 young adult U.S. cigar or cigarillo users to assess perceptions of product features and patterns of use. Most respondents smoked products with flavors infused in the tobacco and the cigarillo's outer wrap. However, some preferred unflavored products because of the lack of chemical additives. Users were excited by the wide variety of flavors available and commonly reported trying many flavored varieties of their favorite brands. They also highlighted the enjoyable aroma of the smoke and a smoother and easier inhalation as benefits. Some former cigarette users reported that a flavored cigar was their first cigar experience and helped facilitate a shift to regular use.

Flavored little cigar and cigarillo use has been tied to smoking cannabis in a form of blunt<sup>9</sup> (Delnevo et al., 2015; Giovenco et al., 2017). Sifaneck and colleagues (2005) found that flavors greatly influenced young peoples' choice of cigars to use as blunts, as a flavored cigar wrapper can be used to mask cannabis odor or could help conceal cannabis smoking in public as a blunt in cigar form (Sifaneck et al., 2005). In the aforementioned study by Giovenco and colleagues (2017), many blunt users reported that flavors enhanced the taste of cannabis and made smoking more enjoyable, although some users disliked flavored cigars, particularly with high-quality cannabis.

See Box 2-1 for information about the regulatory implications of flavored cigars, Chapter 3 for more information on the popularity of flavored cigars, and Chapter 5 for discussion of the potential health effects of adding flavors to cigars.

# CONCLUDING OBSERVATIONS

Despite the many different types of cigars in the U.S. market, including premium cigars, all cigar tobaccos contain the highly addictive compound nicotine, as well as toxicants and carcinogenic tobacco-specific nitrosamines. During smoking of all types of cigars, these compounds are transferred to the smoker along with multiple combustion products, many of which are toxic or carcinogenic. While specific data on chemical composition of premium cigar smoke are minimal, it is probable that the mixture of carcinogens and toxicants is qualitatively similar to that of other cigar types. See Chapter 5 for additional information on the health

 $<sup>^{9}</sup>$  Defined by Delnevo and colleagues (2015) as a cigar with its tobacco filler removed and replaced with cannabis.

#### CHARACTERISTICS OF CIGARS

effects of these toxicants. The committee has added some new data on premium cigar characteristics, including weight and nicotine content, through commissioned work (see Appendix F).

Although it has been shown that the pH of tobacco products affects nicotine delivery, its effect on inhalation patterns and nicotine absorption in premium cigar users has not been studied systematically. Higher pH (more alkaline) of premium cigar smoke appears to facilitate nicotine absorption even in users who do not inhale. Data on premium cigar smoke inhalation topography are limited; however, past or concurrent users of other combustible tobacco products appear to puff more intensely on cigars compared to those users who only smoke cigars.

Methods are available for the analysis of premium cigar tobacco for hazardous and potentially hazardous compounds, but developing standardized conditions for quantitation of constituents of premium cigar smoke is a research priority; CORESTA may be well placed to develop these reproducible methods. Studies on puffing topography and systemic exposure to nicotine and toxicants from premium cigars also need to be prioritized. See Box 2-2 for more key research and measurement gaps.

#### BOX 2-1 Regulatory Implications of Flavored Cigars

The Family Smoking Prevention and Tobacco Control Act<sup>1</sup> (TCA) of 2009 gave the Food and Drug Administration (FDA) regulatory authority over cigarettes. Flavors in cigarettes had been used to target youth and increase smoking initiation, so the TCA also banned the sales of cigarettes that contain any artificial or natural flavors other than tobacco and menthol (FDA, 2020). The TCA specifies that "a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke." As described in Chapter 1, FDA declared jurisdiction over cigars in 2016 (FDA, 2016), but the new ruling did not regulate flavors. Flavors banned in cigarette products under the TCA are still permitted for cigars (Chowdhury and Gill, 2021).

Removal of characterizing flavors in cigars sold in the United States could benefit public health considerably by reducing cigar smoking prevalence and increasing cessation. Rostron and colleagues (2019) estimated that flavored cigar elimination would lead to approximately 800 (90 percent prediction interval: 400–1,200) fewer cigar smoking-attributable deaths in the United States each year and 112,000 fewer cigar users (90 percent prediction interval = 76,000–139,000) in each cohort of 18-year-olds.

More than 270 U.S. cities and counties have restricted the sale of flavored tobacco products, sometimes including cigars. For example, Massachusetts and California enacted laws in 2020 prohibiting sales of most flavored tobacco products; California's ban includes sales of menthol cigarettes and flavored e-cigarettes, smokeless tobacco, and some cigars (Long, 2021). Sales data indicate that the market share of concept-named cigars, such as "tropical," increased from 9 to 15 percent of the cigar market in the United States from 2012 to 2016, which could have resulted in part from local policies restricting flavored cigars (Gammon et al., 2019). For example, a 2019 study found a 74 percent increase in sales of concept-named cigars in that city (Rogers et al., 2020). Giovenco and colleagues (2017) found that some cigar users who were former cigarette users switched to cigars after flavors were banned from cigarettes.

<sup>1</sup> Public Law 111-31.

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#### CHARACTERISTICS OF CIGARS

	BOX 2-2 Key Research and Measurement Gaps
	<i>urement</i> Lack of reproducible methods for machine smoking of premium cigars
· · ·	ch Gaps Laboratory studies to measure nicotine, toxicants, and carcinogens in to- bacco and smoke emitted from premium cigars and other cigar types. Comparative biomarker studies of premium, traditional, and other cigar users. Studies to assess how pH of premium cigar smoke affects puffing topogra- phy, as well as sites and extent of nicotine absorption. Studies that precisely measure "real-life" puffing topography and patterns of use. Studies that systematically evaluate how various premium cigar characteris- tics (e.g., cigar size, shape, type of tobacco, flavor, sugar content, moisture, smoke pH) affect puffing topography and toxicant exposure.

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3

# Patterns of Use and Prevalence of Cigars

Patterns of use are affected by premium cigar characteristics and marketing and perceptions of use, which in turn affect exposure to potentially toxic substances and ultimately health effects (see Figure 1-1). This chapter provides an overview of what is known about patterns of use of "premium"<sup>1</sup> cigars, beginning with an overview of overall cigar consumption over time, followed by the prevalence and trends of premium cigar use compared to other cigar<sup>2</sup> types and combustible tobacco products, and an overview of the available data on co-use of premium cigars with other tobacco products or substances and what is known about premium cigar initiation and transition to other tobacco products. Finally, it ends with key findings and research gaps. Appendix A contains the research questions that this chapter addresses.

#### CIGAR CONSUMPTION OVER TIME

At the beginning of the 20th century in the United States, cigar smoking was common; however, the 1930s saw a rapid decline, coinciding

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<sup>&</sup>lt;sup>1</sup>Note that quotations are used at first occurrence of the term "premium" in each chapter, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information.

<sup>&</sup>lt;sup>2</sup> Note that when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

with the increasing popularity of cigarettes (NCI, 1998). By mid-century, events impacting the use of cigarettes, such as the first Surgeon General's Report on Cigarette Smoking in 1964 and the Tobacco Control Act in 2009, which banned flavors in cigarettes but not cigars, often produced notable, concomitant changes in cigar consumption (for more information, see Delnevo et al., 2017b). For example, sales restrictions and price increases aimed at cigarettes often resulted in increases in cigar sales (however, when the discount market for cigarettes grew, little cigars lost their appeal).

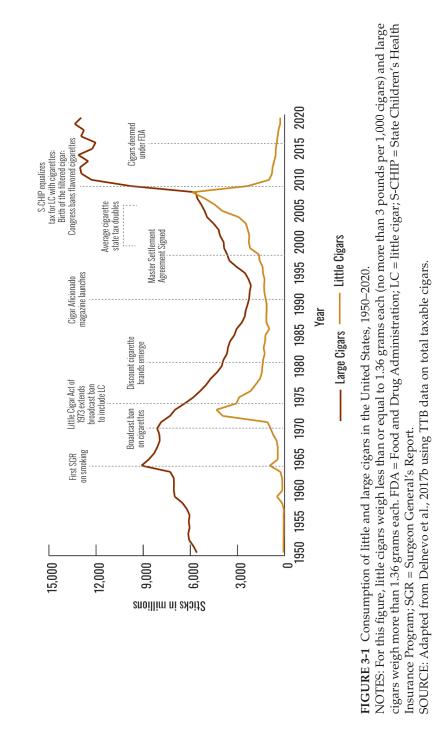
As shown in Figure 3-1, large cigars have been the dominant cigar type (versus little cigars) for much of the last century, although few notable spikes merit attention. First, sales of little cigars, which resemble cigarettes, guadrupled between 1971 and 1973 when the federal Public Health Cigarette Smoking Act banned cigarette ads on TV but allowed on-air marketing of little cigars (Delnevo and Hrywna, 2007). During this period, consumption of large cigars was declining annually. Both little and large cigar consumption began declining in the mid-1970s and reached the lowest annual level in 1993. However, in the late 1990's cigar consumption began to rise again, for the first time in decades. Many believe the revival of cigars was caused by the cigar lifestyle magazine Cigar Aficionado, along with endorsement of premium cigars by celebrity "connoisseurs" (see Chapter 4 for more on this topic) (Delnevo and Hrywna, 2007). Between 1993 and 1998 the fastest growing cigar product was the large cigar, increasing in consumption 66 percent. Little cigars soon became more prominent with an increase of 259 percent compared to 55 percent for large cigars between 1998 and 2008. In 2009 legislation expanded the State Children's Health Insurance Program (S-CHIP), which increased taxes on cigarettes and little cigars. This increase caused the consumption of little cigars to decline 95 percent from 2008 to 2020, however, the consumption of large cigars increased almost 129 percent.<sup>3</sup> This increase is almost exclusively due to little cigar manufacturers "converting" their products into heavier filtered cigars to take advantage of the lower federal excise tax on large cigars (Delnevo et al., 2017b; Wang et al., 2016). Despite this marked divergence in sales patterns, overall consumption has continued to make modest annual gains every year since the release of the NCI's cigar monograph in 1998 (approximately 145 percent from 1998 to 2020).<sup>4</sup>

While actual consumption of premium cigars was not explicitly detailed in the 1998 NCI monograph (the only comprehensive review of cigars), it noted that according to the Maxwell Reports (a trade publication that provides cigar sales data), from 1993 to 1996, premium cigars

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<sup>&</sup>lt;sup>3</sup>Calculated using TTB data on taxable cigars, see Figure 3-1.

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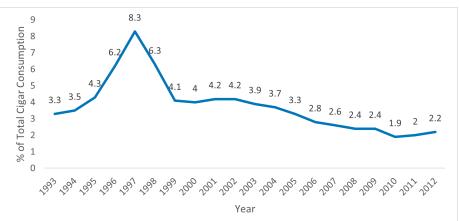


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experienced greater growth than little or large cigars. As shown in Figure 3-2, data abstracted from the 1996, 2003, and 2012 Maxwell Reports highlight the increase in premium cigar consumption in the early 1990s, which peaked in 1997, but the reports'<sup>5</sup> data suggest that premium cigars have made up a small percent of the total cigar market since then. The last year of production of the Maxwell Report was 2017, with the last report released in early 2018.

This trend is further confirmed with Alcohol and Tobacco Tax and Trade Bureau (TTB) data, which can be used as a proxy for nonpremium and premium cigar consumption, with some caveats (TTB, 2019). For taxation purposes, large cigars (which include cigarillos) are reported in two groups, those with a pretax value below \$763.222 per thousand and those above; these groupings correspond with federal excise tax structures. Prior to 2003, these two groups were referred to as Classes A–G and Class H cigars, respectively<sup>6</sup> (Treasury Department and ATF, 2002; TTB, 2011). While these designations are no longer used, historically, the cigar industry has referred to premium cigars as Class H (Hoyt, 2008), although all Class H cigars may not be premium (e.g., they could include machinemade cigars). Nonetheless, as shown in Table 3-1, these data are consistent with prior reports from the industry (e.g., Maxwell Reports) and others



**FIGURE 3-2** Premium cigars as a percentage of total cigar consumption. SOURCES: Data from Maxwell, 2006, 2013; NCI, 1998.

<sup>&</sup>lt;sup>5</sup> The Maxwell Report of the Cigar Industry defines premium cigars as 1) being handmade; 2) made entirely of natural, long filler tobacco; and 3) retailing between \$1 and \$25 each.

<sup>&</sup>lt;sup>6</sup> Personal communication with T. Baston, Alcohol and Tobacco Tax and Trade Bureau on May 14, 2021. Available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

	Small Cigars	Large Cigars	Large Cigars— Class H	% of Market
_	Not Premium	Not Premium	May Be Pre- mium	- That May Be Premium
2010	0.98	11.95	0.33	2.5%
2011	0.80	12.57	0.36	2.6%
2012	0.76	12.75	0.28	2.0%
2013	0.66	12.27	0.23	1.7%
2014	0.56	12.92	0.21	1.5%
2015	0.55	12.01	0.23	1.8%
2016	0.50	11.69	0.34	2.7%
2017	0.44	12.58	0.38	2.8%
2018	0.39	12.38	0.39	3.0%
2019	0.28	12.80	0.36	2.7%
2020	0.28	12.56	0.39	2.9%

**TABLE 3-1** U.S. Cigar Consumption in Billions of Sticks, 2010-2020

SOURCE: TTB December Statistical Release Reports, 2010–2020 (TTB, 2021).

that premium cigars have made and continue to make up a small percentage of the U.S. cigar market. These findings are inconsistent with Soneji et al. (2021), which commingled the terms "premium" and "large" when examining cigar imports—and considered all large cigar imports, which are indeed growing over time, to be premium.

Figure 3-1 and Table 3-1 also show the dominance of large cigars over much of the past two decades. As illustrated in Chapter 2, the term "large cigars" is a misnomer, as it includes filtered cigars, most of which resemble cigarettes; mid-size cigarillos, with or without a plastic or wood tip; and larger traditional cigars. The products in this category are extremely diverse, varying in terms of size, flavorings, packaging, and tip styles (see Chapter 2 for more information). Sales data are useful to understand features that are driving growth in nonpremium or machine-made cigars. An analysis of convenience store sales data from 2008 to 2015 found that cigar sales increased 23 percent (Delnevo et al., 2017a; Delnevo et al., 2021). Moreover, sales of flavored cigars increased by nearly 50 percent during this period and, in 2015, they comprised more than half of the cigar market. Inexpensive two- and three-packs, which were rare in 2008, were 40 percent of the market share in 2015. Two brands, Black & Mild and Swisher Sweets, dominated the convenience store channel; they alone were nearly two out of every three cigars sold (Delnevo et al., 2017a; Delnevo et al., 2021).

# PREVALENCE AND TRENDS OF PREMIUM CIGARS VERSUS OTHER CIGAR TYPES AND CIGARETTES

While TTB and Nielsen market scanner sales data are useful and provide rich information about cigar market trends, they do not describe the users and what their patterns of use are. Unfortunately, data are sparse on the prevalence and use patterns of premium versus nonpremium cigars, due in large part to lack of cigar measurement by regulators, despite numerous inadequacies noted in the 1998 NCI monograph (NCI, 1998). The monograph recommended that tobacco surveys assess duration of cigar smoking among those who ever smoked cigars and some measure of frequency and type of cigar smoked. Several national surveys now collect some detailed information about cigar use patterns, including the PATH survey,<sup>7</sup> National Survey on Drug Use and Health (NSDUH),<sup>8</sup> National Adult Tobacco Survey (NATS),9 and Tobacco Use Supplement (TUS) to the Current Population Survey (CPS).<sup>10</sup> However, no survey collects specific information about premium cigar use, largely because the lack of an accepted definition (see Chapter 1) means that it needs to be assessed indirectly through self-reported brand data. Given the limited literature on premium cigars, the committee commissioned two analyses of premium cigar and overall cigar patterns of use to characterize recent trends and use patterns—pooled analyses of NSDUH 2010-2019 data (age 12+) and analyses of PATH adult (age 18+) data from Waves 1–5 covering 2013–2019<sup>11</sup> (see Appendixes C and D for more information and Chapter 4 for a description of where premium cigars are typically obtained and used). In the following section, unless noted otherwise, premium cigar users are those reporting use for at least 1 of the past 30 days.

#### **Overall Trends**

Although national health surveys do not collect specific information about premium cigars, researchers have developed approaches to

<sup>&</sup>lt;sup>7</sup>See https://pathstudyinfo.nih.gov (accessed November 10, 2021).

<sup>&</sup>lt;sup>8</sup> See https://nsduhweb.rti.org/respweb/homepage.cfm (accessed November 10, 2021).

<sup>&</sup>lt;sup>9</sup>See https://www.cdc.gov/tobacco/data\_statistics/surveys/nats/index.htm (accessed November 10, 2021).

<sup>&</sup>lt;sup>10</sup> See https://cancercontrol.cancer.gov/brp/tcrb/tus-cps (accessed November 10, 2021).

<sup>&</sup>lt;sup>11</sup> The PATH analysis focused on adults because premium cigar use is very limited in youth. The supplementary data for Appendix D provides data for young adults (18–34) and is available upon request from PARO@nas.edu. In Appendix D, the authors reported Wave 4 data because it provides truly nationally representative numbers (as does Wave 1). However, in this chapter, the committee reports Wave 5 data because it is the most recent.

Data for Waves 2, 3, and 5 are provided in the Appendix D supplemental materials, available upon request from PARO@nas.edu.

characterize their use based on self-reported brand data to classify large cigar users as premium or nonpremium users (Corey et al., 2018; Corey et al., 2014; Delnevo et al., 2015). The few studies available in the literature reporting national prevalence estimates of premium cigar use in the United States rely on this approach (Corey et al., 2018; Corey et al., 2014), which was also adopted in the two commissioned papers. Most data reported in this section on patterns of use for premium cigars are based on this methodology.

TTB consumption data highlight that premium cigars make up a small percent of the total cigar market; this trend has been fairly stable over time. This is consistent with PATH data, which show that premium cigar use among adults was 0.6–0.8 percent from 2013 to 2018. Likewise, according to NSDUH data, past 30-day use of premium cigars is low and similar to that found in PATH, despite differences in study design and sampling (see Figure 3-3; see Table 3-2 for the prevalence of tobacco use from selected national surveys and the committee's commissioned work).

### **Demographics**

Published analyses of PATH and NATS data highlight differences in the demographic characteristics of users of premium cigars, cigarillos or machine-made cigars, filtered cigars, and cigarettes (Corey et al., 2018; Corey et al., 2014). Premium cigar users are overwhelmingly male, older, white, and more affluent (i.e., higher education and income) compared to those who smoke cigarillos or little filtered cigars. Cigarillo users are younger, more likely to report being non-Hispanic Black, and have lower levels of education and/or income. Also, while cigarillo use was more common among men, it was not inconsequential among women. Compared to users of other types of cigars, filtered little cigar users were most likely to be female. Filtered cigar users are also older and have lower levels of education or income. Lastly, nearly half of current cigarette users are female, and the majority of them are older and have lower levels of education and income. Two recent studies examined the 2018-2019 TUS-CPS with respect to demographic correlates of cigar smoking, but neither addressed premium cigar use despite the availability of brand data. Phan et al. (2021) chose to collapse little cigars and cigarillo smoking into a single category, whereas Azagba et al. (2021) reported large cigars, cigarillos, and little cigars separately. Unsurprisingly, findings from both studies are similar, since they used the same dataset and are consistent with demographic patterns reported in PATH and NATS. The authors of both papers highlight that non-Hispanic Black adults, in particular non-Hispanic Black young adults (Phan et al., 2021), are more likely to smoke little cigars and cigarillos (Azagba et al., 2021).

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2019 2.7% 0.9% 2018 3.0% 0.7% 2.9% 2017 0.9% l 2016 2.8% 0.9% I l 2015 2.9% 0.9% 2014 2.9% 0.8% 2013 3.0% 0.8% 2012 3.5% 0.9% / 2011 3.2% 1.1%2010 3.4% 1.1%Nonpremium 3% 2% 1%%0 4% --- Premium

FIGURE 3-3 Prevalence of premium verses nonpremium current cigar smoking (past-30-day use), NSDUH 2010-2019. SOURCE: Manderski et al., 2022.

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PATTERNS OF USE AND PREVALENCE OF CIGARS

				Commissio	oned Analyses
	Corey et al. (2018) (PATH Wave 1, 2013-2014)	Chen- Sankey et al. (2021) (PATH Wave 3, 2015–2016)	Azagba et al. (2021) (TUS-CPS, 2018–2019)	Jeon and Mok (2022) (PATH Wave 5, 2018-2019)	Manderski et al. (2022) (NSDUH, 2010–2019)
Premium cigar	0.7 (0.6, 0.7)			0.7 (0.7–0.8)	0.9 (0.8–0.9)
Traditional or large cigars	$1.5^{b}$	1.4 (1.2–1.5) <sup>a</sup>	1.1 (1.0–1.2) <sup>a</sup>	1.2 <sup>b, c</sup>	
Cigarillos	1.7 (1.5–1.8)	1.2 (1.1–1.3)	0.4 (0.4–0.5)	1.4 (1.4–1.5)	—
Little filtered cigars	0.9 (0.8–1.0)	0.8 (0.7–0.9)	0.3 (0.3–0.4)	0.8 (0.7–0.9)	—
Pipe	—	—	—	—	0.8 (0.8–0.9)
Cigarettes	18.1 (17.6–18.6)	_	_	16.4 (16.0– 16.9)	18.2 (18.0–18.4) <sup>d</sup>
Smokeless tobacco	—	—	—	—	3.3 (3.2–3.4)

**TABLE 3-2** Prevalence (%, 95% confidence interval; past-30-day use) of Tobacco Use Among Adults from Select National Surveys and Commissioned Analyses

#### NOTES:

<sup>*a*</sup> Prevalence estimates reflect established traditional cigar smoking (for Chen-Sankey et al., 2021) or large cigar smoking (for Azagba et el., 2021) and may include premium and nonpremium cigars.

<sup>b</sup> CI not available.

<sup>c</sup> Sum of premium (0.7) and nonpremium large cigars (0.5).

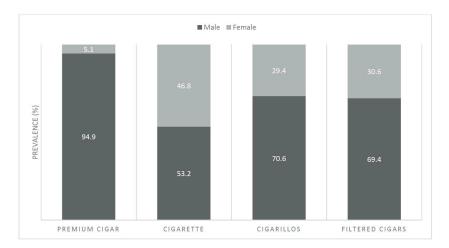
<sup>*d*</sup> Defined as 100 cigarettes in lifetime.

- Estimates not reported.

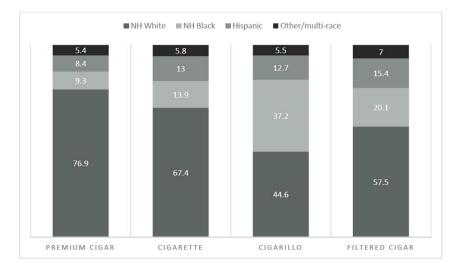
SOURCES: Azagba et al., 2021; Chen-Sankey et al., 2021; Corey et al., 2018; Jeon and Mok, 2022; Manderski et al., 2022.

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These demographic patterns in the published literature are consistent with the commissioned PATH and NSDUH analysis papers (see Appendixes C and D and Figures 3-4 and 3-5). The pooled NSDUH analyses, in contrast to the published literature, include youth as well as adults. Those data in both commissioned papers further reinforce that premium cigar users are older than users of other cigar types; only 0.6 percent of those



**FIGURE 3-4** Tobacco use by sex, PATH Wave 5. SOURCE: Data from Jeon and Mok, 2022.



**FIGURE 3-5** Tobacco use by race and ethnicity, PATH Wave 5. NOTE: NH = non-Hispanic.

SOURCE: Data from Jeon and Mok, 2022.

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PATTERNS OF USE AND PREVALENCE OF CIGARS

who reported smoking a premium cigar brand in the past 30 days were under 18 (see Table 1, Appendix C). Additionally, very few premium cigar users (2.5 percent) in NSDUH identified as lesbian, gay, or bisexual—in contrast, 9.7 percent of nonpremium cigar users did so. This is consistent with NATS data showing that the prevalence of premium cigars as a usual cigar was greater among heterosexual than among lesbian, gay, and bisexual adults (Corey et al., 2014).

#### Frequency of Use

#### Current or Past 30-Day Use

Current or past 30-day use of cigars was 4.7 percent in the pooled 2010–2019 NSDUH analyses, and the majority of current cigar users reported a nonpremium brand. Overall, 0.9 percent of U.S. youth (aged 12–17) and adults reported current use of premium cigars (Manderski et al., 2022). Past 30-day use of premium cigars was very rare (0.1 percent or less) among those under 18 and women. The prevalence of premium cigar use was higher (but still low) among men (1.7 percent), non-Hispanic white people (1.1 percent), adults aged 26–34 (1.4 percent), and college graduates (1.5 percent). Nonpremium cigar use was highest among young adults (7.5 percent), non-Hispanic Black people (6.5 percent), and those who identify as bisexual (6.3 percent). Youth nonpremium cigar use was 1.9 percent, with higher rates for boys (2.6 percent) than girls (1.2 percent) (Manderski et al., 2022).

These patterns of use are consistent with those seen in data from PATH Waves 1–5 (Jeon and Mok, 2022). In particular, the prevalence of premium cigars in Wave 5 was 0.7 percent, in comparison with 0.5 percent for nonpremium cigars, 1.4 percent for cigarillos, 0.8 percent for filtered cigars, and 16.4 percent for cigarettes.

Despite limited data on youth and premium cigars, the findings from the NSDUH pooled analysis, are, unsurprisingly, consistent with analyses of 2010–2011 NSDUH data focused on flavored cigar use, where preference for premium cigar brands was rare for youth and more common for adults over the age of 25 (Delnevo et al., 2015).

#### Frequency, Intensity, and Duration of Use

In general, and in contrast to cigarette smoking, cigar use has historically been less frequent and referred to as an "occasional" behavior (NCI, 1998). In the NSDUH pooled analyses, for example, among all cigar users, 2 out of 3 reported smoking on 5 or fewer days in the 30 days preceding the survey, with 46 percent reporting they smoked only 1 or 2 days

a month; only 1 out 10 cigar users report smoking daily (Manderski et al., 2022). However, different patterns of use are noted for those who use premium versus nonpremium cigars. Among premium cigar users, 60.3 percent reported smoking on only 1 or 2 days in the 30 days preceding the survey compared to 38.1 percent of nonpremium cigar users. Moreover, frequent use (defined as 20 or more days in the past 30 days) was less common among premium (7.6 percent) compared to nonpremium (20.8 percent) users. Daily use was rare (3.5 percent) among premium cigar users, whereas 13.1 percent of nonpremium users reported daily use (Manderski et al., 2022).

In the most recent PATH data (Wave 5), daily smoking was infrequent among premium cigar users (6.4 percent) but highest among filtered cigar users (42.1 percent percent), followed by cigarillo (22.7 percent) and nonpremium traditional cigars (14.1 percent) (Jeon and Mok, 2022). In comparison, daily cigarette smoking was frequent (75.5 percent). While the point estimates for daily smoking among cigar users by cigar type and among cigarette users varied slightly across all five waves, the relative daily smoking patterns between products were consistent across all waves (Jeon and Mok, 2022).

Likewise, the median number of days smoked in the past 30 days in Wave 5 was lowest for premium cigars (1 day), highest for filtered cigars (20 days), followed by cigarillos (5 days) and nonpremium traditional cigars (3 days) (Jeon and Mok, 2022). For comparison, the median number of days smoked for cigarettes was 30.<sup>12</sup> The median number of cigars smoked per day was 0.1 for premium cigars and nonpremium traditional cigars, 0.2 for cigarillos, and 1.7 for filtered cigars. The median number of cigarettes smoked per day was 10. While the estimates for number of days smoked and number of cigars or cigarettes smoked per day varied across the five waves, the lower frequency of use for premium versus other cigar types and cigarettes is consistent across all waves, suggesting that at least since 2013, the frequency and quantity of use for all cigar types has not notably changed (Jeon and Mok, 2022).

PATH Wave 5 data show that compared to cigarette and cigarillo users, premium cigar users were older at first regular use (median age was 25 compared to 17 for cigarette users and 19 for cigarillo users) (Jeon and Mok, 2022). They also had a shorter duration of use, a key determinant of health effects, since first regular use compared to cigarette users and nonpremium cigar users but a longer duration compared to cigarillo and filtered cigar users (median duration was 16, 19, 14, 10, and 26 years)

<sup>&</sup>lt;sup>12</sup> The median was calculated using the methods by Corey et al. (2018): respondents reporting smoking less than one cigar per day on the days smoked were assigned as 0.5 cigars per day.

for premium cigar, nonpremium cigar, cigarillo, filtered cigar, and cigarette users, respectively) (Jeon and Mok, 2022).

### **Flavored Cigar Use**

Flavors are common in the nonpremium cigar market (CounterTobacco.Org, n.d.; Delnevo et al., 2017a; Delnevo et al., 2021). One component of this report's operational definition for premium cigars is that the cigar or brand does not have a characterizing flavor other than tobacco. A few brands, such as Acid, resemble premium cigars (they are large, handmade, wrapped in whole tobacco leaf with long filler tobacco, and lacking tips) but do offer flavored varieties. Understanding the role of flavors in cigar use is important because of the stark differences in the mass-produced versus premium cigar marketplace. See Chapters 2 and 5 for more information about flavored cigar manufacturing and potential health effects.

In recent years, cigars with characterizing flavors, such as menthol,<sup>13</sup> fruit, alcohol, or candy, have become increasingly popular. For example, flavored cigar sales in convenience stores increased from \$801.2 million in 2008 to \$1,173.7 million in 2015 (Delnevo et al., 2017a; Delnevo et al., 2021).<sup>14</sup> Research has found that fruit and sweet tasting flavors capture over 60 percent of the national market share of flavored cigar sales (Delnevo and Hrywna, 2015). Alcohol-flavored cigars that include wine, beer, spirits, liquors, and mixed drinks have significantly gained U.S. market shares of flavored cigar products during the past decade (Delnevo et al., 2017a; Delnevo et al., 2021; Jackler et al., 2018). Reporting use of a flavored usual brand occurred less frequently by premium cigar users (11.9 percent) compared with all other cigar types (53.0–61.0 percent, all p < .01) (Corey et al., 2018); commissioned analysis of PATH Wave 4 data found a similar pattern (Jeon and Mok, 2022). Availability of cigars in flavors (48.6-71.9 percent) was a common reason given by at least half of cigar users regardless of type. Specifically, 48.6 percent (43.2-54.1) of premium cigar users endorsed the reason "They come in flavors I like" for cigar smoking (Corey et al., 2018). Rostron et al. (2020) found that in 2016–2017 across all cigar types, more than 50 to almost 75 percent of users reported that flavors were a reason to select particular cigars.

Flavored tobacco products are generally known to appeal to young people, but flavored cigars are especially popular among youth (Chen-Sankey et al., 2019; Corey et al., 2015; Delnevo and Hrywna, 2015; HHS,

<sup>&</sup>lt;sup>13</sup>Menthol makes up a small percent of the cigar market and is exclusively limited to little or filtered cigars.

<sup>&</sup>lt;sup>14</sup> Adjusted for inflation to 2015 dollars.

2012; King et al., 2014; Kong et al., 2019).<sup>15</sup> Importantly, users report that cigar products are appealing for reasons such as palatability, and this factor also predicts their use (Soldz and Dorsey, 2005; Wray et al., 2012). A multivariate analyses of NSDUH data found that youth, young adults, women, Black people, cigarette users, blunt users, and daily cigar users are significantly more likely to report a usual cigar brand that is flavored (Delnevo et al., 2015). Additionally, preference for a usual brand that produces flavored cigars decreases significantly with age. A study of Texas college students found that among past 30-day cigar users, three out of four reported that they regularly chose flavored cigars, and younger, female, and racial and ethnic minority cigar users had significantly greater odds of using flavored cigars than their counterparts (Hinds et al., 2018). Another study found that smoking flavored cigars, especially alcohol flavors, is prevalent among young adult Black dual users: about 70 percent of study participants smoked at least one alcohol-flavored cigar, and alcohol was the most frequently smoked flavor type (34.4 percent, followed by sweet [23.4 percent] and mint [5.7 percent]) (Chen-Sankey et al., 2019). Additionally, a study of PATH data found that among Wave 4 (2016–2017) youth, 22.2 percent of traditional cigar users reported "I don't know" regarding flavor use. Rostron et al. (2020) hypothesized that these responses could reflect the growing use of nonspecific concept descriptors, such as "tropical" for flavored cigars.

Research has also shown that women are more likely than men to smoke flavored tobacco (Glasser et al., 2017; King et al., 2013). Chen-Sankey et al. (2019) found that women had nearly three times greater odds of smoking alcohol-flavored cigars. Flavor options may also appeal to pregnant women who have sensitivities to tobacco smell and flavor (King et al., 2013). Potential reasons for sex-based differences in flavor preference include women's sensitivity to the sensory effects of smoking (Perkins, 1996) and marketing strategies that target women (Brown-Johnson et al., 2014).

# **Geographic and Seasonal Differences**

Data are scant on geographical differences in cigar use, premium or otherwise. Analysis of NATS found that premium cigars were more commonly used in the Northeast than little filtered cigars among cigar users, in contrast to other census regions, where premium cigars were

<sup>&</sup>lt;sup>15</sup> Vargees, C., Stroup, A. M., Niznik, T., Dunn, D., Wyatt, R., Hoetger, C., Ben Taleb, Z., Cohn, A. M., Cobb, C. O., Fetterman, J. L. 2022. Patterns of Use, Perceptions, and Cardiopulmonary Health Risks of Cigar Products: A Systematic Review. Unpublished. Submitted to the committee by A. Stroup and available upon request at <u>PARO@nas.edu</u>.

the least common (Corey et al., 2014). Analysis of the 2014–2015 TUS-CPS noted differences in state prevalence rates of current cigar use: from 1.0 percent in Utah to 3.5 percent in Alaska (Odani et al., 2018).<sup>16</sup> The pooled NSDUH analyses found that 65.0 percent of premium cigar users reside in a large metro area versus 50.5 percent of nonpremium users, and only 6.5 percent of premium cigar users report residing in a nonmetro area versus 16.5 percent of nonpremium users. Similarly, findings from the 2018–2019 TUS-CPS showed that the prevalence (past 30-day use) of large cigar smoking was higher in the Northeast and the West and lower in the South compared to that of cigarette use, current cigar smoking was lowest in the Northeast and Highest in the Midwest and South (Odani et al., 2018).

Anecdotal data raise questions whether there are seasonal patterns in cigar use and, in particular, premium cigar use. This is plausible and is certainly the case for cigarette smoking in the United States; it declines in the winter and increases in the summer (Chandra and Chaloupka, 2003). However, no research literature is specific to cigars.

# Secondhand Smoke Exposure

While some anecdotal data suggest that premium cigars may be used outdoors (e.g., while golfing), premium cigars are also smoked indoors at cigar lounges. No data are published on secondhand smoke exposure to cigars overall or premium cigars in particular. An important data gap exists regarding secondhand exposure of nonusers, including children in the home and occupational risk for those who work in cigar lounges that are typically exempted from smoke-free air policies (see Chapter 5 for a discussion on health effects of secondhand cigar smoke).

# CO-USE OF PREMIUM CIGARS WITH OTHER TOBACCO PRODUCTS OR SUBSTANCES

# **Co-Use with Other Cigar Types**

No previous study examined prevalence of co-use of premium cigars with other cigar types. The commissioned analysis of the PATH study of adults addressed poly or co-use of four cigar product types among current established cigar users (see Table 3-3). Premium cigar users across all survey waves were least likely to report co-use with another type of

<sup>&</sup>lt;sup>16</sup> Current users were defined as persons who reported ever use and used cigars "every day" or "some days" at the time of survey.

		Nonpremium		
	Premium Cigars	Cigars	Cigarillos	Filtered Cigars
Wave 1	16.5 (11.8–22.5)	61.4 (55.5–67.0)	37.7 (33.9–41.6)	41.6 (38.0–45.3)
Wave 2	19.3 (14.5–25.2)	50.0 (42.8–57.2)	34.9 (32.1–37.8)	37.2 (32.8–41.9)
Wave 3	16.8 (11.9–23.3)	49.0 (40.7–57.4)	38.7 (34.0–43.7)	39.3 (33.9–45.0)
Wave 4	16.4 (11.2–23.3)	52.8 (44.5-60.8)	32.8 (29.1–36.7)	42.2 (36.8–47.9)
Wave 5	18.4 (13.7–24.3)	53.9 (47.3–60.5)	36.7 (32.3–41.4)	38.6 (31.7–46.0)

**TABLE 3-3** Co-Use of 2+ Types of Cigars Among Current Established Users of Four Cigar Types in U.S. PATH Adults, % (95% CI)

NOTES: Wave 1 = 2013–2014; Wave 2 = 2014–2015; Wave 3 = 2015–2016; Wave 4 = 2016–2017; Wave 5 = 2018–2019. CI = confidence interval.

SOURCE: Jeon and Mok, 2022.

cigar product, with less than one out of five reporting concurrent use with other cigar types. In contrast, users of nonpremium large cigars, cigarillos, and filtered cigars were significantly more likely to report using at least one additional cigar product compared to premium cigar users (Jeon and Mok, 2022). This is consistent with Kasza et al. (2017), who found that of adults who use more than one type of tobacco product, 12 percent used two or more cigar types.

#### **Co-Use with Non-Cigar Tobacco Products**

Co-use or poly-tobacco use is common (Baggett et al., 2016; Kasza et al., 2017; Spears et al., 2019), particularly among young people, and cigars are often one of the products that are co-used with other tobacco products (Frazier et al., 2000; Ishler et al., 2020; Pérez et al., 2020), most notably cigarettes. However, no research literature exists on co-use of premium cigars specifically with other tobacco products for youth.

Corey et al. (Corey et al., 2014) analyzed data from the 2012–2013 NATS among U.S. adults who smoke cigars "every day," "some days," or "rarely." Of the 7.3 percent who did so, more than half (52.5 percent) reported information that could be used to assign a usual cigar type. Premium cigar users were defined as those reporting that their usual cigar did not have a filter or tip and their usual brand was hand rolled or described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper. Current cigarette smoking among those who usually smoked premium cigars (35.1 percent) was lower than those who usually smoked cigarillos/mass-market cigars (58.3 percent)

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or little filtered cigars (75.2 percent). Never cigarette smoking was highest among those who usually smoke premium cigars (41.9 percent) compared to cigarillos/mass-market cigars (26.4 percent) or little filtered cigars (12.4 percent).

Jeon and Mok (2022) replicated and extended Corey et al. (2018) for adults in the five waves (2013–2019) (see Table 3-4). Cigarette smoking was substantially less common among premium cigar users (range across waves: 20.7–30.1 percent) than adults who used nonpremium traditional cigars (50.1–58.8 percent), cigarillos (54.7–61.0 percent), and filtered cigars (66.0–72.7 percent) but more common than in the overall U.S. adult population (16.4–18.6 percent). The prevalence of current use of any noncigar/ noncigarette tobacco product was comparable across current premium cigar (range across waves: 26.1–33.2 percent), nonpremium traditional cigar (28.8–38.6 percent), cigarillo (28.3–31.4 percent), and filtered cigar (27.1–33.5 percent) users.

The NSDUH analysis compared those who typically smoke premium and nonpremium cigars (Manderski et al., 2022). Table 3-5 shows that current premium cigar users had substantially lower past-30 day cigarette smoking prevalence (23.3 percent) than current nonpremium cigar users (50.7 percent). Current premium cigar users had slightly lower past-30 day pipe use prevalence (4.8 percent) than current nonpremium users (6.8 percent). Current premium cigar users had similar rates of past-30 day smokeless tobacco use (12.9 percent) as current nonpremium users (12.5 percent). Rates of never established use of cigarettes were higher for premium (47.5 percent) than for nonpremium (35.1 percent) users but lower for never use of pipes (61.7 versus 70.5 percent).

#### **Co-Use with Other Substances**

In this report's commissioned analysis of 2010–2019 pooled nationally representative U.S. data from NSDUH, premium cigar users had a higher prevalence of past 30-day alcohol use than nonpremium cigar users (89.0 vs. 74.9 percent) and lower prevalence of past 30-day cannabis use (16.8 vs. 40.7 percent) (Table 3-6) (Manderski et al., 2022). The higher rates of cannabis use among nonpremium cigar users is not surprising, given that inexpensive cigars and cigarillos are often co-used with cannabis as "blunts." This relationship between cannabis and cigar use, most notably among young people, has been well established in the literature (Cohn et al., 2018; Cornacchione Ross et al., 2020; Delnevo et al., 2015).

Comparisons of past-year alcohol, cannabis, and illicit (noncannabis) drug dependence in NSDUH are reported in Table 3-7 (Manderski et al., 2022); past-30-day premium cigar users had a higher prevalence of each form of substance dependence than those who did not use any tobacco

TABLE 3-4 CuriTypes, Current (	<u> </u>	ent Use of Noncigar Tobacco Products among Current Established Users of Four C ligarette Users, and the Overall Adult Population in U.S. PATH Adults, % (95% CI)	o Products amon rall Adult Popula	g Current Establ ation in U.S. PAT	ished Users of ] TH Adults, % (9,	Four Cigar 5% CI)
	Premium Cigars	Nonpremium Cigars	Cigarillos	Filtered Cigars	Cigarettes	Overall U.S. Adult Population
Current establis	Current established cigarette smoking					
Wave 1	28.5 (22.9–34.7)	58.8 (52.6–64.8)	58.0 (55.5-60.4)	66.0 (59.1–72.2)	NA	18.1 (17.8–18.4)
Wave 2	30.1 (23.2–38.1)	56.2 (49.8–62.4)	61.0 (57.0–64.9)	72.3 (67.7–76.5)	NA	18.6 (18.3–19.0)
Wave 3	28.5 (23.5–34.2)	52.1 (46.5–57.7)	56.0 (49.4–62.4)	69.0 (63.9–73.8)	NA	18.3 (17.9–18.6)
Wave 4	25.7 (19.3–33.3)	50.1 (43.8–56.4)	60.2 (57.2–63.2)	70.5 (64.9–75.6)	NA	17.7 (17.3–18.1)
Wave 5	20.7 (14.7–28.4)	53.1 (44.3–61.6)	54.7 (49.8–59.5)	72.7 (67.1–77.7)	NA	16.4 (16.0 - 16.9)
Currently use a	Currently use any noncigar, noncigarette tobacco product use	e tobacco product use				
Wave 1	33.2 (28.4–38.2)	32.8 (29.5–36.2)	28.8 (25.5–32.3)	27.1 (21.9–32.9)	15.8 (14.9–16.8)	6.47 (6.31–6.63)
Wave 2	31.6 (26.7–36.8)	32.9 (25.7–41.0)	31.4 (28.0–35.1)	32.5 (27.4–38.0)	17.1 (16.3–18.0)	6.90 (6.65–7.17)
Wave 3	30.7 (26.0–35.8)	30.9 (24.3–38.4)	30.2 (24.3–36.7)	32.6 (25.4–40.8)	15.6 (14.7–16.5)	6.73 (6.50–6.97)
Wave 4	26.1 (21.0–31.9)	28.8 (21.5–37.4)	28.3 (24.2–32.9)	26.8 (21.1–33.2)	15.4(14.1 - 16.8)	6.51 (6.26–6.78)
Wave 5	30.2 (25.3–35.7)	38.6 (31.3-46.4)	30.6 (27.4–34.1)	33.5 (27.9–39.6)	17.2 (15.8–18.7)	7.49 (7.17–7.81)
NOTE: Wave 1	NOTE: Wave 1 = 2013–2014; Wave 2 = 2014–2015; Wave 3 = 2015–2016; Wave 4 = 2016–2017; Wave 5 = 2018–2019	= 2014–2015; Wave 3 =	= 2015–2016; Wave 4 =	2016–2017; Wave 5 =	2018–2019.	

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SOURCES: HHS, 2021; Jeon and Mok, 2022.

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	Prer	nium Cigars	Nor	npremium Cigars
	%	(95% CI)	%	(95% CI)
Recency of established cigaret	te smoking			
past 30 days	23.3	(21.5 , 25.2)	50.7	(49.6 , 51.9)
30 days–1 year	4.1	(3.2, 5.1)	3.5	(3.2, 3.9)
1–3 years ago	3.3	(2.6, 4.1)	2.6	(2.3 , 2.9)
> 3 years ago	21.8	(19.8 , 24.0)	8.0	(7.3, 8.9)
never established	47.5	(45.0, 50.0)	35.1	(34.2 , 36.0)
Recency of pipe smoking				
past 30 days	4.8	(4.1, 5.7)	6.8	(6.2, 7.4)
> 30 days ago	33.5	(31.2 , 35.8)	22.7	(21.8 , 23.7)
never established	61.7	(59.2,64.1)	70.5	(69.5 , 71.4)
Recency of SLT use				
past 30 days	12.9	(10.7 , 15.4)	12.5	(11.6 , 13.4)
30 days–1 year	3.6	(2.7, 4.6)	6.1	(5.6, 6.6)
1–3 years ago	5.8	(4.5 , 7.4)	6.8	(6.2, 7.4)
> 3 years ago	28.7	(25.2 , 32.4)	19.4	(18.1 , 20.8)
never used	49.1	(45.5 , 52.7)	55.2	(53.6 , 56.9)

**TABLE 3-5** Tobacco Use Characteristics of Individuals Who Smoke Premium and Nonpremium Cigars, 2010–2019 NSDUH

NOTES: CI = confidence interval; SLT = smokeless tobacco. NSDUH does not measure ecigarette use.

SOURCE: Manderski et al., 2022.

product in the past 30 days, with larger differences between these two groups for alcohol dependence and smaller differences for cannabis or illicit drug dependence. Cannabis dependence prevalence was substantially lower among premium (1.3 percent) than nonpremium (7.4 percent) cigar users and slightly lower among premium cigar than cigarette (2.5 percent) users. Alcohol dependence was slightly lower in premium (7.3 percent) than nonpremium (9.6 percent) cigar users and the same as cigarette users (7.3 percent). It appears that, except for alcohol dependence, substance dependence was higher among premium cigar users than nontobacco users but lower than among nonpremium cigar and cigarette users.

# TRANSITIONS IN CIGAR USE AND OTHER TOBACCO PRODUCTS

The committee found no studies on initiation and transition to use of premium cigars specifically; several studies reported data for cigars

	Prei	Premium Cigars		Nonpremium Cigars	
	%	(95% CI)	%	(95% CI)	
Recency of alcohol consumption	п				
past 30 days	89.0	(87.2,90.6)	74.9	(74.1 , 75.8)	
30 days–1 year	4.8	(3.7, 6.3)	12.8	(12.2 , 13.4)	
more than 1 year	5.1	(4.0, 6.4)	8.2	(7.6, 8.9)	
never used	1.1	(0.7 , 1.6)	4.1	(3.6 , 4.6)	
Recency of cannabis use					
past 30 days	16.8	(15.2 , 18.6)	40.7	(39.7 , 41.8)	
30 days–1 year	9.7	(8.5 , 11.1)	11.5	(10.9 , 12.2)	
more than 1 year	48.8	(46.4 , 51.2)	29.1	(28.0 , 30.2)	
never used	24.7	(22.8 , 26.6)	18.7	(17.8 , 19.7)	

**TABLE 3-6** Substance Use Recency Among Individuals Who SmokePremium and Nonpremium Cigars, 2010–2019 NSDUH

NOTE: CI = confidence interval.

SOURCE: Manderski et al., 2022.

more generally. This section also includes data from the committee-commissioned PATH analysis.

### Youth Initiation of Cigars

A study using data from PATH Waves 1-3 (2013-2016) found that weighted cross-sectional prevalence of past 30 days' cigar use was stable for adults 25+ but decreased in youth and young adults aged 18-24, raising questions as to whether cigar initiation might be decreasing (Edwards et al., 2020). Another study analyzed the age at initiation of cigarillos, filtered cigars, and/or traditional cigars among a longitudinal sample from PATH study youth (aged 12-17) at Wave 1 (2013-2014) followed until Wave 4 (2016–2017) (Chen et al., 2020). The study found that past 30-day use initiation for all three cigar products increases by age, with marked increases starting at age 17. In particular, the cumulative incidence of traditional cigars' past 30-day use increased from 0.8 to 5.9 percent from ages 17 to 18, reaching 11.7 percent by age 20. Among men, the cumulative incidence of traditional cigar use increased from 1.3 percent at age 17 to 8.2 percent at age 18 and 17.4 percent at age 20. Among women, the cumulative incidence of traditional cigar use increased from 0.4 percent at age 17 to 3.2 percent at age 18 and 5.8 percent at age 20. Overall, men were 233 percent (HR: 3.33; 95 percent CI: 2.63-4.35) more likely to initiate past 30-day traditional cigar use at a younger age than women. Compared to

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TABLE 3-7	Substanc	TABLE 3-7 Substance Dependence of U.S. Adults by Tobacco Use Type, 2015–2019 NSDUH	ce of U.	S. Adults by	Tobaco	co Use Type,	2015-3	2019 NSDU	Н		
	Current	Current Premium Cigar Current Nonpremium Smoking Cigar Smoking	Current Cigai	rrent Nonpremium Cigar Smoking	Curren Cigare	Current Established Cigarette Smoking	No P Tob	No Past-30-Day Tobacco Use	Neve	Never-Tobacco Use	Use
	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	CI)
Alcohol											
Dependence	7.3	(5.7 9.3)	9.6	$(8.9 \ 10.4)$	7.3	(7.0 7.6)	1.9	(1.8 2.1)	0.8	(0.7	0.9)
Cannabis											
Dependence	1.3	$(0.9 \ 1.8)$	7.4	(6.6 8.1)	2.5	$(2.3 \ 2.6)$	0.5	$(0.5 \ 0.5)$	0.2	(0.1)	0.2)
Illicit Drug <sup>a</sup>											
Dependence	1.9	1.9 (1.1 3.1)	5.8	(5.2 6.5)	4.8	4.8 (4.5 5.1)	0.5	$(0.4 \ 0.5)$	0.2	(0.2	0.3)
NOTES: "other t	han cannab	NOTES: <sup><i>a</i></sup> other than cannabis. CI = confidence interval.	nce interve	al.							
SOURCE: Manderski	łerski et al.,	et al., 2022.									

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non-Hispanic white youth, non-Hispanic Black and Hispanic youth were 51 percent (HR: 0.49; 95 percent CI: 0.35–0.69) and 44 percent (HR: 0.56; 95 percent CI: 0.45–0.70) less likely to initiate past 30-day traditional cigar use at younger ages, respectively (Chen et al., 2020).

### **Discontinuing Use**

In another study of PATH Waves 1-3 data, among adult past 30 days users of each type of tobacco product at baseline, the rate of discontinuing use of cigars at the following wave was 48.6 percent (95 percent CI: 47.0-50.2 percent), which was lower than the discontinuation rate of electronic nicotine delivery systems (ENDS) (52.6 percent; 95 percent CI 50.9-54.4 percent) and hookah (63.8 percent; 95 percent CI 61.6-66.0 percent) but higher than that of cigarettes (13.4 percent; 95 percent CI 12.8-14.1 percent) and smokeless tobacco (25.9 percent; 95 percent CI 24.2-27.7 percent) (Kasza et al., 2020). Individuals aged 40–54 and 55+ had lower odds than those aged 18-24 to discontinue cigar use (AOR: 0.7; 95 percent CI: 0.6-1.0 and AOR: 0.4; 95 percent CI: 0.3-0.6, respectively). Male cigar users were less likely to discontinue use than female users (AOR: 0.8; 95 percent CI: 0.7–1.0). Non-Hispanic Black cigar users were less likely to discontinue use than non-Hispanic white cigar users (AOR: 0.7; 95 percent CI: 0.5–0.8). Those who identified as gay or lesbian were more likely to discontinue use than those who identified as straight/heterosexual (AOR: 1.6; 95 percent CI: 1.0-2.6). Lastly, hookah use (AOR: 0.8; 95 percent CI: 0.6-0.9) and frequent cigar use (AOR: 0.4; 95 percent CI: 0.3-0.5) were negatively associated with discontinuation (Kasza et al., 2020).

Among adult current established users of cigars at baseline, the rate of making a quit attempt at follow-up was 56.2 percent (95 percent CI: 53.6–58.7). This was lower than the rate of quit attempts for hookah users (61.5 percent; 95 percent CI: 58.6–64.3) but higher than that of cigarettes (35.6 percent; 95 percent CI: 34.6–36.7), ENDS (45.8 percent; 95 percent CI: 43.8–47.8), and smokeless tobacco (39.2 percent; 95 percent CI: 36.5–42.0) (Kasza et al., 2020). Factors associated with making a cigar quit attempt were younger age, Hispanic ethnicity, cigarette smoking, and higher dependence score. Factors negatively associated with a cigar quit attempt were having a Bachelor's degree or more education, higher income, and daily cigar use.

### Stability and Transitions in Use of Premium Cigars Across Time

In the commissioned analysis of PATH adults across the five waves (2013–2019) (see Appendix D), the prevalence of different types of withinperson changes in tobacco use patterns from one wave to the next wave

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12 months later was analyzed (Jeon and Mok, 2022). This involved studying the change or stability in use and co-use patterns for premium cigars, other cigars (nonpremium traditional or large cigars, cigarillos, or filtered cigars), and cigarettes from Wave 1 to Wave 2, Wave 2 to Wave 3, Wave 3 to Wave 4, and Wave 4 to Wave 5. For each two-wave pairing, a transition probability was calculated that estimated the frequency of changing the type of tobacco used, and these were averaged across the four two-wave pairings to provide a mean 1-year transition probability.

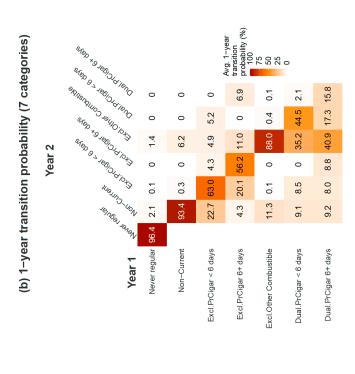
For exclusive users of one of the three respective products, the probability of continuing to use the same product 1-year later was higher for premium cigar users (75 percent) than for other nonpremium cigar users (59 percent) but lower than for exclusive cigarette users (89.2 percent). Depicted in Figure 3-6 (Panel A), the approximately 75 percent of exclusive premium cigar users who continued to smoke them 1 year later included 69.2 percent who remained exclusive premium cigar users, 2.5 percent and 2.8 percent who became dual users with other cigar types and cigarettes, respectively, and 0.5 percent who became poly-tobacco users of premium cigars, other cigars, and cigarettes. For the 59 percent who smoked exclusively other (nonpremium) cigar types and continued to smoke other cigars, 46.9 percent remained exclusive users, 2.2 percent dual users with premium cigars, 9.6 percent dual users with cigarettes, and 0.3 percent poly-tobacco users of all three product types (Jeon and Mok, 2022).

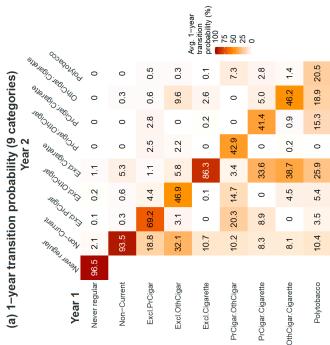
For exclusive users of one of the three products, the probability becoming a nonuser of any cigar or cigarette product was higher for premium cigar (18.8 percent) than cigarette (10.7 percent) users but lower than for exclusive users of other cigar types (32.1 percent). The probability of transitioning to cigarette smoking 1 year later was lower for exclusive premium (5 percent) than for exclusive nonpremium (15.7 percent) cigar users. Of dual users of premium and nonpremium cigars, only slightly more than 40 percent remained so in the following year. About 34 percent of dual users of premium cigars and cigarettes became exclusive cigarette users within a year (Jeon and Mok, 2022).

Additional analyses comparing frequent and infrequent use of cigars found variable transition patterns as well (see Figure 3-6). About 68 percent of exclusive premium cigar users who smoked less than 6 days in the past 30 days continued smoking premium cigars in the following year either as exclusive users (63.0 percent) or dual users with other combustible tobacco products (5.2 percent) (Figure 3-6, Panel B). While only 4 percent of less frequent exclusive premium cigar users (less than 6 days in the past 30 days) increased use frequency within a year, about 20 percent of more frequent exclusive premium cigar users (6+ days in the past 30 days) decreased use frequency. Less frequent exclusive premium

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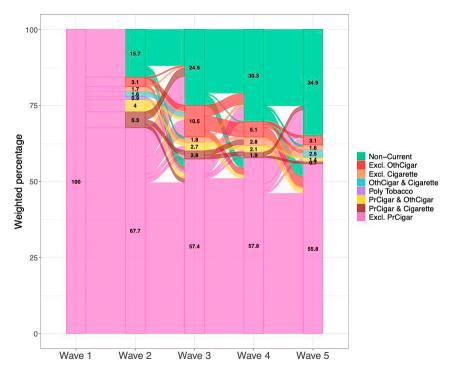
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use with <6 days of use in past 30 days (Excl.Prcigar <6 days), exclusive current established premium cigar use with 6+ days of use days), and dual current established use of premium cigar with 6+ days of use in past 30 days and other combustible tobacco use NOTES: Two alternative use categorizations were used: (a) never cigar and cigarette use (Never regular), non-current cigar and cigarette use (Non-Current), exclusive current established premium cigar use (Excl.PrCigar), exclusive current established use of other cigar types (Excl.OthCigar), exclusive current established cigarette use (Excl.Cigarette), dual current established use of premium cigars and other cigar types (PrCigar.OthCigar), dual current established use of premium cigars and cigarettes (PrCigar. Cigarette), dual current established use of other cigar types and cigarettes (OthCigar:Cigarette), and polytobacco use; (b) never cigar and cigarette use (Never regular), non-current cigar and cigarette use (Non-Current), exclusive current established premium cigar current established use of premium cigar with <6 days of use in past 30 days and other combustible tobacco use (Dual.PrCigar <6 Dual.PrCigar 6+ days). Each row represents the percentage (averaged across PATH waves) of individuals in a given use category in past 30 days (Excl.PrCigar 6+ days), exclusive current established other combustible tobacco use (Excl.Other Combustible), dual FIGURE 3-6 One-year transition probabilities between cigar and cigarette use categories (PATH study) that remained in the same category (diagonal) or transitioned to a different category by the next year. SOURCE: Jeon and Mok, 2022

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cigar users were more likely to discontinue use within a year compared to more frequent users (22.7 versus 4.3 percent). Dual premium cigar use with other combustible tobacco products is relatively transient; only 44.5 percent of less frequent and 15.8 percent of more frequent premium cigar users remained dual users. About 35.2 percent of less frequent and 40.9 percent of more frequent dual premium cigar users discontinued premium cigar users and became exclusively other combustible tobacco product users within a year (Jeon and Mok, 2022).

Figure 3-7 shows individual trajectories across PATH Waves 1–5 for adult exclusive premium cigar users at Wave 1 who participated in all



**FIGURE 3-7** Longitudinal trajectories of adult exclusive premium cigar users in PATH Wave 1 who participated in all subsequent waves (N = 121).

NOTES: Cigar and cigarette use categories in Waves 2–4 include noncurrent cigar and cigarette use (Non-Current); exclusive premium cigar use (Excl. PrCigar); exclusive use of other cigar types (Excl. OthCigar); exclusive cigarette use (Excl. Cigarette); dual use of premium cigars and other cigar types (PrCigar & OthCigar); dual use of premium cigars and cigarettes (PrCigar &Cigarette); dual use of other cigar types and cigarettes (OthCigar & Cigarette); and poly use of premium cigars, other cigars, and cigarettes (Poly-tobacco use). For each wave, the figure illustrates the percentage of users in each use category that remained in the category or transitioned to one of the other eight categories in the subsequent wave. SOURCE: Jeon and Mok, 2022.

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waves. The figure shows that by Wave 5, about 56 percent of adult exclusive premium cigar users in Wave 1 remained as such, while about 35 percent discontinued all cigar and cigarette use. By Wave 5, less than 5 percent became cigarette users—exclusively or dual with premium or nonpremium cigars. Less than 10 percent of exclusive premium cigar users transitioned to other use categories at Wave 5 (Jeon and Mok, 2022). For comparison, about 23 percent of exclusive cigarette users in Wave 1 became noncurrent users of cigars and cigarettes by Wave 5.

# **KEY RESEARCH GAPS AND FINDINGS**

Despite an overall paucity of data on premium cigars specifically (see Box 3-1 for key research gaps), based on the available data, the committee had some key findings.

Finding 3-1: Large, machine-produced cigars have been the dominant cigar type for much of the last century. Total cigar consumption began declining in the mid-1970s and reached its lowest level in 1993, when promotion of premium cigars reversed overall consumption trends for all cigar types. Since the release of the NCI's 1998 monograph on cigars, overall cigar consumption has increased every year, with a total increase of 145 percent from 1998 to 2020.

Finding 3-2: Premium cigars are consistently a small, stable percent of the U.S. cigar market.

Finding 3-3: About 1 percent of the U.S. adult population smokes premium cigars, a frequency that has remained stable over time.

Finding 3-4: Cigarettes remain the most commonly used combustible tobacco product among adults in the United States. The prevalence of cigarette smoking among adults in 2018–2019 was 16.4 percent compared to 0.7 percent for premium cigars, 0.5 percent for nonpremium cigars, 1.4 percent for cigarillos, and 0.8 percent for filtered cigars.

Finding 3-5: The majority of premium cigar users are male, white, with higher income and education levels compared to those who smoke cigarillos, little filtered cigars, or cigarettes. Premium cigar users are on average 7–10 years older than those who smoke cigarillos or little filtered cigars. Premium cigar use is less common among youth, and only 0.6 percent of those who reported smoking a premium cigar brand in the past 30 days were under the age of 18. Premium cigar

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use is also less common among women, non-Hispanic Black people, and people with less than a high school education.

Finding 3-6: The frequency and intensity of smoking is lower for premium cigars compared to other types of cigars and cigarettes. Only about 5 percent of premium cigar users smoke these daily, whereas 22 percent of nonpremium cigar users, 19 percent of cigarillo users, 40 percent of filtered cigar users, and 76 percent of cigarette users smoke those products daily. The median number of cigars or cigarettes smoked per day is about 0.1 for premium cigars, 0.2 for nonpremium cigars, 0.3 for cigarillos, 1.0 for filtered cigars, and 10 for cigarettes.<sup>17</sup>

Finding 3-7: Premium cigar users are less likely to smoke cigarettes or other cigar types concurrently than other cigar type users. Dual use with cigarettes was highest for filtered cigar users (~70 percent), followed by cigarillo users (~60 percent) and nonpremium cigar users (~50 percent), and lowest for premium cigar users (~26 percent).

Finding 3-8: Premium cigar users are more likely to be never or former cigarette smokers than users of other cigar products. They are also more likely than the general population to smoke cigarettes.

Finding 3-9: The prevalence of alcohol dependence among those who smoke premium cigars is similar to those who smoke nonpremium cigars or cigarettes. The prevalence of cannabis and illicit drug dependence among those who smoke premium cigars is lower than those who smoke nonpremium cigars or cigarettes. However, the prevalence of alcohol, cannabis, and illicit drug dependence among those who smoke premium cigars is higher than for those who do not use any tobacco products.

Finding 3-10: Population Assessment of Tobacco and Health Study analyses suggest that about three-quarters of exclusive premium cigar users continued smoking premium cigars in the following year. Among exclusive premium cigar users in Wave 1 (2013–2014), slightly more than half remained as exclusive premium cigar users in Wave 5 (2018–2019). About 35 percent discontinued use of cigars and cigarettes by Wave 5. Less than 5 percent became cigarette smokers

<sup>&</sup>lt;sup>17</sup> The median was calculated, consistent with the methods used by Corey et al. (2018): respondents reporting smoking less than one cigar per day on the days smoked were assigned as 0.5 cigars per day.

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(exclusive or dual with premium or nonpremium cigars) by Wave 5. Additionally, exclusive premium cigar users who smoked infrequently (i.e., less than 6 days in the past 30 days) were more likely to discontinue use within a year compared to those who smoked more frequently.

#### BOX 3-1 Key Research Gaps

- The available data on patterns of use for premium cigars is very limited, in part because surveys and studies do not regularly collect or report data on cigar type or brand.
- Data on how consumers define cigar use and type are not collected. Although some surveys do collect information on brand, they lack other key data points, such as ever use, ever regular use, and past 12-month use to better capture lifetime use of premium and other cigar products.
- Data on inhalation patterns, how cigars are smoked, and where they are smoked are lacking.
- Paradata (administrative data about the survey) could facilitate a better understanding of potential seasonal and geographic variation and implications for interpreting prevalence estimates.

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4

# **Cigar Marketing and Perceptions**

This chapter summarizes what is known about cigar<sup>1</sup> marketing and promotion, including for "premium"<sup>2</sup> cigars, and consumers' perceptions. FDA charged the committee to examine the health effects of premium cigars. This chapter recognizes the highly effective nature of tobacco advertising and promotion on use behaviors that in turn affect the health consequences of cigars. The chapter begins with the historical context of premium cigar marketing; sales; and awareness, knowledge, and beliefs. Box 4-1 presents terminology used in the chapter.

#### HISTORICAL CONTEXT

The committee is not the first to examine the health effects or marketing and promotion of premium cigars. A comprehensive review of these topics was conducted and reported in the 1998 National Cancer Institute (NCI) Tobacco Control Monograph 9, *Cigars: Health Effects and Trends*. The 2008 NCI Monograph 19, *The Role of the Media in Promoting and Reduc*-

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<sup>&</sup>lt;sup>1</sup> Note that when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

<sup>&</sup>lt;sup>2</sup> Note that quotations are used at the first occurrence of the term "premium" in each chapter, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information.

### BOX 4-1 Terminology

Marketing approaches

- Advertising promotions—Information and lifestyle dimensions communicated to consumers to influence the consumers' attitudes and behaviors (NCI, 1998).
- Selling propositions—"Claims about the unique positive features and benefits of the product (e.g., features, benefits, safety, flavors)" (Shen et al., 2017).

Perceptions

- **Risk perceptions**—Thoughts and feelings about the health harms associated with tobacco use (Kaufman et al., 2020a; Kaufman et al., 2020b).
- Benefit perceptions Thoughts and feelings about the benefits associated with tobacco use (adapted from Kaufman et al., 2020a).

*ing Tobacco Use,* synthesized data to demonstrate a causal relationship between tobacco advertising and promotion and increased use (NCI, 2008). Surgeon General reports on tobacco have underscored that "advertising and promotional activities by the tobacco companies cause the onset and continuation of smoking among adolescents and young adults" (HHS, 2012; HHS, 2014). The committee found no evidence to suggest that the effects of advertising and promotion of premium cigars would differ from that of other tobacco products. This chapter summarizes and identifies the unique literature related to premium cigars and cigars in general, which builds on the conclusions in Monographs 9 and 19.

Cigar use, including of premium cigars, began to increase in 1993 when promotional activities increased (NCI, 1998). Prior to 1994, cigar smoking had declined by 66 percent, a trend that began in the mid-1960s (NCI, 1998). However, as the promotion and sales of large cigars expanded, cigar use grew rapidly between 1993 and 1997, with premium consumption increasing by nearly 50 percent (NCI, 1998). Consolidated Cigar, General Cigar, and Swisher International were major premium cigar companies whose media spending increased during this period (NCI, 1998). Premium cigars (as a percentage of total cigar consumption) decreased from 4.1 percent in 1999 to 2.2 percent in 2012 (Maxwell, 2006, 2013), and has remained relatively constant through 2020 (see Table 3-1 in Chapter 3). Given this sharp reversal, NCI initiated a monograph to explore various aspects of cigar use, including marketing (NCI, 2008).

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Because marketing and promotion play a critical role in increasing the demand for cigars, Monograph 9 included a chapter on the commercial history of cigars, sales patterns, advertising, and promotion. The authors concluded that the promotional activities increased the visibility of cigar consumption, normalized use, and broke down barriers to use among new users, such as children and women, and in new settings (NCI, 1998). In fact, the cigar market was fairly stagnant until the release of *Cigar Aficionado* in the fall of 1992; the magazine's founder, Marvin Shanken, said that it was launched in response to an increase in premium cigar use (NCI, 1998). *Cigar Aficionado* expanded the popularity of cigars, helped launch new magazines, and promoted premium cigars in news stories and at social events.

When Monograph 9 was published, evidence was sufficient to conclude that cigar use increased after *Cigar Aficionado* was launched but insufficient to state that the advertisements and promotion of premium cigars were causally linked to their use, as quantitative and longitudinal data were limited. Ten years later, Monograph 19 concluded that "the total weight of [the] evidence—from multiple types of studies, conducted by investigators from different disciplines, and using data from many countries—demonstrates a causal relationship between tobacco advertising and promotion and increased use of tobacco as manifested by increased smoking initiation and increased per capita tobacco consumption in the population" (NCI, 2008, pp. 11-12).

Factors that supported this strong conclusion were studies that showed that

- Brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking and adolescents' intentions to smoke; and
- 2) A temporal relationship exists between exposure to advertising and adolescent initiation of smoking and subsequent regular smoking (NCI, 2008).

Marketing and promotion of tobacco products is a critical component of sales strategies and still influence their sale and use.

Furthermore, decreasing consumption of any tobacco product can decrease adverse health effects and health care costs. False advertising can lead consumers to have beliefs about a product that are incorrect. Deceptive health claims by manufacturers and distributors can mislead consumers about the harms of a product. Advertising and promotion can influence consumer risk perceptions, which can affect tobacco use.

### CONCEPT OF "PREMIUM"

As discussed in Chapter 1, the definition of premium cigars has not been consistent, thus complicating the committee's assessment of their marketing and promotional activities. "Premiumization" is a marketing strategy that has been used by tobacco companies to encourage consumers to use more expensive brands by purporting that they are better guality and less harmful than mid-priced or discount brands (Xu et al., 2019). Although studies specific to the word "premium" in cigar marketing are limited, research indicates that consumers perceive premium products to be linked to rewarding experiences, exclusive fun, endowed status, or superior craftsmanship (Gofman et al., 2010). Buying them may elicit emotional reactions, including making consumers feel good or more confident (Nielsen, 2016). The definition of premium cigars as "handrolled" may also induce positive perceptions, as "handmade" products are perceived to be of higher quality and thus more attractive (Fuchs et al., 2015). In the context of tobacco products, similar descriptors that convey a positive aspect, such as cigarettes marketed as "organic," "natural," or "additive-free," have previously been associated with reduced harm perceptions, intentions to use, and use (Agaku et al., 2015; Gratale et al., 2018; O'Connor et al., 2017; Pearson et al., 2016; Sanders-Jackson et al., 2018). "Natural," "organic," "additive-free," and "premium" have also been used for brand differentiation in the cigarette market (Dewhirst, 2021; Xu et al., 2019). Consistent with research on cigarettes (Agaku et al., 2015; Pearson et al., 2017; Pearson et al., 2019), these terms may impact harm perceptions, intentions, and use of premium cigars.

#### MARKETING

Tobacco marketing, which includes a range of strategies used by the industry to promote its brands and products, is central to how the industry develops positive perceptions to persuade nonusers to initiate use and current users to continue (NCI, 2008). A strong body of literature shows that tobacco marketing plays a powerful role in shaping positive perceptions of tobacco products and lower risk of harm and in influencing tobacco use behaviors, including initiation, continued use, and decreased cessation (HHS, 2001, 2014; Lovato et al., 2011; NCI, 2008). Tobacco marketing is often tailored and targeted to specific populations, such as youth, women, and racialized and ethnic groups, particularly African American/ Black communities (HHS, 1998, 2001, 2012; NCI, 2008). Sufficient evidence indicates that the tobacco industry does not self-regulate its marketing practices for any product and that restrictions on tobacco advertising and promotion can influence health consequences, including addiction and

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decreasing exposure among targeted populations and the deceptive or misleading nature of marketing (NCI, 2008).

#### Regulations

Federal regulations aim to restrict tobacco marketing. For example, the Master Settlement Agreement and the Tobacco Control Act<sup>3</sup> of 2009 prohibit tobacco marketing in traditional media (e.g., television, radio), billboards, transit stations, and events (e.g., sporting events, concerts) (FDA, 2020; National Association of Attorneys General, n.d.). Despite these restrictions, the cigarette and smokeless tobacco industry spends billions of dollars each year on marketing (FTC, 2021). Premium cigars (along with other tobacco products, such as nonpremium cigars, hookah, pipe tobacco, and electronic cigarettes [e-cigarettes]) are not included in these provisions of the agreement or the act. The most recent federal data on marketing expenditures of cigars, including premium cigars, document a nearly 300 percent increase (\$1.1 million to \$4 million) between 1994 and 1996 (NCI, 1998).

FDA has authority under the Tobacco Control Act to regulate certain types of marketing content for premium cigars (FDA, 2020, 2021); its rules for premium cigars include prohibiting

- 1) The sale of tobacco products to minors;
- The sale and distribution of tobacco products with unsubstantiated modified risk tobacco product (MRTP)<sup>4</sup> health claims or false or misleading claims on labeling or advertising;
- 3) The use of modified risk descriptors (e.g., "light," "low," and "mild"), unless authorized by FDA; and
- 4) The distribution of free samples of tobacco products.

FDA also requires health warnings to be displayed on packaging and advertisements of cigarettes, smokeless tobacco, and e-cigarettes (FDA, 2016). However, on September 11, 2020, the United States District Court ruled that premium cigars, as well as other cigar products and pipe tobacco, should be excluded from this rule (FDA, 2020). Scientific evidence is ample to suggest that a health warning is warranted on any tobacco product because no level of tobacco consumption is safe (Ham-

<sup>3</sup> Public Law 111-31.

<sup>&</sup>lt;sup>4</sup> "Modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" (FDA, 2018).

mond, 2011; HHS, 2020). Despite this scientific evidence, the court ruled to exclude cigars and pipe tobacco, including premium cigars, from this rule.

### Presence of Marketing

Monograph 9 (NCI, 1998) reported that only a small number of cigar companies engaged in conventional advertising. Despite limited measurement of cigar advertisements, media advertisement expenditures of cigar brands, which included premium brands, such as Macanudo, Davidoff, and H-Upmann, rapidly increased between 1994 and 1996 (NCI, 1998). However, since that time (NCI, 1998), data on premium cigars' marketing practices have been limited.

Since tobacco marketing strongly influences perceptions and use behaviors (HHS, 2001, 2014; Lovato et al., 2011; NCI, 2008), the committee reviewed the literature on premium cigar marketing, specifically summarizing articles that were not included in Monograph 9, and conducted primary data collection to elucidate the marketing practices of these companies.

The committee could not identify recent published data on how much premium cigar companies spend on marketing.

### Marketing in Print Media

Premium cigars have been presented to the public through promotional and marketing activities in print media, which includes direct mailers, magazines, and newspapers. Premium cigars are widely promoted in print and, in recent years, digital cigar lifestyle magazines (e.g., *Cigar Aficionado*, *Cigar Journal*, *Cigar Snob*) devoted to promoting them. After *Cigar Aficionado* began, other magazines were launched, including *Smoke* in 1996 by tobacco trade publisher Lockwood (NCI, 1998, p. 206) and *Cigar Snob*, a bimonthly publication that claims to bring "a fresh approach to the old, stuffy take on cigars with stunning photography, impactful editorial, and honest, easy to read cigar ratings" (Cigar Snob Magazine, n.d.). Other lifestyle magazines also include premium cigar advertising. One study examined selling propositions of print tobacco ads between 2012 and 2013 in consumer magazines, local magazines, Sunday magazines, and magazines targeting Latino/Latina/Hispanic readers: out of 1,122 tobacco ads, 87 were for premium cigars (Shen et al., 2017).

### Premium Cigar Companies' Print and Electronic Media Advertising

Given the limited amount of published data on the use of print media, including direct-to-consumer (DTC) advertisements and direct mail to

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promote premium cigar use, the committee obtained data<sup>5</sup> from Mintel Comperemedia (Mintel) to assess premium cigar advertising expenditures from print advertising, direct mail, and e-mail received by a national panel of consumers between June 2018 and September 2021. Mintel tracks all three advertising channels in the United States using a nationally representative sample of panelists comprising 67,000 households and an additional e-mail panel of about 1,300 households who forward paper mail and e-mails to Mintel on a weekly basis (Ganz et al., 2016). Although Mintel does not capture premium cigar advertisements as their own category, the Mintel database was searched for premium cigar brand names as identified in Corey et al. (2018).

The Mintel data consist of advertisement image and associated metadata, which includes: (1) company name; (2) the month/year in which the ad was received; (3) estimated dollar amount spent on the ad (direct mail only); and (4) estimated direct mail volume (direct mail only).

Mintel data provided to the committee had two separate paid ad spreads (see Figure 4-1) from a single premium cigar brand in a free in-flight magazine of a major U.S. airline. These ads featured themes of history, culture, and family, and the rate spent for them was \$159,000 and \$53,100, respectively.

One premium cigar brand, Drew Estate, had several e-mail ads (see Figure 4-2) that promoted an in-person entertainment event/festival to celebrate its 25th anniversary and "The Rebirth of Cigars Movement," promoting branded items, new cigars, and live music featuring rock and hip-hop. These ads used graffiti images with a logo of the Manhattan Bridge and pictures of musical artists who would be featured at the festival; these DJs and musicians gained popularity from the 1990s through mid-2000s. Some of these e-mail ads featured only the brand logo with an image and a description of DJs and musicians without the mention of any premium cigar products. These promotional efforts that highlighted DJs and musicians were part of a larger tobacco industry movement to use music to appeal to consumers. This same strategy was used for menthol cigarettes and the Kool Mix Campaigns and Newport music festivals.

The committee did not identify any premium cigar advertising in direct mail but did observe that cigarillo brands (i.e., Black & Mild, Swisher Sweets, Night Owl, and Havana Honey Cigars) and little cigar brands (i.e., Talon) used direct mail (Rutgers Center for Tobacco Studies,

<sup>&</sup>lt;sup>5</sup> Available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu. This is the committee's analysis of Mintel data; it does not represent the views or opinions of Mintel.

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**FIGURE 4-1** Paid advertisement spreads from a single premium cigar brand in a major U.S. airline's in-flight magazine.

NOTE: All images reproduced with permission from Mintel Comperemedia. SOURCE: Mintel Comperemedia, 2021 (available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu).

n.d.) with strategies including coupons,<sup>6</sup> discounts, rewards and free gifts for purchasing, sweepstakes entry, invitation to visit the brand website or their social media accounts, and links to visit their website for non-cigar-related topics (e.g., a new episode of a reality show featuring a new singer, recipes, concerts).

DTC advertisement is a common source of tobacco advertising and has been used widely by the cigarette and smokeless tobacco industries (FTC, 2021). The Mintel data suggest that cigarillo and little cigar brands are using direct mail with multiple discount strategies, as well as nontobacco-related events and promotional items, to a variety of populations across the majority of U.S. states. With higher price points associated with premium cigars, these may be marketed in other venues not obtained

<sup>&</sup>lt;sup>6</sup> Coupons were not identified in the Mintel data, but this does not imply that they do not exist for premium cigars.



Click here to view this email in your browser



#### Lights Out Entertainment is Coming to DE25! Will You Be There?

This year marks the 25th anniversary of Drew Estate and The Rebirth of Cigars Movement. To celebrate this momentous occasion, the company is inviting you, consumers, retailers and cigar media to its epic blow-out birthday bash, entitled "DE25." DE25 will be held on Sept. 25 at the Southfork Ranch in Parker, Texas, part of the Dallas/Fort Worth Metropolitan area. In addition to receiving over 20+ premium Drew Estate cigars and amazing limited edition swag, the DE25 celebration will include the unveiling of Drew Estate's newest brands with some lights-out entertainment! See who's performing at DE25!

**FIGURE 4-2** Email advertisement promoting an in-person entertainment event. NOTE: All images reproduced with permission from Mintel Comperemedia. SOURCE: Mintel Comperemedia, 2021 (available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu).

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through DTC advertisements. For example, they are advertised in inflight magazines, which are often associated with luxury and travel.

However, third-party retailers are also using DTC to market premium cigar products. An example is Thompson Cigar,<sup>7</sup> which started out as a mail-order cigar company in 1915 (it was sold to Scandinavia Tobacco Group in 2018) and continues to sell premium cigars through mail catalogues, e-mails, and website (Danielson, 2019). When the Mintel database was searched for terms (including "premium," "small batch," "limited edition," "limited refill," "hand rolled," "reserve," and "long leaf") related to how premium cigars could be used in DTC ads, third-party retailers were found that primarily sell premium cigars using e-mail coupons, catalogs, and subscription services (e.g., "get five premium cigars each month"). The e-mails featured coupons (e.g., \$10 off, free lighter/wallet with purchase, time-limited sales) for premium cigars, and some e-mail ads advertised a specific brand. The ads described premium cigars as "highly rated," from a "renowned" brand, and "exclusive" cigars, alluding to a higher class of product.

Although premium cigar brands are generally not using DTC ads, evidence suggests that they are using similar marketing strategies as other cigar brands, such as e-mails to promote non-cigar-specific themes that appeal to young people—music festivals, urban lifestyle, and hip-hop and rock music. Additional evidence indicates that third-party retailers that primarily sell premium cigars are using DTC to market these products using discount strategies similar to those by the nonpremium cigar industry, also alluding to premium cigars as a higher-class product.

### Summary and Conclusion

To assess premium cigar marketing, the committee conducted primary data collection, given the extremely limited literature, to reach its conclusions. It examined:

- 1) Data obtained from Mintel Comperemedia, which collects DTC advertisements using mail and e-mail sent to a national panel of consumers, as well as print advertising (June 2018 and September 2021);
- 2) Content from cigar lifestyle magazines (i.e., *Cigar Aficionado, Cigar Journal,* and *Cigar Snob*) published in 2021; and
- 3) Content from social media platforms and company-owned websites of premium cigar brands.

<sup>&</sup>lt;sup>7</sup>See https://www.thompsoncigar.com (accessed November 12, 2021).

The committee's analysis of Mintel data showed that third-party retailers are using DTC advertisements of premium cigars using coupons, catalogs, and subscription services. These strategies were also commonly used by cigarillo brands, as also observed from the dataset. These observations led the committee to conclude that there is conclusive evidence that third-party cigar retailers are using DTC methods to market premium cigars similar to strategies used by the nonpremium cigar industry. Based on its review of print and electronic media advertising data, the committee concludes:

Conclusion 4-1: Based on the committee's primary data collection, there is **conclusive evidence** that third-party cigar retailers use direct-to-consumer methods to market **premium cigars** using similar strategies as the nonpremium cigar industry.

#### **Content Analysis of Cigar Lifestyle Magazines**

In the early years of *Cigar Aficionado*, celebrities were featured. The magazine launched a line of clothing and men's fragrance and promoted cigar-centered dining and entertainment worldwide. In addition, the number of cigar smoking clubs and bars, which featured premium brands (e.g., Club Macanudo in Chicago), grew (NCI, 1998, p. 209-210). In 1996, other magazines, such as *Smoke* and *Cigar Monthly*, joined the magazine market, and news stories and newspaper articles about premium cigars increased as well (NCI, 1998). Few studies exist that examine the content or practices of current cigar lifestyle magazines.

The committee analyzed<sup>8</sup> magazine covers, articles, and advertisements from eight issues of three popular cigar lifestyle magazines: *Cigar Aficionado* (March/April 2021, May/June 2021, and July/August 2021), *Cigar Journal* (Summer 2021 and Autumn 2021), and *Cigar Snob* (March/ April 2021, May/June 2021, and July/August 2021) to examine a snapshot of recent content. The magazine covers (n = 9, which includes one additional cover featuring a Whisky Advocate special edition included on the back of the May/June 2021 edition of *Cigar Aficionado*), every fifth article (n = 28), and every fifth ad (n = 61) of each issue were coded for major themes outlined in the literature (DeSantis and Morgan, 2003; Falit, 1997; Shen et al., 2017; Wenger et al., 2001a; Wenger et al., 2001b) and of interest to the committee: 1) health risk and benefit related to premium cigars, 2) new cigar trends (e.g., changes to premium products, including industry

<sup>&</sup>lt;sup>8</sup> The codebook used (developed by the committee based on published analyses) and results from this review are available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

practices), 3) enjoyable social activity, 4) luxury, 5) product quality, 6) success, 7) masculinity, 8) sex appeal, 9) taste, and 10) other substance (i.e., alcohol, cannabis).

## Article Analysis

Nineteen (68 percent) of the 28 articles sampled had content related to premium cigars, including ratings and reviews; pairing of cigars with alcohol; interviews with celebrities and people in the cigar industry to discuss topics related to cigars; cigar history and information (e.g., about Premium Cigar Association [PCA]); and a gift guide (e.g., featuring cigar products, such as accessories). One article featured rankings of cigarrelated Twitter accounts that had the most followers by cigar-related organizations, radio stations, companies, and retailers. Nine (32 percent) of the articles that included non-cigar-related topics had travel guides and reviews of vehicles, alcohol, and coffee. See Table 4-1 for the themes in the articles.

Theme	Examples	N (%)
Quality	Use of superior processes and materials in making a product	25 (89%)
Luxury	Fancy packaging (premium cigars); fine art, expensive cars/clothes (nonpremium cigars)	15 (54%)
Social images that show people having fun with other people	People laughing with each other	9 (32%)
Success	Achieving wealth, respect, or fame	13 (46%)
Alcohol	Pairing premium cigars with alcohol, such as whisky or wine	12 (43%)
Masculinity	Hunting, cowboys	11 (39%)
Describing the taste of premium cigars using language similar to how the taste of wine is described	"Core of earth, red pepper, and chocolate ac- companied by a touch of ripe fruit sweetness"	7 (5%)
New cigar trends and innova- tions	Changes to premium cigars, such as the size, tobacco source, wrapping techniques, or new blends of tobacco	5 (18%)

**TABLE 4-1** Themes from Cigar Lifestyle Magazine Articles Sampled (n = 28)

SOURCE: Commissioned magazine analysis (data available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@ nas.edu).

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No articles mentioned health risks related to premium cigars; two (7 percent) mentioned positive health effects (i.e., using premium cigar as stress relief, such as Rush Limbaugh's interview stating, "Cigars relax me. They help me to think"). Based on studies documenting that certain words used in tobacco marketing, such as "natural" and "organic" allude to lower harm and result in lower perceived harm among cigarette smokers and nonsmokers (Baig et al., 2019), the committee also conducted a search of "lower-harm" terms in all digital versions of the magazines, which included three issues each of Cigar Snob and Cigar Aficionado. The search function was used to check for the presence of terms relating to "lower harm," including "organic," "healthy," "clean," "pure," "natural," "fresh," and "light." Forty-six mentions of lower-harm words were found, approximately 7.7 mentions per issue. For example, some of the product names contained these lower-harm terms (e.g., "Churchill Natural"), and the taste, smoke, and wrapper were described as "fresh," "light," and "clean."

Eighteen celebrities were featured in 18 percent of the articles; two articles featured multiple individuals (e.g., celebrities talking about their favorite premium cigar brands; see Table 4-2 for their demographics).

#### Ad Analysis

Forty-four (72 percent) of the 61 ads assessed had content related to premium cigars (i.e., brands, retail shops, magazines, events). The frequency of each theme did not differ between ads that featured premium cigars and noncigar products, so the findings present the overall frequency in which these themes appeared (Table 4-3). Three (5 percent) ads included an image of a celebrity; similar to findings from the article analysis (Table 4-2); these were middle-aged to older men, and their professions were musician, sports figure, and owner of a premium cigar brand.

Six ads (10 percent) featured large-scale events that included festivals hosted by premium cigar brands and cigar magazines targeting consumers and trade partners. These events had premium cigars, food, alcohol, and music. Some festivals specifically featured a combination of premium cigars and alcohol (e.g., "Big Smoke meets WhiskyFest"). Nonpremium cigar festivals included a food and wine festival hosted by the Food Network.

#### Cover Analysis

Eighty-nine percent of the magazine covers (nine total covers) had at least one theme related to premium cigars (covers were coded for both text and images). The only one that did not was the additional cover of

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Demographics	Categories	N (%)
Profession	Sports figure	6 (33%)
	Actor	
	Other (e.g., notable military figures, pundits, writers, CEOs of premium cigar brands)	9 (50%)
Sex	Male	18 (100%)
	Female	0 (0%)
	Nonbinary	0 (0%)
	American Indian or Alaska Native	0 (0%)
	Asian	0 (0%)
Race	Black	3 (17%)
	Hispanic or Latino	
	Native Hawaiian or Other Pacific Islander	0 (0%)
	White	
	Other/Unknown	0 (0%)
	18–30 years old	0 (0%)
	31–50 years old	
Age	51–65 years old	
	65 years or older	6 (33%)

**TABLE 4-2** Demographics of Celebrities (n = 18) Featured in Cigar Lifestyle Magazine Articles Sampled

SOURCE: Commissioned magazine analysis (data available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@ nas.edu).

the *Whisky Advocate* special edition. The content featured on the covers included five (56 percent) interviews, four (44 percent) photo shoots (e.g., scantily dressed young female models posing on a beach or a pool with cigars), three (33 percent) travel tips, two (22 percent) cigar reviews, one (11 percent) alcohol-related content, and 35 percent "other" articles (e.g., social media rankings of cigar-related Twitter accounts, editorials related to premium cigars/industry).

Seven of the nine covers (78 percent) included the image of a celebrity; one magazine had two. The celebrities were models/social media influencers, sports figures, and actors; four (50 percent) were male and four (50 percent) were female, representing diverse age ranges: three (38 percent) 18–30, three (38 percent) 31–50, one (13 percent) 51–65, and one (13 percent) 65 or older. Six (75 percent) of the celebrities were coded as white, one (13 percent) as Black, and one (13 percent) as other (Indian/British).

Themes	Examples	N (%)
High quality	Using words such as "hand-crafted," "quality"	46 (75%)
Social Images that show people having fun with other people	People laughing with each other	18 (30%)
Masculinity	Image of a cowboy, words such as "adventure"	16 (26%)
Luxury	Images of expensive cars, clothes, use of words such as "finest"	14 (23%)
Success	Images of executive chairs and a business meeting room	12 (20%)
Taste	Description of taste of cigar	6 (10%)
New cigar trends and innovations	Ads of new blends of tobacco. Images of a newer tech- nology, such as an image of a tablet to advertise digital cigar magazines	4 (7%)
Included an image of a celebrity		3 (5%)
Featuring a cigar lounge		2 (3%)
Sex appeal	Scantily dressed women	1 (2%)

**TABLE 4-3** Themes from Cigar Lifestyle Magazine Advertisements Sampled (*n* = 61)

SOURCE: Commissioned magazine analysis (data available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@ nas.edu).

In summary, premium cigar lifestyle magazines primarily featured such cigars throughout, including the cover, articles, and ads. The premium cigar industry is shown positively, with virtually no mention of negative health concerns. However, positive benefits, such as using premium cigars to reduce stress and words that allude to lower harm, such as "light," "clean," and "natural," were mentioned multiple times within a single issue.

Based on the articles, advertisements, and covers sampled, cigar lifestyle magazines appear to target middle-aged to older white men, featuring themes that emphasized high quality of the product; a luxurious lifestyle that involves premium cigars but also other products, such as vehicles, coffee, and travel, as well as masculinity and success; and cigar use as a fun social activity. New cigar trends and innovations were less frequently featured. Positions of power or high-level careers were often referenced by articles or covers featuring men in the field of sports, CEOs, or military figures. Despite few cigar ads coded as "sex appeal," these ads pictured women in sexually suggestive poses holding a cigar while scantily dressed.

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Content related to alcohol, such as whisky and wine, were identified in both paid ads and articles. The description of the taste of premium cigars very closely resembles that of wine. The large-scale events and festivals also featured both together, which may be because the same communications company owns *Cigar Aficionado*, *Wine Spectator*, and *Whisky Advocate*.

### Summary and Conclusion

The committee observed in the Mintel dataset that one premium cigar brand (Drew Estate) had several e-mail advertisements that featured an "urban" lifestyle using graffiti and promotion of a music festival that featured musicians and premium cigar products. The committee's content analysis of cigar lifestyle magazines also included advertisements and articles promoting large-scale festivals, which featured premium cigars and alcohol. These findings led the committee to conclude that marketing strategies used by premium cigar companies include festivals, themes of an urban lifestyle, and hip-hop and rock music, which may appeal to young people. Based on its review of Mintel data and cigar lifestyle magazines, the committee concludes:

Conclusion 4-2: Based on the committee's primary data collection, there is **conclusive evidence** that **premium cigar** companies use lifestyle magazines and festivals to promote premium cigars. Some of these marketing strategies, such as sponsoring music festivals and promoting their products with an urban lifestyle and hip-hop and rock music, may appeal to young people.

### Marketing on the Internet and Social Media

The Internet, which includes social media platforms, has become a popular venue for the tobacco industry to market products because it is lightly regulated and can reach a large number of people quickly at a low cost (Freeman, 2012).

Tobacco promotion and marketing on social media was uncommon when Monograph 19 was published in 2008 (NCI, 2008). Since 2008, evidence is growing that tobacco promotion is occurring on social media using strategies such as influencers and celebrities, paid online banner advertisements, and brand accounts without sufficient regulation (HHS, 2014, 2016). The committee found no published studies specifically examining premium cigar marketing on the Internet and social media. However, emerging data indicate that nonpremium cigar products (e.g., little cigars and cigarillos) are heavily marketed on social media platforms,

such as Instagram (Allem et al., 2017; Richardson et al., 2014) and Twitter (Kostygina et al., 2016).

Navarro et al. (2020) examined whether cigar brands were using social media influencers to market cigar products on the brands' Instagram accounts in 2017 to 2018. The brands were identified from the top 20 leading cigar brands from Nielsen Scantrack data that tracks sales from total U.S. convenience stores and outlets (cigar brands from Nielsen data: n = 11) and Euromonitor's list of 2017 U.S. market leaders based on retail volume (additional cigar brands from the Euromonitor list: n = 13). They included all types of cigars, including premium. Seven of the 24 leading cigar brands had an official Instagram account, with at least one influencer in the 20 Instagram posts examined; two were premium<sup>9</sup> cigar brands.

Another study examined whether leading tobacco brands (i.e., cigar, e-cigarette, cigarette, hookah, and smokeless tobacco) had a social media account in 2018 (O'Brien et al., 2020). The authors identified 112 leading brand names of all tobacco products using Nielsen Scantrack data, Euromonitor, and PATH study data (only for hookah). For each brand, the authors searched whether an official account exists on Instagram, Facebook, Twitter, YouTube, Pinterest, and Tumblr. Eight were premium and 16 were nonpremium<sup>10</sup> cigars. Specific conclusions regarding premium cigars cannot be drawn because the data analysts grouped all brands together. This study observed that leading cigar brands (as well as e-cigarette and hookah brands) had at least two social media platforms, with Facebook, Instagram, and Twitter being the most common.

As the Internet and technology rapidly evolve to engage and entertain their users, tobacco companies that market using these sources will also likely evolve, so studies will need to keep up with these changing trends. For example, mobile phone apps could be one way to market premium cigars. In 2012, one study examined the presence of pro-tobacco apps by searching the keywords "smoke," "cigarette," "cigar," "smoking," and "tobacco" on the Apple App Store and Android Market and found 107 apps. Apps relevant to cigars included one that showed where to buy tobacco products, including cigars (the authors did not differentiate cigar type); one for a premium cigar users advocacy group (Cigar Rights of America); and a "Cigar Smoker" app (the authors did not differentiate cigar type, but the example images included premium cigars), which provided information about cigar news, reviews, and deals, as well as options for users to share their own photos of their cigars on social media (BinDhim et al., 2014).

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<sup>&</sup>lt;sup>9</sup> As determined by the committee (see Chapter 1 and Appendix E).

<sup>&</sup>lt;sup>10</sup> As determined by the committee (see Chapter 1 and Appendix E).

The committee's search of premium cigar brand<sup>11</sup> apps on the Google Play Store (for Android phones) and the Apple App Store (for iPhones) indicated that only one brand had its own app. This finding is consistent with a study conducted in 2017 that examined tobacco brand apps in the Google Play Store and Apple iTunes; of 43 cigar brands (along with 20 cigarette, 20 smokeless tobacco, and 30 e-cigarette brands), the authors observed that no cigar (they did not specify type) apps were available on either, while cigarette and smokeless tobacco brand apps were available on Google Play (but not on Apple iTunes) (Navarro et al., 2019). Google and Apple prohibit apps that facilitate the sale of tobacco products. Furthermore, Apple prohibits apps that encourage consumption of tobacco products or encourage minors to consume tobacco products (Apple, 2021), and Google prohibits apps that "encourage the illegal or inappropriate use of alcohol or tobacco" (Google, n.d.).

### Environmental Scan of Premium Cigar Companies' Online Presence

Given the dearth of published literature on premium cigar products, the committee conducted an environmental scan and content analysis of premium cigar companies' social media and web pages<sup>12</sup> to document and describe the presence of their advertising of their products. The committee also assessed selling propositions within the content.

The committee assessed the social media and webpage presence of the 60 cigar brands initially classified as premium (four more were added) (see Appendix E for a description of the methodology used to classify the brands as premium). The committee conducted a web search to document premium cigar brands' online presence, which included a website and/ or a profile on social media platform(s), from June to July 2021. These platforms include Facebook, Twitter, Instagram, YouTube, and Snapchat, which are popular and used worldwide.

The committee assessed if each brand had its own official website. The website's page, the presence of age verification or age gating, and online purchasing options were documented for each one. Regarding social media profiles for Facebook, Twitter, YouTube, and other media, the committee documented the handle for each brand's social media profile/ site. The number of posts made on each platform during the data collec-

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<sup>&</sup>lt;sup>11</sup> The search included the premium brands identified in the committee-commissioned papers (see Appendix F).

<sup>&</sup>lt;sup>12</sup> The codebook used (developed by the committee based on published analyses), and results from this review are available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

tion period was captured. Metadata for the social media sites were also captured, including the number of followers (or subscribers for YouTube), likes, comments, and/or views. In addition, the committee documented the presence of a smartphone app for each brand and the number of downloads. Finally, following the methodology used by Shen et al. (2017) and Escobedo et al. (2018), the committee documented the presence of selling propositions in the online content of each premium cigar brand:

- *Sociability:* content that promotes fun, hip, cool, contests, and adventures;
- *Innovation*: content that promotes simple to use, technology, convenience, and price;
- *Party lifestyle*: content that may include smoke/vapor, nightlife, celebrities, music, party, and holiday;
- *Celebrity endorsement* and the industry in which the celebrity is a part of (e.g., music, art, sports);
- *Music content* and the genre of music (e.g., pop, hip-hop or rap, dance or electronic, alternative, R&B rock, or other genres);
- *Taste:* content that implies smooth taste and/or satisfaction;
- *Harm reduction:* content that implies that premium cigars are safe or less harmful to use than others or are an alternative to quitting smoking;
- *Quality:* content that implies that the product is of high quality, historic, or longer lasting;
- *Masculinity:* content that feature themes, activities, and settings stereotypically considered masculine, such as the outdoors, and activities, such as manual labor or hunting;
- *Femininity:* content that includes encouraging female use of premium cigars, such as hashtags like #girlswhosmoke or #girlssmoketoo; and
- *Sex appeal*, including images or content that shows a "beautiful, glamorous, sophisticated, handsome, or cool-looking individual using tobacco."

A descriptive analysis was conducted to assess the online presence of each premium cigar brand and capture the most common selling propositions.

Of the sample of 60 cigar brands initially identified as premium, eight were sub-brands of five brands and five were not found in online searches, resulting in 47 brands searched (see Table 4-4). Thirty-six premium (77 percent) had an official website, and 31 (66 percent) had a Facebook page. Each brand had an average of 21,341 "likes" and an average of 22,225 followers on its Facebook page. Thirty-one premium

(66 percent) had Instagram accounts, with an average of 842 posts and 34,210 followers. Nearly half (n = 28; 46.7 percent) had a Twitter account with an average of 12,727 account followers and 5,189 tweets. More than one-fifth (n = 11; 23 percent) had a YouTube page, with an average of 4,767 subscribers and 363,391 channel views. Eight (17 percent) of the 47 premium cigar brands used other online platforms: four (8 percent) had content on the Cigar World social media platform, three (6 percent) had LinkedIn accounts, and one (2 percent) had a Pinterest account.

### Summary and Conclusion

The committee's analysis of the online presence of premium cigar brands identified that 77 percent of the brands examined had an official website, 66 percent had a Facebook account, 66 percent had an Instagram account, 57 percent had a Twitter account, and 23 percent had a YouTube account (see Table 4-4). The presence and use of social media to promote premium cigars is not currently captured by existing tracking methods of marketing expenditures. These findings led the committee to conclude that there is conclusive evidence that premium cigar companies have online and social media presences not captured by traditional methods of tracking marketing expenditures.

Online presence	N (%)	Mean engagement per account (Range)
Official premium cigar company website	36 (77%)	_
Facebook	31 (66%)	21,341 "likes" (6–152,259) 22,225 followers (6–150,737)
Instagram	31 (66%)	842 posts (1–3,282) 34,210 followers (4–146,000)
Twitter	27 (57%)	5,189 tweets (3–17,800) 12,727 followers (42–35,500)
YouTube	11 (23%)	4,767 subscribers (70–25,000) 363,391 channel views (974–1,638,628)
Cigar World social media platform	4 (8%)	_
LinkedIn account	3 (6%)	_
Pinterest account	1 (2%)	_

**TABLE 4-4** Online Presence of Premium Cigar Brands (n = 47)

SOURCE: Committee social media commissioned analysis (data available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu).

Conclusion 4-3: Based on the committee's primary data collection, there is **conclusive evidence** that **premium cigar** companies have online and social media presences not captured by traditional methods of tracking marketing expenditures.

#### **Summary Finding**

Based on the committee's 1) review of the literature on the presence of cigar and premium cigar advertising in print media and on the Internet and social media; 2) analysis of data on cigar advertising and marketing expenditures obtained from Mintel; 3) content analysis of cigar lifestyle magazines; and 4) environmental scan of premium cigar brands' web and social media presence, the committee finds:

Finding 4-1: Cigar Aficionado, the first magazine to specifically promote premium cigars as a lifestyle, was associated with the rapid increase in premium cigars in the early 1990s and, along with other cigar lifestyle magazines, continues to promote premium cigars. Since the publication of the NCI Monograph 9, Cigars: Health Effects and Trends, access to data on marketing expenditures has been limited, and there have been limited published data on marketing expenditures of premium cigars through traditional channels (direct mail, e-mail, etc.). Although the committee found it difficult to access marketing data (for both branded and nonbranded<sup>13</sup> marketing) and few published studies on the marketing of premium cigars, this does not mean that marketing is not occurring. Based on the committee's primary data collection, it is evident that cigars are marketed in lifestyle and other magazines and on the Internet and social media platforms. There is evidence that premium cigars are marketed through direct mail advertisements, although the extent of this type of marketing is unknown because the tracking data are not readily accessible.

#### Advertising Promotions and Selling Propositions of Premium and Cigar Products

This section describes the advertising promotions and selling propositions used by cigar tobacco companies and other non-tobacco-industry sources (see Box 4-1 for the definitions used in this chapter of "advertising promotions" and "selling propositions"). The committee's definitions of both align with research that examined tobacco product advertising con-

<sup>&</sup>lt;sup>13</sup> Nonbranded marketing refers to general promotion of premium cigars overall as a product type.

tent (NCI, 2008; Shen et al., 2017). For this review, selling propositions are considered a component of cigar advertising promotions.

This section begins with a summary of articles that examined the general/overall advertising promotions. Next, it describes the unique selling propositions. Articles that examined premium cigar products are described first in each section. Given the absence of published literature focused exclusively on premium cigars, the literature search and subsequent article review were broadened to include those that described cigar products but did not specify type (such as premium, nonpremium, cigarillo, little filtered cigar). Next, the advertising promotions and selling propositions for non-large-cigar products, including cigarillos and little filtered cigars, are described. While the main goal is to describe findings for premium cigars, this section highlights the similarities in advertising promotions and selling propositions and selling propositions for non-large propositions between premium cigars and non-large cigars.

# Advertising Promotions for Premium Cigars and/or Brands

The committee found three articles that exclusively assessed the advertising promotions and selling propositions of premium cigars and/ or premium brands: a Tobacco Industry Ad-Watch (Falit, 1997) and two scientific studies (DeSantis and Morgan, 2003; Wenger et al., 2001a). The articles were published between 1997 and 2003, during a more than 50 percent increase in cigar sales and consumption (Department of Agriculture, 1997; Wenger et al., 2001a). The rise in cigar sales during the late 1990s was due, almost exclusively, to the sale of large cigars (Department of Agriculture, 1997; Wenger et al., 2001a). The stated goal of each article was to understand the role of advertising in increasing cigar sales and consumption. Additionally, the three articles analyzed content from prominent cigar magazines, such as Cigar Aficionado. In 1995, it was the most popular lifestyle magazine in the United States, with a readership of more than 400,000 per issue (DeSantis and Morgan, 2003; NCI, 1998). Falit (1997) cited studies that described the growing popularity of cigar products and increased advertising to 20-, 30-, and 40-year-olds as well as promotion to older adults. Despite this popularity among younger and middle-aged adults, Falit noted an initial delayed public health response to advertisements targeting 20-40-year-olds because they were not specifically targeting children.

### Selling Propositions for Premium Cigars and/or Brands

"Luxury, success, and prestige." Falit's (1997) Ad-Watch in the *Tobacco Control* journal describes the advertisements of cigars and their accom-

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panying products (i.e., humidors, holders, lighters) in magazine publications, such as *Cigar Aficionado* and *Smoke*, and newspapers that were "geared towards older, more affluent adults" (p. 240). Older celebrities, including Hollywood movie stars, such as George Burns and those who have "achieved success and earned the right to smoke a cigar" (p. 240), were prominently featured in *Cigar Aficionado* and *Smoke* holding cigars or smoking them. The Ad-Watch also describes cigars as popular props in several major motion pictures during the late 1990s, notably an advertising campaign for the premium brand Macanudo. It featured "two men one older and one younger—who shared cigars as a common interest and symbol of maturity and success" (p. 241).

Wenger et al. (2001a) conducted a content analysis of content in Cigar Aficionado (1992–1998) and another cigar lifestyle magazine, Smoke (1996–1998) to identify their role in the elevated premium cigar sales and consumption rates in the late 1990s. Overall, approximately 40 percent of the combined articles were focused on cigars. Of these articles, 92 percent portrayed premium cigars positively, highlighting them as "pleasurable, relaxing, and part of a successful lifestyle" (p. 282). Celebrities and influential public figures, including politicians, actors, musicians, and painters, were featured in 34 percent of the articles. Although Wenger et al. mentioned that sometimes the celebrities were "mentioned in passing" (p. 282), usually the articles featured a celebrity who described their favorable views on cigars or the role of cigars as a part of their lifestyle. Premium cigar events were featured in 12 percent of the articles and included social events, such as cigar smoking, eating gourmet meals and dinners (i.e., Cigar Aficionado's "Big Smoke" dinners), drinking "premium" alcohol, and the openings of cigar bars, lounges, and shops in the United States and other countries. The authors concluded that aligning cigar use with celebrities and influential public figures and promoting them at "exclusive" social events normalized and promoted cigar use as a part of a successful lifestyle.

Findings from Wenger et al. (2001a) indicate that approximately 40 percent of these articles advertised premium cigar smoking as a part of a successful, sophisticated lifestyle, which was promoted as a desirable "identity." Additionally, 60 percent of the non-cigar-focused articles in *Cigar Aficionado* and 57 percent in *Smoke* "covered luxury topics such as art, sports, music, fashion, gambling, jewelry, collectibles, and leisure" (p. 280) that are consistent with a successful and desirable lifestyle. The inclusion of elegant content may indicate to the publications' readers that premium cigars are a part of a luxurious lifestyle.

"Cigar benefits outweigh health effects." Cigars during the late 1990s were "not commonly believed to have the same health effects as ciga-

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rettes" and "the health effects of cigar smoking have not been researched nearly as much as those of cigarette smoking" (Falit, 1997, p. 241). Evidence presented in the Falit Ad-Watch indicates that premium cigar advertising promotions downplayed the health dangers of cigar smoking compared to cigarette use and supported the perception that cigars were a safe substitute. The Ad-Watch also notes that "with George Burns as the cigar's most popular 'poster child,' the health dangers of cigar smoking are subtly undercut" (p. 241).

DeSantis and Morgan (2003) conducted a content analysis of 41 *Cigar Aficionado* magazine issues published from 1992 to 2000 to analyze their "pro-smoking messages" (p. 460). DeSantis and Morgan noted that the magazine promoted "premium cigars (i.e., hand-rolled, expensive, and imported)" and included a quote from *Cigar Aficionado* that indicated that the sales and consumption of premium cigars were attributed to their publication (p. 458). From 1992 to 2000, 380 pro-premium cigar-smoking arguments were found, and 9.4 pro-premium-cigar arguments were present per issue (for example, cigars are not cigarettes, life is dangerous, and health benefits arguments).

The "cigars are not cigarettes" argument was the most recurring theme and asserted that cigars were a safer alternative. This argument was based on the "significant differences in [cigar] product and process" and asserted that 1) cigarettes are addictive, whereas cigars are not because they are used infrequently; 2) cigarettes are inhaled, and cigars are not, thus they do not pose health risks to the lungs; 3) cigarettes are impure, but cigars are not because they contain "all-natural ingredients" (p. 466). Also, the cigar-making process purifies the products; and 4) cigarettes are consumed in mass quantities, whereas cigars are smoked "in moderation" (p. 467) and not as a daily habit. The "life is dangerous" argument asserted that cigar use is not as dangerous and/or risky as other behaviors, such as reckless driving, alcohol consumption, and breathing polluted air. The "health benefits" argument asserted that cigar smoking offers many health benefits, including stress reduction, decreasing the risk of several major health problems.

# Advertising Promotions for Cigar Brands

In response to the lack of articles on advertising promotion and selling propositions for premium cigars, the committee broadened its search to include cigar products in general (i.e., not specifying premium, nonpremium, cigarillo, or little filtered cigar but instead using the broader term "cigar").

Two articles described the advertising promotions for "cigar" products. Wenger et al. (2001a) conducted a content analysis of 790 cigar-

focused newspaper and magazine articles published in the five largest U.S. newspapers by circulation between 1987 and 1997 but did not specify the cigar type. The authors coded for the primary focus (e.g., cigar business, events, trends) of the articles, image of cigars (positive: enjoyable, profitable, relaxing; negative: harmful, unpleasant), the tobacco industry portrayal (positive: profitable; negative: harmful; neutral: neither); and the presence of celebrities and public figures. Cigar businesses (39 percent of content) and events (19 percent) were the most prominent focus areas. The report did not describe the types of cigar business or events. The authors also noted that both cigars (62 percent) and the tobacco industry (78 percent) were portrayed positively in the majority of the articles. Celebrities and other public figures were quoted or described in 42 percent of the articles, with 87 percent having favorable attitudes toward cigars. The authors also coded for the presence of health effects, which is described in the relevant section.

Feit (2001) examined 70 cigar images in a sample of women's magazines published between 1992 and 1998 but did not specify the product type. The images were coded for image type (advertisements versus nonadvertisements), the product advertised with or without an image, the presence of product with/without actors (e.g., individuals or cartoon characters), and sex of the smoker. The percentage of female compared to male cigar smokers steadily increased, with 25 percent of cigar images showing them in 1992 and 64 percent in 1998. These data indicated that the presence and portrayal of female cigar smokers increased significantly over the 7 years. The smokers included celebrities, such as actors and athletes.

### Selling Propositions

"Cigar benefits outweigh health effects." Three articles specifically examined and/or described the health effects noted or discussed in the cigar articles or advertising content. In a *Tobacco Control* Ad-Watch piece, Falit (1997) described the targeted marketing of cigars to adults aged 65+. Notably, older celebrities who appeared healthy, such as George Burns, were thought to "subtly undercut" any health dangers (Falit, 1997) (p. 241). Additionally, the awareness of health consequences of cigarette smoking, along with perceptions that cigars are less harmful (Falit, 1997) are speculated to have contributed to adult cigarette smokers' switch to cigars (Falit, 1997; Gerlach et al., 1997; NCI, 1998).

Wenger et al.'s (2001b) content analysis of *Cigar Aficionado* and *Smoke* examined the presence of environmental tobacco smoke (ETS) or scientific research and the health effects of premium cigars. Although health effects were not explicitly defined, the authors described and provided scientific

citations that reported the increased risk of cancer, heart, and pulmonary disease among cigar smokers (p. 279). Only 1 percent (n = 4) of the 353 articles focused primarily on health effects. The central theme of these four articles, all published in *Cigar Aficionado*, was that the purported benefits (e.g., pleasure, relaxation) outweighed the potential adverse health effects. Scientific research on cigar use was mentioned in 2 percent of the articles, and the majority of the evidence was described as "weak" and "flawed." ETS was mentioned in the context of smoking restrictions that denied "... smokers' rights" (p. 282), and the articles noted that scientific evidence on ETS health risks was considered "weak" or "contradictory" (p. 282). Finally, social events, including benefits to raise money for various health charities, were described. The authors purport that advertising these events markets the cigar industry as "socially responsible and supportive of good health while trivializing public health concerns about tobacco use" (p. 283).

Wenger et al. (2001a) coded for health risks (i.e., whether risks were mentioned, types of health effects mentioned, whether or how cigars were compared with cigarettes) in the advertisements. Of the 790 articles reviewed, health effects were the primary focus in 4 percent (35) but mentioned in 21 percent (169). Half (50 percent) of the articles portrayed cigars positively and minimized their health effects. Only 24 percent (41 of the 169) showed the health effects negatively. Fourteen percent of the articles compared the health effects to cigarette use, describing it as less harmful because cigars are consumed differently (i.e., without inhalation) and infrequently and contain fewer chemicals. These articles emphasized cigars being more socially acceptable than cigarettes, implying that they are part of a lifestyle.

"Cigars are a premium product." Shen et al. (2017) examined the unique selling propositions in 171 print tobacco ads collected between August 2012 and August 2013 from the consumer, Sunday, local, and Hispanic-targeted magazines (p. 4). Of those, 22 ads were for "cigar" products. The type of product was not specified, and the term "cigar" was not defined. Overall, the authors found that cigars were being promoted in the advertisements as a "premium product." The advertisements often promoted cigar use for special occasions and indicated that the products were often used by "sophisticated people" (pp. 7 and 17).

# Advertising Promotions and Selling Propositions for Non-Large-Cigar Products

While the peer-reviewed article described next focuses on non-largecigar products, such as cigarillos with brands like Black & Mild and

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Swisher Sweets, the advertising promotions and selling propositions for these products were similar to those reported in peer-reviewed articles examining premium cigar content. Rosario and Harris (2020) examined the messaging strategies of tobacco advertisements within an African American community, including for nonlarge cigars and their variation by tobacco product type. The advertisements were collected from 24 retail stores located in census tracts with more than 70 percent African Americans in Greensboro, North Carolina. Of the 165 ads examined, 33 (20 percent) featured nonlarge cigars. Misdirection of attention messages, which consisted of images and text that redirected consumers' focus from health risks toward positive product attributes, commonly appeared in the nonlarge-cigar ads, with 67 percent of ad content using this messaging strategy. Phrases such as "limited release," "enjoy," and "hand-rolled" were found, with these phrases used to potentially redirect focus from health facts to positive attributes and feelings. The second most common message strategy was reassurance, which sought to convince consumers that tobacco product use is safe despite its health risks. Of the ads, 18.2 percent contained content that was classified as reassurance. Phrases such as "The natural choice...," "Like sweets? Go natural," and "Natural leaf cigarillo" were used to convince consumers that non-large-cigar use is safe.

Similar to what has been documented for nonlarge cigars, premium cigar advertising content has also sought to shift consumers' focus from health risks to positive product attributes, including using premium cigars as an essential component of a successful or luxurious lifestyle. The content in *Cigar Aficionado* and *Smoke* reduces consumers' ambivalence about the health risks by including older celebrities who appear healthy.

### Summary and Conclusion

The committee's review of the literature found three studies published between 1997 and 2003 that specifically examined advertising content of premium cigar brands. Overall, these studies indicate that these were advertised and promoted as an integral component of a successful, luxurious lifestyle, used at "swanky" social events and by those influential celebrities and individuals. The articles noted that this "identity" was promoted in cigar lifestyle magazines, such as *Cigar Aficionado* and *Smoke*. Moreover, some content downplayed the health dangers of premium cigars compared to cigarettes and supported the perception of a safe substitution. Findings from the committee's systematic literature review and environmental scan of premium cigar content online suggest that the most pronounced selling propositions were that the benefits of cigar use outweighed their adverse health effects and that cigars are a premium or quality product.

Conclusion 4-4: Based on the 1998 NCI monograph on cigars, subsequent publications, the committee's primary data collection, and consistent with research on the "premiumization" of tobacco products that purport better quality and less harm, there is **conclusive evidence** that **premium cigars** are advertised and promoted as less harmful than other tobacco products and as having benefits that outweigh their adverse health effects. Premium cigars are also marketed as an integral component of a successful, luxurious lifestyle, used at upscale social events, and by influential celebrities and individuals.

#### SALES

Cigar sales data provide insight into where and how cigars are sold and in what quantities. Consistent with consumption data reported in Chapter 3, sales data from the Alcohol and Tobacco Tax and Trade Bureau (TTB) report that the total number of cigars (large and small) increased from 5.95 billion in 2002 to 10.14 billion in 2012, and per capita cigar sales also increased 6.4 percent annually (Agaku and Alpert, 2016). Notably, the market share for large cigars increased steeply between 2009 and 2012 to reach 93.1 percent during 2012 (Agaku and Alpert, 2016); these estimates include a range of large cigar products, including premium cigars. This increase did not match the prevalence of current cigar smoking by U.S. adults between 2002 and 2012, which remained constant (5.4 and 5.6 percent, respectively) (Agaku and Alpert, 2016).

Another source of sales data is point-of-sale retail tracking. Between 2012 and 2016, Nielsen data from convenience stores and all other outlets showed that cigar sales increased 29 percent in the United States overall (Gammon et al., 2019). During this time frame, this was largely driven by the 78 percent increase in cigarillo sales, from an average monthly sale of 0.432 to 0.768 per capita. In contrast, large cigars decreased by 42 percent (average monthly sale of 0.132 to 0.076 cigars per capita) and little cigars decreased by 20 percent (average monthly sale from 0.52 to 0.42 per capita) (Gammon et al., 2019).

# **Premium Cigar Sales**

Data from TTB (see Chapter 3) suggest that the percentage of the cigar market that may be premium was 1.5–3.0 percent between 2010 and 2020, with the majority of the market composed of large cigars (which include filtered cigars, cigarillos, and larger traditional cigars).

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Few studies have documented the venues through which premium cigars are sold and whether these venues are captured in existing retail surveillance. Studies on sales of large cigars, generally, have identified smoke shops/tobacco specialty or outlet stores (Corey et al., 2018), convenience stores (Corey et al., 2018), pharmacies (Seidenberg et al., 2013), and Internet vendors (Williams and Derrick, 2018). Only one study, conducted in 2013-2014, documented purchasing behaviors of adults who smoke traditional cigars (premium and nonpremium), providing greater insight into differences in their sales among cigar users (Corey et al., 2018). Premium cigar users were less likely to usually buy their cigars in person (77.6 percent premium versus 96.7 percent nonpremium) (Corey et al., 2018). Of those who usually did so, they identified smoke shop/ tobacco specialty or outlet store (46.8 percent), cigar bars (29.9 percent), convenience store/gas station (18.2 percent), and somewhere else (5.1 percent) as the places where they purchase tobacco products most of the time (Corey et al., 2018). In comparison, nonpremium cigar users reported convenience store/gas station (78.5 percent) and smoke shop/tobacco specialty or outlet store (18.4 percent) (Corey et al., 2018). Premium cigar users were least likely among all cigar users to identify "they are affordable" as a reason for cigar smoking (22.7 percent premium versus 66.4 percent nonpremium) (Corey et al., 2018).

An analysis commissioned by the committee of data from the 2016–2017 PATH Wave 4 provides updated estimates on purchasing behavior for adults who smoke traditional cigars (premium and nonpremium), cigarillos, filtered cigars, and cigarettes (see Table 4-5) (Jeon and Mok, 2022). These updated estimates show that people who smoke premium and nonpremium cigars were equally likely to usually buy in person (76.4 percent versus 84.0 percent nonpremium). Of those, premium cigar users identified cigar bars (35.4 percent) as the most common place, followed by smoke shop/tobacco specialty or outlet store (44.3 percent). In comparison, nonpremium cigar users reported convenience store/gas station (64.5 percent). Approximately two-thirds (71.5 percent) of premium cigar users usually purchased a single cigar at a median price of \$7.00 per stick. Similar to the Corey et al. (2018) findings from 2013 to 2014, data from 2016–2017 support that only few people who use premium cigars identify affordability as a reason for use (30.2 percent).

Data submitted to the committee evaluated transaction-level data from five major online cigar retailers in 2017, identifying approximately four million online orders in 2017 by more than one million unique

Smokers, PATH Study Wave 4, 2016–2017						
	Premium cigars ( <i>n</i> = 336)	Nonpremium cigars ( <i>n</i> = 237)	Cigarillos ( <i>n</i> = 918)	Filtered cigars (n = 440)	Cigarettes $(n = 8,590)$	
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	
Has a regular brand	38.4 (31.8–45.4)	73.8 (65.3–80.9)	74.8 (70.2–78.8)	68.0 (59.8–75.4)	92.5 (92.0–93.1)	
Top 5 brands smoked	Cohiba 20.3	Black & Mild 23.6	Black & Mild 51.0	Black & Mild 20.7	Marlboro 34.2	
	(14.0–26.4)	(16.0–31.2)	(46.8–55.2)	(14.8–26.7)	(32.6–35.9)	
	Arturo Fuente 17.9	Acid 12.7	Swisher Sweets 21.1	Cheyenne 18.5	Newport 15.9	
	(11.4–24.5)	(8.0–17.5)	(16.9–25.4)	(12.3–24.8)	(14.6–17.2)	
	Romeo y Julieta 7.8	Dutch Mas- ters 11.8	Backwoods 5.3	Swisher Sweets 7.6	Camel 10.8	
	(4.1–11.5)	(6.6–17.1)	(3.5–7.1)	(4.8–10.4)	(9.8–11.7)	
	Montecristo 6.7	Swisher Sweets 11.6	White Owl 5.0	305′s 7.3	Pall Mall 7.0	
	(4.0–9.3)	(7.7–15.5)	(3.0–7.0)	(2.8–11.8)	(6.1–7.8)	
	Macanudo 5.2	White Owl 5.9	Dutch Mas- ters 2.4	Djarum 6.5	American Spirit 3.6	
	(2.8–7.6)	(3.1-8.7)	(1.0-4.0)	(4.8-8.2)	(3.2-4.0)	
Regular brand flavored or mentholated	7.6 (5.5–10.5)^	50.3 (38.3– 62.3)	55.7 (50.4– 60.9)	48.4 (41.2–55.7)	38.4 (36.8–40.0)	
Usually buy in person	76.4 (69.3– 82.3)	84.0 (74.9– 90.3)	92.5 (89.9– 94.5)	90.0 (85.5–93.1)	94.9 (94.4–95.4)	
Where buy tobacco product						
Cigar bar	35.4 (28.4– 43.1)	*	*	*	NA	

**TABLE 4-5** Tobacco Product Characteristics and Purchasing Behaviors Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study Wave 4, 2016–2017

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	Premium cigars (n = 336)	Nonpremium cigars ( <i>n</i> = 237)	Cigarillos $(n = 918)$	Filtered cigars (n = 440)	Cigarettes ( <i>n</i> = 8,590)
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Convenience store/gas sta- tion	*	64.5 (57.4– 71.0)	85.2 (81.8– 88.1)	73.7 (68.6–78.3)	88.1 (87.2–88.9)
Smoke shop/to- bacco specialty or outlet store	44.3 (35.2– 53.8)	*	11.3 (9.0–14.2)	22.1 (18.4–26.2)	10.0 (9.0–11.2)
Somewhere else	*	*	*	*	1.9 (1.3–2.6)
Usual purchase size					
Single	71.5 (66.7– 75.9)	41.9 (35.1– 49.0)	52.1 (48.4– 55.8)	79.4 (74.4–83.7)	2.5 (2.1–2.9)
Box or pack	28.5 (24.1– 33.3)	58.1 (51.0– 64.9)	47.9 (44.2– 51.6)	20.6 (16.4–25.6)	83.3 (82.0–84.5)
Carton	NA	NA	NA	NA	14.2 (13.1–15.4)
Price per stick (median, IQR)	\$7.00 (4.00–10.00)	\$1.07 (0.71–2.00)	\$1.00 (0.66–1.08)	\$0.11 (0.07–0.26)	\$0.30 (0.25–0.35)

#### **TABLE 4-5**Continued

NOTES: PATH = Population Assessment on Tobacco and Health

\* = The estimate has been suppressed because it is statistically unreliable. It is based on a (denominator) sample size of less than 50, or the relative standard error of the estimate (or its complement) is larger than 30 percent.

 $^{+}$  = PATH included 8.9 percent of premium cigar smokers who reported that their regular brand was flavored or mentholated. In the committee's working definition of premium cigars (see Chapter 1), they are not flavored. Thus, the definition used for PATH does not necessarily reflect that used by the committee.

SOURCE: Jeon and Mok, 2022.

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customers across 54,554 stock keeping units (SKUs).<sup>14</sup> The average number of cigar SKUs per retailer was 10,911, highlighting the diversity of products offered. The majority of these orders (3.6 million) included premium cigars: 125,314,590 sold across 51,123 SKUs. The average number of cigars per order was 34.6, at an average price of \$3.00 per; the average amount per order was \$61.26.15 Premium cigar sales from these five online retailers in 2017 totaled \$376.6 million. The majority of premium cigars sold in 2017 were not in sampler packs that include more than one type of cigar (87 percent). Data provided by some of the retailers for other years (2014–2018) also show that most premium cigar orders are for boxes of five or more cigars (95 percent) without single cigars or multipacks (2-4 cigars); more than 60 percent of orders included only one or two brands.<sup>16</sup> Online cigar sales also exhibit seasonality, with the lowest purchases in January and February and peak purchasing during the summer months.<sup>17</sup> Using the TTB data for large cigars, Class H (see Table 3-1), as the denominator (380,000,000 sticks consumed in 2017), these data suggest that approximately 33 percent of premium cigars were purchased online in 2017. Survey data do not currently capture online purchasing behavior in premium cigar users. PATH only asks about where cigars are usually purchased for those who purchase in stores.

Data from these online retailers across 2014–2018 also allowed for exploration of demographics of premium cigar purchasers through age verification and geocoding of 80 percent of purchaser addresses to census tracts. Based on age verification for 83 percent of these orders, the mean age was 55.3; more than half (54 percent) of purchasers were over the age of 55, and approximately one-third (34 percent) were 35–54.<sup>18</sup> The median household income in the census tracts of online premium cigar purchasers (\$65,573) was higher than the U.S. median household income (\$57,617); 15 percent of them live in a census tract with a median household income above \$100,000, compared with 10 percent in the U.S. population overall.<sup>19</sup> More than 20 percent of them live in census tracts where more than 50 percent of the population aged 25 and older has a bachelor

- <sup>16</sup> Ibid.
- <sup>17</sup> Ibid.
- <sup>18</sup> Ibid.
- <sup>19</sup> Ibid.

<sup>&</sup>lt;sup>14</sup> This paper was prepared for the Cigar Association of America, Inc., Cigar Rights of America, and the International Premium Cigar and Pipe Retailers Association by Richard P. Voith and Peter Angelides at Econsult Solutions, Inc. The full report is available in the project public access file and by request from the National Academies Public Access Records Office at PARO@nas.edu.

<sup>&</sup>lt;sup>15</sup> Ibid.

degree compared with 15 percent in the U.S. population.<sup>20</sup> Limitations of this study include that it was limited to sales from large, online retailers; customer demographics are based on census tract data, not actual customer demographics; and no unique customer identification numbers were included, so individuals cannot be tracked across vendors to ensure unique customers across retailers (Voith, 2021).

## Summary and Conclusion

Based on the committee's examination of cigar sales data from TTB and Nielsen, published and commissioned analyses from PATH (see Appendix D), and data submitted by the Cigar Association of America on major online cigar retailer transactions in 2017, the committee concludes:

Conclusion 4-5: There is **strongly suggestive evidence** from survey data that consumers of **premium cigars** who buy in person typically purchase their cigars from cigar bars or smoke/tobacco specialty shops or outlet stores, whereas **nonpremium large traditional cigar** users typically purchase their cigars at convenience stores/gas stations. A lower proportion of premium cigar users buy their cigars in person than nonpremium large traditional cigar users. Data from online cigar retailers shows that a large proportion of premium cigar sales occur online, though this is not directly captured in current surveys of cigar users.

### Premium Cigar Retailer Density

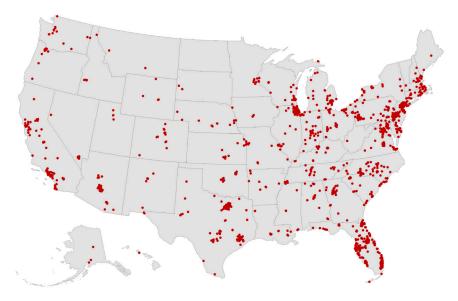
An exploratory analysis commissioned by the committee (Kong, 2022) mapped U.S. retailers registered with the PCA to better understand the distribution of brick-and-mortar retail venues throughout the country. To be included in these analyses, retailers had to 1) be located in the United States, 2) have a valid address, and 3) currently be open upon review of the address.<sup>21</sup> PCA provided the committee with a retailer-level dataset that included current members in 2019–2021, with all physical brick-and-mortar retailers with necessary state tobacco licensing and where the majority of sales were for premium cigars or pipe tobacco; retailer types, such as convenience stores, hookah/head shops, and vape stores, were excluded. The original dataset included 1,316 unique retailers. However, upon review of the address fields and states, 25 retailers were removed, leaving 1,291. All premium cigar retailers were spatially joined to their respective census tract and corresponding sociodemographic data to

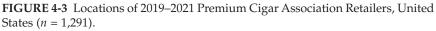
<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Not every address was reviewed.

explore the density of premium cigar retailers and the characteristics of census tracts in which they were present. Figure 4-3 shows the distribution of premium cigar retailers across the United States.

Table 4-6 shows the total count and density of PCA retailer members by state. All states except two (North Dakota and Vermont) had premium cigar retailers, ranging from 1 in West Virginia to 220 in Florida. The density per 1,000 residents of outlets in states with at least 1 retailer ranged from 0.96 in Iowa to 25.1 in Delaware. Examination of data at the census tract level found that premium cigar retailers were present in a small proportion (1.7 percent) of tracts, with a median density of 0.0 retailers per 1,000 people and a maximum density of 8.2. Census tracts with a higher percent of non-Hispanic white residents had greater odds of having at least one (versus none) retailer (OR: 1.06; 95 percent CI: 1.03–1.09). In contrast, tracts with a higher percent of Black (OR: 0.92; 95 percent CI: 0.88–0.96) and Hispanic/Latino/Latina (OR: 0.90; 95 percent CI: 0.84–





NOTE: Supplemental materials available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

SOURCE: Kong, 2022.

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State	Count	Total Population	Density per 1,000,000 Residents
Alabama	17	4,876,250	3.49
Alaska	3	737,068	4.07
Arizona	40	7,050,299	5.67
Arkansas	13	2,999,370	4.33
California	70	39,283,497	1.78
Colorado	15	5,610,349	2.67
Connecticut	11	3,575,074	3.08
Delaware	24	957,248	25.07
District of Columbia	4	692,683	5.77
Florida	220	20,901,636	10.53
Georgia	29	10,403,847	2.79
Hawaii	3	1,422,094	2.11
Idaho	6	1,717,750	3.49
Illinois	60	12,770,631	4.70
Indiana	35	6,665,703	5.25
Iowa	3	3,139,508	0.96
Kansas	12	2,910,652	4.12
Kentucky	23	4,449,052	5.17
Louisiana	11	4,664,362	2.36
Maine	2	1,335,492	1.50
Maryland	27	6,018,848	4.49
Massachusetts	17	6,850,553	2.48
Michigan	32	9,965,265	3.21
Minnesota	8	5,563,378	1.44
Mississippi	6	2,984,418	2.01
Missouri	19	6,104,910	3.11
Montana	3	1,050,649	2.86
Nebraska	13	1,914,571	6.79
Nevada	15	2,972,382	5.05
New Hampshire	14	1,348,124	10.38
New Jersey	31	8,878,503	3.49
New Mexico	6	2,092,454	2.87

**TABLE 4-6** Total Count and Retailer Density of 2019–2021 PremiumCigar Association Member Retailers by State, United States

continued

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State	Count	Total Population	Density per 1,000,000 Residents
New York	39	19,572,319	1.99
North Carolina	53	10,264,876	5.16
North Dakota	0	756,717	-
Ohio	34	11,655,397	2.92
Oklahoma	16	3,932,870	4.07
Oregon	13	4,129,803	3.15
Pennsylvania	84	12,791,530	6.57
Rhode Island	8	1,057,231	7.57
South Carolina	25	5,020,806	4.98
South Dakota	2	870,638	2.30
Tennessee	31	6,709,356	4.62
Texas	104	28,260,856	3.68
Utah	4	3,096,848	1.29
Vermont	0	624,313	-
Virginia	50	8,454,463	5.91
Washington	13	7,404,107	1.76
West Virginia	1	1,817,305	0.55
Wisconsin	20	5,790,716	3.45
Wyoming	4	581,024	6.88

## TABLE 4-6 Continued

NOTE: Supplemental materials available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu. SOURCE: Kong, 2022.

0.96) residents had lower odds of having at least one retailer. Findings from these analyses support that while the majority of census tracts do not have a retailer, density varies widely at the state level.

# Summary Finding

Based on the committee's 1) review of the literature on cigar sales; 2) analysis of data on consumer purchasing behavior; and 3) analysis of data on premium cigar retailers, it finds:

Finding 4-2: Large cigar retail outlets include smoke shops/tobacco specialty or outlet stores, convenience stores (Corey et al., 2018), pharmacies, and Internet vendors. Premium cigar users report purchas-

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ing their cigars primarily in cigar bars and smoke shops/tobacco specialty or outlet stores. Data from online retailers suggest that a large proportion of premium cigar sales occur online, but this is not currently captured in national surveys of cigar users. Data provided to the committee show that all but two U.S. states have a physical premium cigar retailer and the density of premium cigar retailers varies by state, with some states having a significantly higher density of shops than others; there are no data on the location or sale of premium cigars in cigar bars. Based on an exploratory analysis, premium cigar retailers are more likely to be present in census tracts with a higher percentage of white residents; premium cigar purchasers are more likely to reside in census tracts with higher median income and education compared to the general population.

### AWARENESS, KNOWLEDGE, AND BELIEFS

Consumers' uptake of the use of tobacco products occurs through a series of steps, from initial awareness, to knowledge of the product and its features, to formulating beliefs, such as perceived risks, to trial and sustained use (Rees et al., 2009). Consumers' awareness, knowledge, and beliefs can be influenced by factors characterized elsewhere in this chapter and this report, such as advertising and marketing, point-of-sale availability, and product characteristics (see Chapter 2) (Rees et al., 2009). Beliefs such as risk perceptions (i.e., people's thoughts and feelings about risks) are central to numerous health behavior theories and have been the focus of decades of tobacco research (Kaufman et al., 2020a; Kaufman et al., 2020b; Slovic, 2001). Risk perceptions are also often the targets of interventions to prevent and reduce tobacco use (Kaufman et al., 2020b), such as required health warning labels on tobacco packaging/marketing and mass media campaigns designed to raise awareness about the risks. This section reviews the evidence on consumers' awareness of premium cigars, knowledge, risk perceptions, and other perceptions, such as perceived benefits and reasons for use, and on how beliefs such as risk perceptions relate to patterns of use of premium cigars and other forms of tobacco.

#### Awareness

Researchers have examined awareness of tobacco products, including various types of cigars, in U.S. adults and youth. These studies use data from population-based surveys, such as PATH, or other population-based data sources.

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## Adults

Weaver et al. (2016) assessed awareness by asking participants if they had ever heard of various tobacco products, including "large, premium cigars," before the survey. Overall, 90.5 percent of U.S. adults were aware of large premium cigars, and awareness did not differ significantly among never, current, and former cigarette smokers. For comparison, 87.3 percent of adults were aware of little cigars/cigarillos, 93.8 percent were aware of traditional smokeless tobacco (i.e., chew, snuff, dip), and 91.9 percent were aware of e-cigarettes.

Fong et al. (2019) report awareness of tobacco products among U.S. adults in 2013–2014, assessed using product images to clarify products of reference to participants. Overall, 66 percent of U.S. adults were aware of "traditional cigars" (see Table 4-7 for the percentages of U.S. adults who were aware of other types of tobacco products).

Nayak et al. (2017) report data on awareness of tobacco products (see also Weaver et al., 2016)) among lesbian, gay, and bisexual (LGB) adults compared to heterosexual adults. They did not report raw data for awareness, but the data indicate that awareness of traditional/large cigars was near or exceeded 90 percent and was comparable in heterosexual and LGB adults. This was similar for all tobacco products assessed.

# Youth

Kasza et al. (2017) report data on tobacco product awareness among U.S. youth in 2013–2014; 40.1 percent reported awareness of traditional cigars (see Table 4-7 for the percentages of U.S. youth who were aware of other types of tobacco products). For all tobacco products assessed, including traditional cigars, only age groups were reported. Awareness was higher for all products among those aged 15–17 than 12–14 years.

# **TABLE 4-7** Awareness of Tobacco Products Among U.S. Adults andYouth, 2013–2014 (%, 95% CI)

	Adults	Youth
Traditional cigars	66.0 (65.2–66.9)	40.1 (39.0–41.3)
Cigarillos and filtered little cigars	81.6 (80.6–82.5)	46.2 (45.1–47.3)
Traditional smokeless tobacco	81.6 (80.9–82.3)	75.9 (75.0–76.9)
E-cigarettes	85.7 (84.9–86.3)	89.5 (88.8–90.3)

SOURCES: Fong et al., 2019; Kasza et al., 2017.

### Summary on Awareness of Premium Cigars

Only one study provides data on U.S. adults' awareness of premium cigars, and research on youth awareness is less available. Some studies used measures that capture awareness of cigar products that likely include premium cigars, such as "large cigars" and "traditional cigars." These studies have heterogeneity in measurement that likely contributes to variation in estimates of awareness. For example, estimates of awareness among U.S. adults from PATH that characterized "traditional cigars" and used product images to aid in measurement are lower than other population-based data collected around the same time using different measurement methods (e.g., Weaver et al., 2016). Noting these limitations, the available evidence suggests that awareness of cigar products that likely include premium cigars (e.g., large cigars, traditional cigars) is high among U.S. adults, that it is lower among youth than adults, and that youth awareness increases with age. Evidence is limited on whether awareness varies by sociodemographic and tobacco-related characteristics among adults or youth. Available data are limited to adults and suggest no substantial variability in awareness by cigarette smoking status (Weaver et al., 2016) and in LGB adults compared with heterosexual adults (Navak et al., 2017).

From a research perspective, more specific measures are needed that distinguish premium cigars to capture awareness in the U.S. population. For example, PATH research using images to clearly depict different product types (e.g., premium cigars, nonpremium cigars, little filtered cigars, cigarillos) may help improve assessment of awareness.

#### Knowledge

No research directly examines consumers' knowledge of what are, or what defines, premium cigars and what makes them distinct from other types of cigars. Some small, observational studies with convenience samples provide suggestive evidence about consumers' knowledge of premium cigars

#### Adults

In Casseus et al. (2016), participants (self-identified cigarette smokers) were shown photos of tobacco products without packaging and asked to identify whether it was a cigarette, little cigar, cigarillo, cigar, or roll-yourown (RYO) cigarette. The products did not include premium cigars. Overall, variability was noted in the proportion of participants who identified cigar products as cigarettes and those who indicated that they were little

cigars, cigarillos, or cigars, including by sex and age. The results suggest adult cigarette users are likely to misclassify cigar products.

Dickinson et al. (2016) report data from focus groups conducted in five U.S. cities in 2014. Adults who used cigars, cigarillos, and little cigars were included. Participants were shown pictures of cigar products and asked how they identify them. Overall, use of brand names was common. Participants were most likely to identify the picture of a large/traditional cigar as a "cigar": however, they also used brand names (e.g., Cohiba), and some referred to large/traditional cigars as "blunts." Little cigars, tipped cigarillos, and untipped cigarillos were predominantly identified by brand names and also as "blunts." Little filtered cigars were most consistently misidentified as cigarettes, and many participants did not consider little filtered cigars, tipped cigarillos, and untipped cigarillos to be cigars. Finally, participants were asked whether they considered cigar users to be "smokers." Most preferred the term "cigar smoker," and others indicated that they would only use the label if they smoked several times a week or daily. Participants reported little cigars and cigarillos to be more common daily use products and large/traditional cigars as something for leisure time or special occasions. They were less likely to view large/traditional cigar users as "smokers." Participants had mixed responses on whether inhaling the smoke means someone is a smoker and the connotations of the term (e.g., negative connotations associated with cigarette smoking).

# Youth

Yerger et al. (2001) report data from focus groups conducted with Black/African American youth on understanding of cigar products and cigar use. The groups included cigar users and nonusers (the types of cigars used by participants were not specified), but results are reported for all participants combined. The findings indicate that youth had three distinct ways of referring to cigars, describing larger, premium-type cigars as "cigars"; however, participants rarely used these, viewing them as primarily used by older, wealthier people. Other types of cigars were predominantly referred to by brand, such as "Black & Milds." "Blunt" was used solely for cigars used for smoking cannabis. The participants were a small, nongeneralizable sample, but the results suggest that the youth studied associate products that likely include premium cigars with older, adult smokers.

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### Summary on Knowledge of Premium Cigars

No research has directly examined consumers' knowledge of what premium cigars are, what distinguishes them from other types of cigars, or their health effects. Studies have used convenience samples and qualitative methods to examine views on cigar products and terminology used to describe them. None have specifically investigated if and how consumers identify or distinguish "premium" cigars. This is a research gap that would need to be filled to better understand consumers' knowledge of premium cigars and how they view them relative to other cigar products.

#### Beliefs

#### Perceived Risks

Several studies have investigated perceived risks of cigars among U.S. adults and youth, including comparisons with other tobacco products and examining if perceived risks vary by population groups. Most of these do not detail specific health risks caused by cigarette or other tobacco use but assess perceived health harm of the product alone (absolute harm) and in comparison to a standard reference product, typically cigarettes (relative harm). Many of these studies used population-based data representative of the United States, such as from PATH.

**Adults** Fong et al. (2019) report perceived risks of noncigarette tobacco products relative to cigarettes among U.S. adults using data from PATH Wave 1 (2013–2014; n = 32,320). Perceived relative harm was measured as whether participants viewed traditional cigars, cigarillos, filtered cigars, traditional smokeless tobacco (chew, snuff, dip), and e-cigarettes as less harmful than, about the same as, or more harmful than cigarette smoking or whether they did not know. These data are shown in Table 4-8. For all products except e-cigarettes, the majority of adults viewed them to be about the same as or more harmful than cigarettes. The largest proportion of adults viewed e-cigarettes to be less harmful (40.7 percent), followed by traditional cigars<sup>22</sup> (12.1 percent).

Multivariable analyses examined demographic and tobacco-related factors associated with the perception that traditional cigars are less harmful than cigarettes. The findings are shown in Table 4-9.

Corey et al. (2018) reported data from PATH Wave 1 on smoking patterns, purchasing behaviors, and reasons for use, including perceived

<sup>&</sup>lt;sup>22</sup> Traditional cigars were defined as "contain[ing] tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others" (Fong et al., 2019).

	Less harm	About the same	More harm	Don't know
Traditional cigars	12.1 (11.5– 12.8)	61.7 (60.6– 62.8)	23.9 (22.8– 24.9)	2.3 (2.0–2.6)
Cigarillos	7.1 (6.7–7.6)	70.7 (70.0– 71.5)	19.8 (19.1– 20.5)	2.4 (2.1–2.7)
Filtered cigars	7.6 (7.2–8.0)	75.5 (74.8– 76.3)	14.5 (13.9– 15.2)	2.3 (2.0–2.7)
Traditional smokeless tobacco	8.6 (8.1–9.1)	60.9 (60.0– 61.7)	27.6 (26.8– 28.4)	3.0 (2.7–3.4)
E-cigarettes	40.7 (39.8– 41.5)	47.3 (46.6– 48.0)	6.9 (6.4–7.3)	5.1 (4.7–5.6)

**TABLE 4-8** Perceived Harm of Noncigarette Tobacco ProductsRelative to Cigarettes Among U.S. Adults, 2013-2014 (%, 95% CI)

SOURCE: Fong et al., 2019.

risks by cigar type among U.S. adults. Information including brand and other characteristics (such as price) was used to categorize smokers' usual brand as filtered cigar, cigarillo, or traditional cigar, which was further categorized as premium or nonpremium. Overall, comparable proportions of premium cigar, nonpremium cigar, cigarillo, and filtered cigar smokers indicated that cigars may be less harmful than cigarettes (see Table 4-10).

These estimates differed by cigarette smoking status. Across the four cigar products, the proportion of cigarette smokers indicating that cigars may be less harmful was the lowest for current and higher among former and never-cigarette smokers (see Table 4-11).

Analyses of Waves 2-5 of the PATH data commissioned for this report (see Appendix D) indicate some variability from year to year. For example, the proportion of premium cigar smokers indicating that cigars may be less harmful than cigarettes was 32.1 percent at Wave 2, 25.2 percent at Wave 3, 16.5 percent at Wave 4, and 36.9 percent at Wave 5 (Jeon and Mok, 2022). The variability may be attributable in part to methodological issues, such as attrition, in subsequent waves; it may also reflect the timing of survey completion, given potential seasonality in cigar use.

Wackowski and Delnevo (2016) assessed tobacco use behavior (cigarette smoking; menthol cigarette use; past 30-day use of cigars, smokeless tobacco, and waterpipe; and ever use of e-cigarettes) and perceived harm of cigars, e-cigarettes, waterpipe, snuff, dip, chew, snus, and menthol cigarettes relative to cigarettes in U.S. young adults. The measures excluded filtered little cigars but included large cigars and cigarillos. Young adults were more likely to indicate that e-cigarettes (57.8 percent) and waterpipe (24.5 percent) were less risky than they were to indicate that cigars

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Comparison	Categories	Odds Ratio (95% CI)
Men vs. women		2.17 (1.88–2.51)
	Associate's degree	1.60 (1.05–2.44)
Higher education vs. those with < high school education	Bachelor's degree	1.95 (1.21–3.07)
	Master's degree+	1.66 (1.12–2.47)
Higher household income vs. those with	\$75,000-\$99,999	1.48 (1.13–1.95)
<\$10,000 household income	\$100,000+	1.66 (1.28–2.16)
Current or former tobacco user vs. never-	Current	2.36 (1.87–2.99)
tobacco user	Former	1.88 (1.47–2.42)
Less knowledge of the health risks of smoking overall		1.13 (1.09–1.17)
Current traditional cigar use		3.25 (2.84-3.73)

**TABLE 4-9** Demographic and Tobacco-Related Factors Associated with the Perception That Traditional Cigars Are Less Harmful Than Cigarettes

SOURCE: Fong et al., 2019.

# **TABLE 4-10** Cigar Smokers Indicating that Cigars May Be Less Harmful Than Cigarettes

Cigar smoker type	(%, 95% CI)	
Premium cigar smokers	31.4 (26.0–36.7)	
Nonpremium cigar smokers	27.1 (22.7–31.5)	
Cigarillo smokers	24.5 (21.9–27.1)	
Filtered cigar smokers	27.7 (23.4–32.1)	

SOURCE: Corey et al., 2018.

# **TABLE 4-11** Perception That Cigars May Be Less Harmful Than Cigarettes by Cigarette Smoking Status (%, 95% CI)

	Premium Cigars	Nonpremium Cigars	Cigarillos	Filtered Cigars
Current cigarette smokers	14.1 (6.0–22.1)	20.7 (15.9–25.9)	17.8 (14.6–21.0)	23.3 (18.0–28.6)
Former cigarette smokers	37.9 (28.0–47.8)	36.2 (23.2–49.2)	31.0 (23.2–49.2)	44.8 (31.5–58.1)
Never-cigarette smokers	39.3 (31.5–47.0)	36.7 (26.4–47.0)	34.6 (29.6–39.7)	32.6 (22.3–42.9)

SOURCE: Corey et al., 2018.

(13.9 percent), menthol cigarettes (2.5 percent), and traditional smokeless tobacco (7.1 percent) were. They were also more likely to indicate that cigars are less risky than cigarettes compared to traditional smokeless tobacco, snus, and menthol cigarettes. In adjusted models, men were more likely than women, Black and Hispanic young adults were less likely than white young adults, and those with more than high school education were more likely to perceive cigars to be less risky than cigarettes.

Smith et al. (2007) report data from a sample of college students assessing perceived risks relative to cigarettes (less harmful, as harmful/ more harmful) for nicotine patch, nicotine gum, nicotine water, nicotine lollipop, nicotine inhaler, ultra-light cigarettes, waterpipe, light cigarettes, cigarillos, cigars, and smokeless tobacco along with demographic and tobacco-related predictors of perceived risks. Overall, 80.4 percent of participants perceived a nicotine patch to be less harmful, 75.9 percent for nicotine gum, and 47.1 percent for a nicotine inhaler. Overall, 40.4 percent of participants perceived ultra-light cigarettes were less harmful, 37.0 percent for a waterpipe, 35.2 percent for light cigarettes, 17.4 percent for cigarillos, and 16.9 percent for cigars. Although perceptions of some nicotine and tobacco products assessed varied by demographic and tobacco-related characteristics, there were no differences based on these variables for perceptions of cigars.

In a second paper, Smith-Simone et al. (2008) reported psychosocial profiles, including perceived risks, associated with cigarette smoking, waterpipe tobacco use, and cigar smoking. In multivariable models, lower perceived likelihood of sickness from cigar smoking was associated with ever and current (past 30 day) cigar smoking, and lower perceived likelihood of addiction was associated with current cigar smoking. Although different perception items were associated with use of cigarettes and waterpipe, the general patterns were consistent across these three products (i.e., lower perceived risks, higher likelihood of use).

**Groups of adults** Campbell et al. (2019) surveyed adult patients enrolled in addiction treatment centers on demographics, tobacco use, and perceived risks; 77 percent were cigarette smokers, 8.3 percent were cigar smokers, 15.3 percent were little filtered cigar/cigarillo users, 11.4 percent were smokeless tobacco users, and 26.3 percent were e-cigarette users. Perceived risks were measured using a third-person scenario in which participants were asked to estimate the risks (0–100 percent chance) of lung cancer, having trouble breathing, and having a heart attack from cigarette smoking, and cigar, little filtered cigar/cigarillo, smokeless tobacco, and e-cigarette. Responses were averaged by product to create an overall score. Average perceived risks were 61.8 for cigarettes, 58.8 for cigars, 58.4 for little filtered cigar/cigarillos, 41.6 for smokeless tobacco, and 40.0

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for e-cigarettes. Health risk perceptions were only associated with current e-cigarette use (higher perceived risk, lower odds of use) in analyses adjusting for demographics and treatment program type.

**Youth** Strong et al. (2019b) measured risk perceptions as "How much do you think people harm themselves when they use [product]?" For some products, two other items measured "How long do you think someone has to use [product] before it harms their health?" and "Is using [product] less harmful, about the same, or more harmful than smoking cigarettes?" Another question assessed perceived addictiveness as "How likely is someone to become addicted to [product]?"

In this analysis, all cigar types were combined. Harm perceptions were combined into a composite index, with higher scores (range 1-3) reflecting greater perceived harm. Overall scores were highest for cigarettes (mean 2.79), followed by pipe tobacco (mean 2.50), smokeless tobacco (mean 2.49), cigars (mean 2.47), waterpipe (mean 2.22), and e-cigarettes (mean 1.95). Statistically, compared with smokeless tobacco, youth perceived cigars, waterpipe, and e-cigarettes as significantly less harmful. For cigars, perceived harm was associated with age and race and ethnicity: older youth (14–15, 16–17) perceived lower harm than younger (12–13) youth, and Black youth perceived lower harm than non-Hispanic white, Hispanic, and other non-Hispanic youth. For perceived addictiveness (score range 1-5; higher is more addictive), scores were highest for smokeless tobacco (mean 4.33), followed by cigarettes (mean 4.09), pipe tobacco (mean 4.07), cigars (mean 3.99), waterpipe (mean 3.99), and e-cigarettes (mean 3.60). Perceived addictiveness of cigars was lower among youth who were older (14-15 and 16-17 versus 12-13) and male and female respondents.

Strong et al. (2019b) also analyzed perceived harm and addictiveness relative to youth susceptibility to using each product and tobacco use behavior. For cigars, compared with never-users, those who were susceptible, those who had ever tried but had not used cigars in the past 30 days and those who had used cigars in the past 30 days endorsed significantly lower perceived harm and perceived addictiveness. Moreover, compared with never-users, those who had smoked cigarettes only, smoked cigarettes and used one or more other tobacco product, or used noncigarette combustible tobacco reported significantly lower perceived harm of cigars. Compared with never-tobacco users, all youth tobacco user groups reported significantly lower perceived addictiveness of cigars. Despite some variability, these associations were relatively consistent across perceived harm and addictiveness of tobacco products examined (i.e., susceptible youth and youth tobacco users tend to perceive tobacco products as less harmful and addictive).

Parker et al. (2018) analyzed risk perceptions among youth in an analysis similar to Strong et al. (2019b), but risk perception measures were not combined in an index. Absolute harm was measured as "How much do you think people harm themselves when they smoke/use [product]?" The findings are in Table 4-12. Overall, 30.6 percent of youth indicated that cigars were more harmful than cigarettes, and 11.5 percent indicated that they were less harmful. These proportions are similar to smokeless tobacco and pipes, but more youth reported that waterpipe and e-cigarettes are less harmful than smoking compared with cigars.

# Summary of Cross-Sectional Studies of Perceived Risks

The evidence suggests that most U.S. youth and adults perceive cigar products that likely include premium cigars to be harmful and addictive. However, the same measurement limitations noted for awareness (particularly for PATH) apply to these findings. Studies measuring perceptions of cigars typically lump cigar products together or at best define "traditional cigars" or "large cigars," which likely include but are not limited to premium cigars. Only one study differentiated risk perceptions by U.S. adults who smoke premium cigars, nonpremium cigars, cigarillos, and filtered cigars (Corey et al., 2018). Future research must improve the measurement of risk perceptions, including using more specific measures that follow expert recommendations for risk perception measurement (Kaufman et al., 2020a; Kaufman et al., 2020b) and measures that distinguish perceptions of premium and other cigars.

Despite these limitations, the available evidence indicates that most U.S. adults perceive that cigars have associated risks of health harm and addiction similar to those of cigarette smoking. Among adults, men, those with higher education, current cigar users, and former tobacco users

Tobacco product	% Indicating a Lot of Harm
Cigarettes	84.8
Smokeless tobacco	61.4
Cigars (traditional cigars, cigarillos, and filtered cigars)	60.2
Pipes	58.2
Waterpipe	38.8
E-cigarettes	26.6

**TABLE 4-12** Perceived Absolute Risk of Tobacco Products AmongYouth Ages 12–17, 2013–2014

SOURCE: Parker et al., 2018.

are more likely to perceive lower harms associated with cigar smoking. Among youth, generally perceived risks of cigars are comparable to other combustible tobacco products (e.g., cigarettes, waterpipe) and smokeless tobacco and higher than e-cigarettes. Some evidence indicates that risk perceptions of cigars vary by youth sociodemographic characteristics, including age (lower among older youth) and race and ethnicity (lower among racial and ethnic minority youth), but these data are limited. Among youth, current tobacco users tend to perceive lower risks of cigars than nonusers, a pattern consistent with most other tobacco products (i.e., lower perceived harm of tobacco products is associated with a higher likelihood of use). Overall, however, these findings should be interpreted with respect to measurement limitations of the evidence reviewed, as most of the available the data are not specific to premium cigars.

## Perceived Benefits and Reasons

No studies investigated perceived benefits of premium cigar smoking. Some studies have examined similar constructs, such as reasons for use, and are described below.

Adults Corey et al. (2018) reported data from PATH Wave 1 on reasons for use by cigar type among U.S. adults; the findings are summarized in Table 4-13. Overall, premium cigar users were less likely than other cigar users to indicate that they choose premium cigars because they are affordable, come in flavors that they like, are promoted by people in the media or public figures, are an alternative to quitting tobacco altogether, feel like a regular cigarette, and are a way to cut down cigarette smoking. Premium cigar users were more likely to indicate that they smoke them when they socialize. For the data stratified by cigarette smoking status, many point estimates could not be provided for premium cigar users due to small sample sizes. Thus, these stratified analyses do not provide additional meaningful insights as to reasons for use of premium cigars by cigarette smoking groups beyond the overall numbers summarized.

Analyses of Waves 2–5 of the PATH study data commissioned for this report (see Appendix D) indicate that the reasons for smoking premium cigars were relatively stable over time. For example, at Wave 2, the most commonly reported reason was socializing (76.1 percent of premium cigar smokers), followed by flavors (38.9 percent), and affordability (26.6 percent). In analyses of data for Waves 3–5, however, not all data were collected/available for reasons for use (e.g., smoking while socializing was not available for analyses) (Jeon and Mok, 2022).

DeSantis (2002) conducted an ethnographic study of patrons of a cigar shop to understand their reasons for continued cigar smoking, despite

	Premium cigars	Nonpremium	Cigarillos	Filtered cigars
They are affordable	22.7 (18.5–26.9)	66.4 (62.1–70.7)	71.7 (68.8–74.5)	80.2 (75.7–84.7)
The come in flavors I like	48.6 (43.2–54.1)	67.1 (61.7–72.5)	71.9 (68.7–75.1)	70.1 (66.3–73.9)
I like socializing when smoking them	76.6 (71.8–81.4)	63.4 (57.9–68.9)	60.6 (57.1–64.1)	49.9 (44.8–55.0)
People in the media or other public figures smoke them	12.1 (8.8–15.4)	21.0 (17.0–25.0)	17.7 (15.5–19.9)	17.5 (13.7–21.4)
The advertising appeals to me	9.7 (6.3–13.0)	15.1 (11.8–18.4)	12.4 (10.1–14.7)	13.7 (10.8–16.6)
I smoke them as an alternative to quitting tobacco altogether.	7.9 (5.2–10.5)	17.8 (14.1–21.5)	15.8 (13.2–18.3)	18.6 (15.0–22.1)
I can smoke them at times when or in places where cigarette smoking is not allowed	8.0 (5.3–10.7)	12.4 (9.1–15.6)	11.5 (9.5–13.5)	12.9 (9.6–16.2)
Smoking them feels like a regular cigarette	6.3 (3.6–9.1)	26.8 (22.3–31.3)	25.6 (22.8–28.4)	52.4 (48.2–56.7)
Smoking them helps people to quit smoking cigarettes	5.2 (3.0–7.4)	17.7 (14.0–21.4)	14.9 (12.6–17.3)	19.1 (15.2–23.1)
I smoke them as a way to cut down cigarette smoking	16.3 (9.7–22.9)	28.5 (23.4– 33.6)	28.2 (24.4–31.9)	29.8 (24.0–35.6)

**TABLE 4-13** Reasons for Using Types of Cigars Among U.S. Adults,2013–2014 (%, 95% CI)

SOURCE: Corey et al., 2018.

known health risks, with more than 600 hours of fieldwork to collect information on behaviors and conversations from 1997 to 2000. From the description, this setting appears to be one where premium cigars are sold and consumed, but this is not explicit in the paper. The analysis included coding and synthesis of transcripts from individual interviews and group interactions and showed that cigar shop patrons supported six common pro-cigar arguments:

 Smoking cigars in moderation reduces health harms, and patrons adapted their definition of moderation to their own user patterns (i.e., cognitive dissonance);

- 3) Cigars are not cigarettes; cigarettes are full of chemicals, the quantity smoked is more, and smokers inhale them;
- 4) Research on health effects of cigars is flawed and inconsistent over time;
- 5) Other hazards are far more likely to cause harm than cigar smoking (e.g., pollution, car accidents); and
- 6) Following the death of a fellow cigar shop patron, that other causes were the primary contributors to his heart attack.

Groups of adults Campbell et al. (2019) surveyed adult patients enrolled in a network of addiction treatment centers on demographics, tobacco use, and reasons for use; 77 percent were cigarette smokers, 8.3 percent were past 30-day cigar smokers, 15.3 percent were past 30-day little filtered cigar/cigarillo smokers, 11.4 percent were past 30-day smokeless tobacco users, and 26.3 percent were past 30-day e-cigarette users. Cigar (33.3 percent) and little filtered cigar/cigarillo users (25.1 percent) were more likely to indicate that they use these products because they enjoy the taste/flavor than smokeless tobacco (15.3 percent) and e-cigarette users (10.5 percent). Cigar users were less likely than users of all other products assessed to indicate they choose the product when they cannot smoke cigarettes (10.4 percent, versus 17.1 percent for little filtered cigars/cigarillos, 48.1 percent for smokeless, and 25.0 percent for e-cigarettes). In total, 7.3 percent of cigar users indicated that they smoked cigars to reduce health risks, compared with 5.1 percent for little filtered cigars/cigarillos, 6.9 percent for smokeless tobacco, and 11.2 percent for e-cigarettes. Cigar smokers were least likely to indicate that they smoke cigars to reduce/ quit smoking cigarettes (8.3 percent, versus 9.1 percent for little filtered cigars/cigarillos, 11.5 percent for smokeless tobacco, and 29.3 percent for e-cigarettes). More than 40 percent of cigar and little filtered cigar/ cigarillo users indicated "other" reasons (not specified) for using these products, higher proportions than smokeless tobacco (18.3 percent) and e-cigarette users (24.0 percent).

Smith-Simone et al. (2008) reported psychosocial profiles, including perceived social acceptability, associated with cigarette smoking, waterpipe tobacco use, and cigar smoking in a convenience sample of college students (n = 411). In multivariable models, only the perception that cigar smoking looks cool among peers was associated with current (past 30-day) cigar smoking. Despite different perceived benefits items associated with use of cigarettes and waterpipe, the general patterns were consistent across these three products (greater perceived social benefit is

associated with product use). The authors also report on an overall perceived product attractiveness score, an index of perceived social benefits, and social acceptability: cigars and waterpipes were perceived to be more attractive socially than cigarette smoking.

Youth Tucker et al. (2020) report data from a survey of youth experiencing homelessness in Los Angeles County, California. They assessed cigarette smoking and past 30-day use of other tobacco (natural cigarettes, e-cigarettes, little cigars/cigarillos, and cigars). Among tobacco users, the assessed reasons for use included that "you can use it in places where cigarette smoking is not allowed," "I like socializing while using it," "it tastes good," "it smells good," "you get more nicotine for the cost," and "it gives you a good buzz." These are reported descriptively for users of each product but not compared statistically. Notably, e-cigarette, little cigar/cigarillo, and cigar users were more likely to support these products because of the taste (74.2 percent e-cigarettes, 61.9 percent little cigars/ cigarillos, 65.8 percent cigars) and smell (67.3 percent e-cigarettes, 57.2 percent little cigar/cigarillos, 56.8 percent cigars) than cigarette (50.3 percent taste, 36.6 percent smell) and natural cigarette (50.3 percent taste, 36.6 percent smell) users. E-cigarette users (72.3 percent) were more likely than little cigar/cigarillo (26.0 percent) and cigar users (24.0 percent) to indicate using e-cigarettes in places where cigarette smoking is not permitted.

# Summary of Perceived Benefits and Other Perceptions of Premium Cigars

Research is limited on perceived benefits and reasons for using premium cigars. Only one study assessed reasons for use in a representative sample of U.S. adults using PATH data (Corey et al., 2018). The findings indicate adult premium cigar users are more likely than those who use other types of cigars to indicate socializing as a reason for use, and they are less likely to indicate smoking premium cigars for reasons related to cigarette smoking, such as smoking them in places where cigarette smoking is not allowed or to cut down cigarette smoking.

Other ethnographic (DeSantis, 2002) and observational research on groups of adults (Campbell et al., 2019; Smith-Simone et al., 2008) used convenience samples, so the generalizability of findings is more limited. The only study assessing perceived benefits or reasons for using cigars among youth was (Tucker et al., 2020); although the measures used likely capture use behavior and reasons for using premium cigars, they were not specific to those, and it is unlikely that cigar use in this study reflected premium cigars.

Overall, the evidence is very limited on U.S. adults' and youths' perceived benefits and reasons for using premium cigars. Research is needed to better understand these populations' motives.

# Associations Between Perceptions of Premium Cigars and Patterns of Use

Longitudinal studies have examined associations between perceptions of cigars and patterns of use among U.S. adults and youth. All of these studies have focused on risk perceptions (perceived harms, addictiveness) as predictors of use behavior.

# Adults

Elton-Marshall et al. (2020) examined tobacco product risk perceptions, changes over time, and associations with use behavior among U.S. adults using PATH Waves 1 and 2. Risk perceptions of noncigarette tobacco products were measured relative to cigarettes. They examined change in perceived harm from Wave 1 to Wave 2 (decreased, no change, stayed the same) and how perceptions at Wave 1 relate to use behavior at Wave 2. Current users were defined as those who used the products every day or some days. Nonusers were those who never used or used previously but not currently.

Perceptions that traditional cigars are less harmful than cigarettes declined from Wave 1 (12.3 percent) to Wave 2 (8.6 percent). The proportion of adults who reported that traditional cigars are as harmful as cigarettes ("about the same") increased from Wave 1 (61.4 percent) to Wave 2 (64.3 percent), with a slight increase for those who reported that traditional cigars are more harmful (24.3 to 24.8 percent). Relative to other products assessed, the proportion of respondents indicating e-cigarettes (41.2 to 29.0 percent) and waterpipe (17.8 to 13.6 percent) were less harmful than cigarettes declined, but there was little change in perceived harm of other noncigarette tobacco products.

In prospective analyses, for traditional cigars and all other noncigarette tobacco products, perceptions that the product is less harmful than cigarettes at Wave 1 were associated with increased odds of using the product at Wave 2 (Elton-Marshall et al., 2020). Traditional cigars, waterpipe, and smokeless tobacco had a significant interaction between product use at Wave 1 and perceptions of harm at Wave 1 on product use at Wave 2. The association between perceived lower harm at Wave 1 and product use at Wave 2 was stronger in Wave 1 traditional cigar users (OR: 2.28; 95 percent CI: 1.79–2.91) than Wave 1 nonusers (OR: 1.37; 95 percent CI:

0.96–1.94). The association between lower perceived harm of traditional cigars and subsequent use was also modified by sex, age, and race and ethnicity. Generally, the association was stronger among women, older adults (ages 55+), and those who identified as Hispanic/Latino. It was not modified by sexual orientation, income, or education.

For all products assessed except pipe tobacco, the prevalence of having decreased harm perceptions from Wave 1 to Wave 2 was highest among those who transitioned from nonuse to use (Elton-Marshall et al., 2020). For traditional cigars, among those transitioning from nonuse at Wave 1 to use at Wave 2, 20.2 percent had decreased harm perceptions. In comparison, 14.8 percent of those who were nonusers at both waves, 13.8 percent of those who transitioned from users at Wave 1 to nonusers at Wave 2, and 13.7 percent of those who were users at both waves decreased harm perceptions. These findings are consistent with the observed phenomenon of cognitive dissonance: some users tend to shift their risk perceptions to rationalize their own behavior.

# Youth

Strong et al. (2019a) analyzed prospective data from U.S. youth aged 12–17 from PATH Wave 1 to Wave 2. The authors examined whether perceived harm and addictiveness of tobacco products changed over time, whether perceived harm and addictiveness at Wave 1 predicted initiation at Wave 2, and whether trying the product between Wave 1 and Wave 2 predicted decrease in perceived harm and addictiveness at Wave 2. They did not perform longitudinal analyses of change in perceptions for cigar products because the questions changed from Wave 1 to Wave 2. Questions captured absolute harm (how much does [product] harm your health?), how long someone needs to use [product] to harm their health, and perceived harm relative to cigarettes. Items were combined to reflect a score of 1–3, with higher values indicating greater perceived harm. Perceived addictiveness was measured with a single item and coded to a three-level variable for comparability.

The absolute percentages of youth indicating "high" perceived harm are shown in a figure, and point estimates are not provided. However, visual inspection indicates most youth report high perceived harm of cigars, a greater proportion than for waterpipe and e-cigarettes, and comparable proportions to cigarettes and smokeless tobacco. The proportion of youth reporting low perceived harm of cigars was greater among older youth (16–17) and non-Hispanic Black youth, although statistical differences were not reported. At Wave 1, the majority of youth reported high perceived addictiveness of cigars, and, similar to perceived harm, the proportion reporting low perceived addictiveness was higher among older

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youth (16–17) and non-Hispanic Black youth. The authors also report that perceived addictiveness of cigars increased from Wave 1 to Wave 2 in nearly all demographic groups, but they do not present associated data.

For nearly all tobacco products assessed, the probability of initiation from Wave 1 to Wave 2 was highest among those with low or medium perceived harm at Wave 1, followed by those who had high perceived harm, who were unsure, or who had not heard of the product. The median effect size across products for the association between low perceived harm and initiation was OR: 4.71. For perceived addictiveness, the probability of initiation from Wave 1 to Wave 2 was highest among those with low or medium perceived addictiveness at Wave 1, followed by those with high perceived addictiveness, those who were unsure, and those who had not heard of the product. The median effect size across products for the association between low perceived addictiveness and initiation was OR: 4.82. For traditional cigars, these results suggest that lower perceived harm and addictiveness among youth is associated with higher odds of subsequent initiation, a pattern that was consistent across the tobacco products examined.

Parker et al. (2018) analyzed the associations between perceived product-specific harms, perceived harm relative to cigarettes, and tobacco use initiation among youth from Wave 1 to Wave 2. This analysis is similar to (Strong et al., 2019b), but risk perception measures were not combined in an index. Specific group analyses are not reported, but models are adjusted for age, sex, race, region, parental education, ever alcohol use, and ever-tobacco use at Wave 1.

For absolute harm perceptions of cigars, compared to those who reported a lot of harm, those who reported no or a little harm at Wave 1 were significantly more likely to initiate use at Wave 2 (OR: 2.6). Those who reported some harm had an increased odds of initiation as well, but the difference was not statistically significant (OR: 1.3). For e-cigarettes, pipes, waterpipe, and smokeless tobacco, youth who reported no or a little harm at Wave 1 had higher odds of initiation at Wave 2. Adjusted models examining the association between perceived harm relative to cigarettes at Wave 1 and initiation at Wave 2 showed similar patterns.

Youth who perceived cigars to be less harmful than cigarettes at Wave 1 were more likely to initiate cigar smoking at Wave 2 (OR: 1.5) compared with those who perceived cigars to be more harmful. This pattern was consistent for perceived relative harm of e-cigarettes, waterpipe, and smokeless tobacco but not for pipe tobacco. Overall, these data indicate that for most noncigarette tobacco products assessed, perceived lower absolute harm and perceived lower harm than cigarette smoking is associated with an increased likelihood of initiation among youth.

# Summary on Perceptions and Use Behavior

Lower perceived harm and addictiveness of cigars is associated with cigar use in prospective studies, including current use among adults and initiation among youth. These patterns for cigars are consistent with those observed for almost all other noncigarette tobacco products, with few exceptions, in the literature (e.g., pipe tobacco). The same measurement issues noted for awareness and cross-sectional studies of risk perceptions (particularly for PATH study data) apply to these conclusions. Measurement of perceptions of cigars typically lumps the products together or, at best, defines "traditional cigars" or "large cigars," which likely include but are not limited to premium cigars when assessing risk perceptions and associations with use behavior. The measurement of risk perceptions needs to be improved, including using more specific measures of perceived risks following expert recommendations (Kaufman et al., 2020a; Kaufman et al., 2020b) and measures that distinguish between premium cigars and other cigar products. Despite these limitations, the available evidence indicates that lower perceived risks of cigars, which likely includes premium cigars, is associated with subsequent use.

## **Summary and Conclusions**

National surveys, local surveys, focus groups, and ethnography studies have provided data to inform what is known about consumer awareness, knowledge, perceived risk, perceived benefits, and the relationship between perceptions and patterns of use of premium cigars. These studies include nationally representative and convenience samples that used different methods to assess various measures to inform the conclusions and research recommendations.

# Awareness and Knowledge

In the committee's review, cross-sectional data from three large U.S.based national surveys assessed adult and youth awareness of cigars. Although different questions and methods were used in each survey, all surveys asked about whether respondents had ever heard of a particular cigar type. These were large probability or population-based samples, but none of the surveys captured data on awareness or knowledge of the "health effects" of any specific cigar type, including premium cigars.

*Conclusion* 4-6: *There is no research that examines whether consumers distinguish premium cigars from large cigars or other cigar types, consumers' knowledge of premium cigars, or what defines premium cigars.* 

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Three studies among youth and adults, one quantitative and two qualitative, provide insight into consumer's knowledge of cigar types and their ability to distinguish cigarettes from cigars and cigar types. None of the studies captured data on consumer knowledge of the health effects of any specific type, including premium. Data that capture consumer knowledge of cigar products show that consumers misclassify them, even when shown images. There is a need to develop more specific measures that distinguish between premium cigars and other types to capture awareness of premium cigars in the U.S. population, and knowledge of the risks associated with them. For example, like the PATH study measures, using images to clearly depict different product types may help improve assessment of awareness and knowledge.

## Perceived Risks and Benefits

The committee's review indicates perceived risks of cigars vary by tobacco user status, age, sex, race, ethnicity, and educational attainment. For example, tobacco users perceive risks of cigars of any kind but tend to have lower perceived risk of the health effects or harms than nonusers. This is based on data from cross-sectional studies that include multiple PATH waves, the National Young Adult Health Survey, and a large survey of adults enrolled in addiction treatment centers. Studies reported data on relative and absolute perceived risks of tobacco products compared to cigars of any type and focused on perceived harmfulness of cigars relative to other tobacco products, perceived health effects, and addictiveness of the tobacco products. Three studies, one among adults and two among youth, included data on absolute perceived risk of the health effects (i.e., heart attack, lung cancer) of any cigar type. Adult respondents in this survey (PATH) had lower perceived health risk of any cigar type compared to cigarettes.

The research reviewed did not distinguish between people's perceptions of premium cigars and other types directly; however, studies reviewed assessed perceptions of products that likely include premium cigars. Improved measurement of perceived risks of premium cigars is needed, including more specific measures that follow expert recommendations for risk perception measurement (Kaufman et al., 2020a; Kaufman et al., 2020b) and measures that distinguish perceptions of premium and other cigar products.

Evidence is very limited on perceived benefits or reasons for using premium cigars in the U.S. population. Thus, little is known about how adult and youth perceive their benefits and whether these or reasons for use differ from other cigar types. The literature includes cross-sectional

and qualitative data, but most studies do not specifically examine premium cigar use.

Conclusion 4-7: There is **strongly suggestive evidence** that the U.S. population perceives **cigar products overall** to be harmful and addictive. However, there is **no research** that examines the knowledge of the specific health effects of **premium cigars**.

# Perceptions and Patterns of Use

In the committee's review, research analyzing prospective populationbased data from PATH demonstrated that lower perceived risks (lower perceived health harm, addictiveness) of cigars is associated with subsequent use among U.S. adults and initiation of use among U.S. youth. These studies did not differentiate premium cigars from other cigar products.

Conclusion 4-8: There is **strongly suggestive evidence** from prospective studies that lower perceived harm and addictiveness of **cigars in general** is associated with cigar use behavior, including current use in adults and initiation in youth.

# CONCLUDING OBSERVATIONS

Marketing and promotion are designed to increase the sales of tobacco products and increase consumer demand. Relative to other tobacco products, the committee found limited published data specific to the marketing and sales and consumers' awareness, knowledge, and perceptions of premium cigars. As a result, primary data collection was needed to understand their marketing and promotion practices. Thus, the committee conducted primary content analyses of magazines; examined direct print and e-mail marketing; conducted secondary analysis of existing surveys; conducted an environmental scan of marketing on social media; examined online marketing; collected data on retail marketing; and conducted literature reviews. Based on the available research and the committee's efforts, key insights can be drawn.

Consistent with research on the "premiumization" of other tobacco products, it is clear that premium cigars are marketed as a quality product with benefits that outweigh their potential risks. Marketing occurs through channels that are unique to premium cigars, such as lifestyle magazines and festivals, and through channels that are common to other tobacco products, such as DTC and online marketing. Premium cigar marketing uses strategies to increase product appeal by emphasizing

premium cigars as part of a successful, luxurious lifestyle, use at upscale social events, and appealing to influential celebrities and individuals. Sales of premium cigars are also distinct from other forms of tobacco— consumers most often purchase them from cigar bars and tobacco specialty shops versus convenience stores and other retail locations. Online premium cigar sales are prevalent, though not captured in national surveys of cigar users. Finally, despite limited direct evidence on consumers' awareness, knowledge, and perceived benefits of using premium cigars, consistent with research on other tobacco products there is evidence that lower perceived risks of cigar products in general promote initiation and current use of cigars. See Box 4-2 for key research and measurement gaps.

#### BOX 4-2 Research Gaps

Further research is needed for the following:

- Determine the extent to which "health" messages are marketed in lifestyle magazines. In the committee's review, content within these magazines included language that implied that the health effects of premium cigar use are lower compared to cigarette use and supported the perception that premium cigars are a safe substitution for cigarette use.
- Capture the current marketing practices for premium and nonpremium cigars, including examining the marketing of premium and nonpremium cigars in nontraditional venues (e.g., festivals, cigar bars, social media) by thirdparty retailers.
- Track premium cigar sales by retail venue and assess purchasing behavior in premium cigar users, including online purchasing and seasonality of purchasing and use behaviors.
- Develop more specific measures that distinguish between premium cigars and other types to capture awareness of premium cigars in the U.S. population and knowledge of the risks associated with them. For example, like the PATH study measures, using images to clearly depict different product types may help improve assessment of awareness and knowledge.
- Improve the measurement of risk perceptions, including using more specific measures of perceived risks following expert recommendations and measures that distinguish between premium cigars and other cigar products.

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CIGAR MARKETING AND PERCEPTIONS

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# **Chapter 4 Annex**

# **Evidence Tables**

The following table provides descriptive and methodological information on the studies cited in Chapter 4; study findings and results are discussed in the chapter proper. See the Chapter 4 reference list for full citations.

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apter 4	Definitions of types of cigars (including premium) and/ or tobacco products studied	s/ Not specified cco,	<ul> <li>Not specified</li> <li>tta</li> <li>d</li> <li>old</li> </ul>
<b>TABLE 4A-1</b> Descriptive and Methodological Information on Studies Cited in Chapter 4	Types of cigars (including premium) and/or tobacco products studied	Cigars, little filtered cigars/ cigarillos, smokeless tobacco, and e-cigarettes	Products shown were ma- chine-injected RYO cigarettes, Winchester little cigar, Santa Fe filtered cigarillo, Black and Mild filtered cigarillo, Nat Sherman cigarette, and Nat Sherman Black and Gold cigarette
ation on	Sample size	1,153	344
dological Informa	Study participants	Adult patients en- rolled in addiction treatment centers	Convenience sample of adult cigarette smokers (smoked ≥1 ciga- rette per day) ages 18–64
nd Metho	Study design	Cross- sectional survey	Cross- sectional survey
riptive a	Year(s) data col- lected	2016	Not speci- fied
-1 Desc	Data source	Survey	Online survey
TABLE 4A	Reference	Camp- bell et al. (2019). PMID: 30206006	Casseus et al. (2016), PMID: 26604260

on Studies Cited in Chanter A 102 L I \_ 4 JNL : Ĺ 7 TABLE AN

Definitions of types of cigars (including premium) and/ or tobacco products studied	"Traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others."	"Cigarillos and filtered cigars are smaller than traditional cigars. They are usually brown. Some are the same size as cigarettes, and some come with tips or fil- ters. Some common brands are Black & Mild, Swisher Sweets, Dutch Masters, Phil- lies Blunts, Prime Time, and Winchester."	Not specified
Types of cigars (including premium) and/or tobacco products studied	Filtered cigars, cigarillos, or traditional cigars, which were further categorized as premium or nonpremium		Cigars, cigarillos, and little cigars
Sample size	32,320		123
Study participants	U.S. adults		U.S. adults
Study design	National longitudi- nal study		Focus groups conducted in five U.S. cities
Year(s) data col- lected	2013– 2014		2014
Data source	PATH Wave 1		Focus groups conducted in five U.S. cities
Reference	Corey et al. (2018). PMID: 29059423		Dickin- son et al. (2016). PMID: 26826209

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continued

TABLE 4A-1 Continued	A-1 Contin	nued					
Reference	Data source	Year(s) data col- lected	Study design	Study participants	Sample size	Types of cigars (including premium) and/or tobacco products studied	Definitions of types of cigars (including premium) and/ or tobacco products studied
Elton- Marshall et al. (2020). PMID: 32145496	PATH Waves 1 and 2	2013– 2014; 2014– 2015	National longitudi- nal study	U.S. adults	32,320; 28,362	Traditional cigars, filtered cigars, cigarillos, waterpipe, smokeless tobacco, pipe, and e-cigarettes	See Corey et al., 2018
Fong et al. (2019). PMID: 30502927	PATH Wave 1	2013– 2014	National longitudi- nal study	Population-based, representative sample of U.S. adults	32,320	Traditional cigars, cigarillos and filtered little cigars, tradi- tional smokeless tobacco, and e-cigarettes	See Corey et al., 2018
Kasza et al. (2017). PMID: 28121512	PATH Wave 1	2013– 2014	National longitudi- nal study	Population-based, representative sample of U.S. youth	13,651	Traditional cigars, cigarillos and filtered little cigars, tradi- tional smokeless tobacco, and e-cigarettes	See Corey et al., 2018
Nayak et al. (2017). PMID: 28579496	TPRPS	2014, 2015	Probabil- ity-based cross- sectional survey	Lesbian, gay, and bisexual adults (compared to het- erosexual adults)	11,768	E-cigarettes, 'large, premium cigars," little cigars/cigarillos/ filtered cigars, and waterpipe (hookah)	Not specified
Parker et al. (2018). PMID: 30397167	PATH Waves 1 and 2	2013- 2014; 2014- 2015	National longitudi- nal study	Youth ages 12–17	10,081	Cigarettes, e-cigarettes, cigars (traditional cigars, cigarillos, and filtered cigars combined together), pipes, waterpipe, and smokeless tobacco	See Corey et al., 2018

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

Definitions of types of cigars (including premium) and/ or tobacco products studied	Not specified	Not specified	See Corey et al., 2018
Types of cigars (including premium) and/or tobacco products studied	Nicotine patch, nicotine gum, nicotine water, nicotine lollipop, nicotine inhaler, ul- tralight cigarettes, waterpipe, light cigarettes, cigarillos, cigars, and smokeless tobacco (relative to cigarettes)	Cigarette smoking, waterpipe tobacco use, and cigar smok- ing	All cigar types (little cigars/ cigarillos, filtered cigars, and traditional cigars) were combined
Sample size	411	411	13,651
Study participants	Online convenience sample of college students	Online convenience sample of college students	Population-based, representative sample of U.S. youth
Study design	Cross- sectional Internet survey	Cross- sectional Internet survey	National longitudi- nal study
Year(s) data col- lected	2004	2004	2013– 2014
Data source	Cross- sectional Internet survey	Cross- sectional Internet survey	PATH Wave 1
Reference	Smith et al. (2007). PMID: 17763115	Smith- Simone et al. (2008). PMID: 18783890	Strong et al. (2019). PMID: 30623806

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TABLE 4A-1 Continued	v-1 Contin	nued					
Reference	Data source	Year(s) data col- lected	Study design	Study participants	Sample size	Types of cigars (including premium) and/or tobacco products studied	Definitions of types of cigars (including premium) and/ or tobacco products studied
Tucker et al. (2020). PMID: 31396821	Sample from 25 street and service sites in Los Angeles County	2017– 2018	Survey	Probability sample of youth experienc- ing homelessness in Los Angeles County, California	426	Past-30-day use of other tobacco (natural cigarettes, e-cigarettes, little cigars/ciga- rillos, and cigars)	Not specified
Wack- owski and Delnevo (2016). PMID: 26304709	National Young Adult Health Survey	2011	Stratified random digit dial cell phone survey	Nationally repre- sentative sample of young adults ages 18–34	2,871	Cigars, e-cigarettes, waterpipe, snuff, dip, chew, snus, and menthol cigarettes relative to cigarettes; excluded filtered little cigars but included large cigars and cigarillos	"Regular cigars can be large cigars or smaller in size such as cigarillos. They are not little cigars that have spongy filters like cigarettes. They are usually sold indi- vidually or in packs of 5 or 8. Some common brands are Black and Mild's, Swisher Sweets cigarillos, and Phil- lies Blunts, but there are others" (p. 329).

Premium Cigars: Patterns of Use, Marketing, and Health Effects

Reference	Data source	Year(s) data col- lected	Study design	Study participants	Sample size	Types of cigars (including Sample premium) and/or tobacco size products studied	Definitions of types of cigars (including premium) and/ or tobacco products studied
Weaver et al. (2016). PMID: 26560309	TPRPS	2014	Probabil- ity-based cross- sectional survey	Representative noninstitutionalized U.S. adults	5,717	"Large, premium cigars"	"Large, premium cigars"
Yerger et al. (2001). PMID: 11211649	Focus groups	1998	Focus groups	Black/African American youth ages 14–18	50	Cigar (types not specified)	"The word 'cigar' encom- passes several types and sizes of smokable non- cigarette tobacco products, their common factor being a nonpaper, tobacco leaf or tobacco-containing outer wrapper" (p. 316).

NOTE: PATH: Population Assessment of Tobacco and Health Study; RYO: roll-your-own; TPRPS: Tobacco Products and Risk Perceptions Survey.

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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5

# Health Effects of Premium Cigars

## **INTRODUCTION**

The potential adverse health effects of "premium"<sup>1</sup> cigars need to be viewed in the context of harms of combusted tobacco smoking broadly. Cigarette smoking is the most common form of combusted tobacco use, and its health effects are well established. These include increased overall mortality, cardiovascular disease (CVD), chronic obstructive lung disease, cancer, susceptibility to respiratory infection, adverse reproductive outcomes, and other diseases (HHS, 2004, 2010, 2014). When tobacco is burned, the generated toxicants are generally similar across tobacco types. The extent of inhalation and the frequency and duration of use are major factors in determining whether tobacco smoking will cause disease. The health risks of little cigars and cigarillos, which are commonly inhaled and may be smoked more frequently, may be expected to be similar to those of cigarette smoking. Chapters 2 and 3 address inhalation and frequency of use for large cigars.

Mechanisms of tobacco smoke toxicity and biomarkers of toxicant exposure are applicable to understanding the potential harms of premium

<sup>&</sup>lt;sup>1</sup> Note that quotations are used at the first occurrence of the term "premium" in each chapter, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information. In addition, when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

cigars. The toxicants generated by combustion of tobacco include oxidizing chemicals, carcinogens (such as nitrosamines and polycyclic hydrocarbons), carbonyls (such as acrolein, formaldehyde, and acetaldehyde), carbon monoxide (CO), metals and particulates. When these substances are inhaled, oxidant stress, systemic inflammation, endothelial dysfunction, DNA damage, hypercoagulability, and changes in microbial populations occur, which lead to organ dysfunction and disease (HHS, 2010). While inhalation is necessary to deliver toxicants to the heart, lungs, and other body organs, taking tobacco smoke into the mouth without inhalation exposes the mouth, pharynx, and esophagus to various toxicants. Thus, upper respiratory tract and esophageal disease can occur even in tobacco users who do not inhale, which is typical of some premium cigar smokers.

While products of combustion are thought to be responsible for most of the disease caused by smoking, nicotine may also contribute. Nicotine comes from the tobacco itself, and its absorption does not require combustion or even inhalation. Nicotine is a weak base, and, in the presence of an alkaline pH, is readily absorbed across mucous membranes, such as the mouth. Users of smokeless tobacco products absorb, on average, similar amounts of nicotine each day as do cigarette users (Piano et al., 2010). While fewer data are available on cigar users who do not inhale, the potential for substantial nicotine exposure is clear (see Chapter 2). In contrast to cigarettes, where the wrapper is paper, cigar wrappers contain tobacco, so nicotine can be absorbed orally through direct contact with the tobacco leaf, as well as through the smoke.

The most important harmful effect of nicotine is sustained use of combusted tobacco by causing addiction (Benowitz, 2010); evidence of addiction in premium cigar users is discussed later in this chapter. Other effects of concern include contributions to cardiovascular disease, increased risk of diabetes and pro-atherogenic lipid profiles, reproductive toxicity, including low birth weight and effects on fetal neurodevelopment, and possible adverse effects on adolescent brain maturation (Benowitz and Burbank, 2016; HHS, 2010). Nicotine also releases catecholamines, which cause constriction of blood vessels, which in turn may promote oral pathology or result in impaired wound healing after surgical procedures.

Other tobacco and substance use behaviors also need to be considered in assessing potential adverse effects of premium cigar use. Former or concurrent cigarette or small cigar users are more likely to inhale more intensively compared to users who have smoked exclusively large and premium cigars (see Chapter 2). All tobacco products, including premium cigars, are commonly used in conjunction with drinking alcoholic beverages (see Chapter 3). Alcohol and smoking act synergistically to increase the risk of head and neck and esophageal cancer.

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To assess the health effects of premium cigars, including secondhand smoke, this chapter considers biological plausibility, including the chemical nature of the tobacco leaf and emissions from premium cigars compared to other combusted tobacco products, and the evidence for the extent of inhalation of premium cigar smoke, including use of biomarkers of exposure that might establish levels of systemic exposure (see Chapter 2). This chapter reviews harmful constituents of tobacco smoke, the epidemiology of overall mortality and particular diseases in relation to cigar use, and the issue of addiction to cigar smoking. Because the epidemiology on premium cigar use is quite limited, the committee examined cigar use in general, with particular focus on inhalation, frequency, and duration. These data were considered as a whole to assess specific disease risks. Because most studies did not specify the type of cigars, the committee was unable to compare risks among various types. (See Appendix A for the list of research questions that were reviewed for this chapter.)

## HEALTH EFFECTS OF EXPOSURE TO HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS OF CIGAR SMOKE

FDA has established a list of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke (FDA, 2012). All of these compounds have been detected in cigarette smoke. While studies of cigar smoke specifically, and particularly of premium cigar smoke, have not reported analyses of all HPHCs, there is every reason to believe that each of these compounds would be detected in premium cigar smoke if the specific analyses were performed, because they are all either transferred from tobacco during smoking or formed during smoking by combustion processes. HPHC concentrations in premium cigar smoke may be different from those in the smoke of cigarettes and other cigars, but the spectrum of compounds will be similar if not identical. Thus, the health effects of HPHCs per gram of premium cigar tobacco smoked are expected to be very similar to those observed from nonpremium cigar smoking.

The carcinogenic and other health effects of tobacco smoking can be expected to follow a dose–response relationship: health risks will depend on the total toxicant and carcinogen exposure. A recent review concluded that mechanisms of interaction of tobacco smoke constituents with human genetic material after use of tobacco products other than cigarettes are similar to those associated with cigarette smoking (Szyfter et al., 2019). See Box 5-1 for a list of HPHCs organized by category and discussed below.

A plethora of adverse health effects of compounds in each category are well established, and some are briefly summarized here. Nicotine is the major chemical component responsible for addiction to tobacco prod-

## BOX 5-1 List of Established Harmful and Potentially Harmful Constituents (HPHCs)

- Tobacco alkaloids. Nicotine, nornicotine, anabasine
- Volatile inorganic compounds. Carbon monoxide, ammonia, hydrogen cyanide, hydrazine
- Volatile organic compounds. Acetaldehyde, acetamide, acetone, acrolein, acrylamide, acrylonitrile, benzene, butadiene, coumarin, crotonaldehyde, ethyl carbamate, ethylbenzene, ethylene oxide, formaldehyde, furan, isoprene, methyl ethyl ketone, naphthalene, nitrobenzene, nitromethane, 2-nitropropane, phenol, propionaldehyde, propylene oxide, quinoline, styrene, toluene, vinyl acetate, vinyl chloride
- Tobacco-specific nitrosamines. 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), N'nitrosonornicotine (NNN),
- Other nitrosamines. *N*-nitrosodiethanolamine, *N*-nitrosodimethylamine, *N*nitrosodiethylamine, *N*-nitrosomethylethylamine, *N*-nitrosomorpholine, *N*-nitrosopiperidine, *N*-nitrosopyrrolidine, *N*-nitrososarcosine
- **Polycyclic aromatic hydrocarbons**. Benz[*a*]anthracene, benz[*j*]aceanthrylene, benzo[*b*]fluoranthene, benzo[*k*]flluoranthene, benzo[*a*]pyrene, benzo[*c*]phenanthrene, chrysene, cyclopenta[*c*,*d*]pyrene, dibenz[*a*,*h*]anthracene, dibenzo[a,h]pyrene, indeno[1,2,3-*cd*]pyrene, 5-methylchrysene
- Aromatic amines and heterocyclic aromatic amines. 4-aminobiphenyl, 1-aminonaphthalene, 2-aminonaphthalene, *o*-anisidine, *o*-to-luidine, 2,6-dimethylaniline, 2-amino-6-methyldipyrido[1,2-*a*:3',2'-*d*] imidazole(Glu-P-1),2-aminodipyrido[1,2-*a*:3',2'-*d*]imidazole(Glu-P-2),2-amino-3-methylimidazo[4,5-*f*]quinolone (IQ), 2-amino-9H-pyridole[2,3-*b*]indole (AαC), 2-amino-3-methyl-9*H*-pyridole[2,3-*b*]indole (MeAαC), 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine (PhIP), 3-amino-1,4-dimethyl-5*H*-pyrido[4,3-*b*] indole (Trp-P-1), 3-amino-1-methyl-5*H*-pyridole(Trp-P-2)
- Phenois. Catechol, cresols, phenol
- Metals. Arsenic, beryllium, cadmium, chromium, cobalt, lead, mercury, nickel, polonium-210, selenium, uranium-235, uranium-238
- Miscellaneous organic compounds. Aflatoxin B1, benzo[b]furan, caffeic acid, chlorinated dioxins/furans

SOURCE: FDA, 2012.

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ucts, exerting its effects by stimulation of nicotine acetylcholine receptors. In its unprotonated state, it readily crosses cell membranes and enters the body. When inhaled, unprotonated nicotine is more volatile and acts on nicotinic cholinergic receptors in the mouth and throat, producing sensations of irritation and harshness (Benowitz et al., 2021; Leventhal et al., 2021). Since cigar smoke is often more alkaline than smoke from cigarettes or small cigars, more nicotine in the smoke is in the unprotonated state, so the smoke is more irritating and difficult to inhale (see Chapter 2). For this reason, the pH of cigar smoke is a critical factor influencing whether or how deeply a user inhales, and the expression of nicotine's effects. Other established properties of nicotine include acute toxicity at high doses and negative effects on maternal and fetal health (England et al., 2017). The negative effects of nicotine withdrawal on cognitive function have been established. It is also associated with dysphoric mood, including anxiety and depression. Relief of these symptoms is rewarding (termed "negative reinforcement") and contributes to nicotine addiction. Nicotine exposure during adolescence causes long-term structural and functional changes to the brain in rodents and might also do so in human youth (HHS, 2014). Some evidence exists for abuse potential of the minor tobacco alkaloids nornicotine and anabasine, which could play a role in abuse potential of tobacco products, including premium cigars (Hoffman and Evans, 2013). Some evidence also suggests the endogenous nitrosation of nornicotine in the human body, leading to formation of the carcinogen NNN (Knezevich et al., 2013; Stepanov et al., 2009).

Considerable amounts of CO (for example, 97 mg/cigar in the Macanudo premium cigar brand) are present in premium cigar smoke (NCI, 1998). CO binds rapidly with hemoglobin in the blood, diminishing its oxygencarrying capacity and potentially leading to a number of negative health effects, particularly in people with underlying cardiovascular or pulmonary disease. Ammonia causes a burning sensation in the eyes, nose, throat and respiratory tract, and hydrogen cyanide is a known poison.

Acetaldehyde has some addiction potential and binds to DNA (Balbo et al., 2012; FDA, 2012). As the major initial metabolite of ethanol, most of its potentially toxic, genotoxic, and carcinogenic effects are associated with alcohol consumption (IARC, 2012c). Acrolein (55–60 µg/g cigar tobacco smoked) is one of the most irritating and toxic compounds in tobacco smoke (Haussmann, 2012; NCI, 1998). It reacts with DNA to form well-characterized adducts (Paiano et al., 2020) and is considered probably carcinogenic to humans by the International Agency for Research on Cancer (IARC) (IARC Monographs Vol 128 group, 2021). Benzene is a known human carcinogen causing acute myeloid leukemia/acute nonlymphocytic leukemia (IARC, 2012e), and 1,3-butadiene is considered "carcinogenic to humans" by IARC, causing cancer of the hematolym-

phatic organs (IARC, 2012e). IARC also considers ethylene oxide and formaldehyde carcinogenic to humans. The former is based on evidence from studies in laboratory animals and compelling evidence from genotoxicity studies in humans (IARC, 2012c). Formaldehyde is an accepted cause of cancer of the nasopharynx and of leukemia (IARC, 2012d).

Tobacco-specific nitrosamines are among the most well-characterized carcinogens in unburned tobacco and tobacco smoke, with consistently problematic levels in both, as summarized in Chapter 2. NNK causes tumors of the lung in all species tested, including rats, hamsters, ferrets, and multiple strains of mice, independent of the route of administration (Hecht, 1998). The lowest total dose of NNK shown to induce lung tumors in rats was 1.8 mg/kg body weight. The carcinogenicity of NNN has also been established in multiple species, including various strains of rats and mice and in Syrian golden hamsters and mink (Hecht, 1998). In one study, chronic oral administration of (*S*)-NNN (the major form in tobacco) at a dose of 14 ppm in drinking water induced 89 benign and malignant oral cavity tumors and 122 esophageal tumors in a group of 20 rats (Balbo et al., 2013). IARC considers NNK and NNN, which always occur together in tobacco and tobacco smoke and are present in all tobacco products, carcinogenic to humans (IARC, 2012b).

Polycyclic aromatic hydrocarbons (PAH) represent a well-established class of carcinogens that are formed by incomplete combustion of organic matter, including tobacco. They are widespread environmental contaminants also found in air, water, soils, sediments, and broiled foods. Multiple PAH are present in tobacco and tobacco smoke. One study tentatively identified more than 500 different PAH in tobacco smoke condensate fractions (Snook et al., 1978). Benzo[*a*]pyrene (BaP) is the most extensively investigated, and many of its properties are illustrative of the class (IARC, 2012e). BaP induces tumors in laboratory animals by various routes of administration; is a complete carcinogen (affects tumor cells in all stages of development) and tumor initiator when applied to mouse skin; and induces tumors at the injection site and sometimes lungs in mice when administered by subcutaneous injection. Many other PAH have similar carcinogenic properties as those of BaP, which IARC considers carcinogenic to humans (IARC, 2012e).

Aromatic amines, such as 4-aminobiphenyl and 2-naphthylamine, are recognized human bladder carcinogens in tobacco smoke (IARC, 2012e). Heterocyclic aromatic amines are a broad class of well-established carcinogens formed during high-temperature combustion processes involved in food preparation as well as in cigarette and cigar smoking (Bellamri et al., 2021).

Phenols, such as catechol, occur in relatively high concentrations in cigarette smoke. Catechol is a co-carcinogen, enhancing the tumorigenic

activity of PAH in mouse skin models, and can be involved in oxidative damage by tobacco smoke. Phenols, while generally not carcinogenic themselves, may enhance the activity of carcinogens in smoke (Hecht, 2011).

Metals are among the HPHCs in tobacco and tobacco smoke; some of these, including lead, cadmium, and nickel, have been identified in cigar smoke (NCI, 1998). Prolonged exposure to lead may have a variety of health effects, including high blood pressure, heart disease, and kidney disease (CDC, 2018). Cadmium and nickel are considered carcinogenic to humans by IARC, causing lung cancer as well as some other cancer types (IARC, 2012a).

## Summary and Conclusions

The FDA has established a list of harmful and potentially harmful compounds (HPHCs) in tobacco products and tobacco smoke. This list includes tobacco alkaloids such as nicotine, volatile inorganic compounds such as carbon monoxide, volatile organic compounds such as the human carcinogen benzene, carcinogenic tobacco-specific nitrosamines and other nitrosamines, carcinogenic polycyclic aromatic hydrocarbons, carcinogenic aromatic amines and heterocyclic aromatic amines, toxic phenols, carcinogenic metals, and miscellaneous other toxic and carcinogenic compounds. Cigar smoke, including premium cigar smoke, contains many HPHCs capable of causing cancer and multiple other negative health effects. Smokers of premium cigars will be exposed to this toxic and carcinogenic mixture when they use these products. The level of exposure to specific HPHCs in premium cigar users will depend on how the cigars are smoked, including frequency of smoking and depth of inhalation. The overall exposure to HPHCs in daily users of traditional cigars appears to be similar to daily smokers of nonpremium cigars and daily smokers of cigarettes. Biomarker data showing equivalent exposure comparing daily traditional cigar and cigarette smokers are based on data from a combination of large and premium cigars, however based on biological plausibility, it is likely the results would apply to premium cigar only users as well.

Conclusions 5-1 and 5-2 are based on the known chemical characteristics of combustible tobacco products, including cigars, as well as biological mechanisms by which constituents of combustible tobacco products are processed (in animals and humans). While studies on cigars may include premium cigars, they do not distinguish premium from other cigar types. However, given the conclusive data on tobacco products including cigars in general, and the absence of any important threats to validity, the committee extrapolated these findings to premium cigars.

Conclusion 5-1: There is **conclusive evidence** that **smoke** from **cigars in general**, **including premium cigar smoke**, contains many hazardous and potentially hazardous constituents, capable of causing cardiovascular disease, lung disease, cancer, and multiple other negative health effects.

Conclusion 5-2: There is **conclusive evidence** that the chemical nature of emissions from **cigars in general**, **including premium cigars**, are similar to those of cigarette smoke. There is strong biological plausibility that exposure to these chemicals will cause disease. Thus, if cigar smoke is inhaled and cigars are smoked regularly, the risks are likely to be qualitatively similar to those of cigarette smoking.

## HEALTH EFFECTS OF PREMIUM CIGARS<sup>2</sup>

## ALL-CAUSE MORTALITY

Tobacco smoking is well established as a cause of premature mortality (HHS, 2014). No epidemiologic studies have examined the specific association of premium cigars with all-cause mortality; however, several have examined the association of any cigar use, including premium cigars, with all-cause mortality. This section provides an overview of the evidence from epidemiologic studies examining risk of all-cause mortality with primary cigar smoking (exclusive cigar smoking with no previous history of other combustible tobacco use) and secondary cigar smoking (current exclusive cigar smoking with previous history of use of other combustible tobacco products).

Reviews from the National Cancer Institute (NCI, 1998; 10 studies of cigar use published 1958–1998) and Chang et al. (2015) (7 studies published 1966–2014) conclude that current primary cigar smoking is associated with increased mortality compared to never-tobacco users (Chang et al., 2015; NCI, 1998).<sup>3</sup> A meta-analysis of studies was not performed in these reviews; therefore, the results of the individual studies are presented in the chapter annex. All but one study observed increased risk of mortality, from 2–40 percent (Chang et al., 2015; NCI, 1998). Notably, findings from a study of 442,455 white male participants in the American Cancer Society (ACS) Cancer Prevention Study (CPS)-I, found an 8 percent (95 percent CI: 5–12) increase in all-cause mortality for current primary cigar smokers and a 12 percent (95 percent CI: 6–18 percent) increase in

<sup>&</sup>lt;sup>2</sup> Several studies cover more than one health outcome—study details are included at first occurrence in the chapter. The Chapter 5 Annex includes evidence tables for studies that review primary cigar smoking.

<sup>&</sup>lt;sup>3</sup> Some studies use the comparison group of "never-tobacco users" as opposed to "never-tobacco smokers," as the reference group also excluded users of smokeless tobacco products.

mortality among secondary cigar smokers compared to never-smokers (NCI, 1998). One study (Ben-Shlomo et al., 1994), using data from 19,018 Whitehall Study participants (men aged 40–69 from the British Civil Service), observed lower mortality rates for current primary cigar smokers compared to never-smokers (age-adjusted mortality rate per 1,000 personyears was 5.04 for primary cigar smokers versus 10.50 for never-smokers). However, this study included relatively few deaths among primary cigar smokers (9 of the 4,496 total deaths were among primary cigar smokers).

Since these reviews, four additional prospective epidemiologic studies examining the association of cigar smoking and mortality have been published (Christensen et al., 2018; Inoue-Choi et al., 2019; Rodu and Plurphanswat, 2021; Thomson et al., 2020), including three of nationally representative longitudinal cohorts conducted in the United States (Christensen et al., 2018; Inoue-Choi et al., 2019; Rodu and Plurphanswat, 2021). The results are largely consistent with those included in the prior reviews and support the conclusion of an increased risk of mortality. Christensen et al. (2018) evaluated the association of cigarette, cigar, and pipe use with cause-specific mortality and other health outcomes in the National Longitudinal Mortality Study (NLMS; n = 357,420). The NLMS is a mortality follow-up of the TUS-CPS surveys starting in 1985 followed through 2011, including from 1,139 exclusive current and 2,398 exclusive former cigar users. The cigar use category included use of little cigars, cigarillos, or large cigars. Christensen et al. found increased all-cause mortality among current primary cigar smokers compared to never-tobacco users (HR: 1.20; 95 percent CI: 1.03–1.38); this risk was attenuated among former primary cigar smokers (HR: 1.11; 95 percent CI: 0.99-1.25) (Christensen et al., 2018). Both Inoue-Choi et al. (2019) and Rodu and Plurphanswat (2021) assessed the risk of mortality associated with cigar use using data from the National Health Interview Survey (NHIS) Linked Mortality Files with follow-up through 2015. Inoue-Choi et al. used data from 1991, 1992, 1998, 2000, 2005, and 2010 to evaluate the association between exclusive cigarette, smokeless tobacco, pipe, and cigar use with overall and causespecific mortality (Corrigendum, 2019; Inoue-Choi et al., 2019). The analysis included data from 165,335 adults at least 18 years of age, including 1,595 exclusive cigar users; however, type of cigar was not available. Rodu and Plurphanswat was restricted to men aged 40-79 (N = 52,710) and included data from NHIS 1987. Both studies found increased risk of mortality among current primary cigar smokers, though these findings were not statistically significant (IRR [95 percent CI] were 1.22 [0.93-1.60] for Inoue-Choi et al. and 1.02 [0.86–1.23] for Rodu and Plurphanswat). Thomson et al. (2020) studied 118,840 adults aged 30-69 in Cuba and found that compared to never-smokers, primary cigar smoking was associated with increased all-cause mortality (IRR: 1.27; 95 percent CI: 1.11-1.46).

## Primary Cigar Smoking Relative to Other Tobacco Products and All-Cause Mortality

Relative to other tobacco products, the risk of mortality associated with current primary cigar smoking was generally lower than risk observed for cigarette smokers (cigarette RRs: 1.45–2.40) (Chang et al., 2015; Christensen et al., 2018; Corrigendum, 2019; Inoue-Choi et al., 2019; NCI, 1998; Rodu and Plurphanswat, 2021; Thomson et al., 2020) and higher than the risk observed for pipe smoking (RRs: 0.95–1.20) (Chang et al., 2015; Christensen et al., 2018; Corrigendum, 2019; Inoue-Choi et al., 2019; NCI, 1998). Compared to never-tobacco users, the RRs (95 percent CIs) for mortality for current cigar, cigarette, and pipe smokers were 1.20 (1.03–1.38), 1.98 (1.93–2.02), and 1.09 (0.92–1.28), respectively (Christensen et al., 2018).

## Secondary Cigar Use and All-Cause Mortality

As noted in Chapter 3, roughly half (52.5 percent) of premium cigar smokers in the United States have a history of established cigarette smoking; current co-use of premium cigars with other types of cigars (16.4–19.3 percent) and cigarettes (20.7–30.1 percent) is not uncommon (Jeon and Mok, 2022; Manderski et al., 2022). Mortality risk is higher among secondary cigar smokers (IRR, 95 percent CI: 1.12 [1.06–1.18]) than current primary cigar smokers (IRR, 95 percent CI: 1.08 [1.05–1.12]) (NCI, 1998). In studies reporting effects of secondary cigar smoking, it was associated with increased mortality, with observed risks higher among secondary compared to primary cigar smokers (Chang et al., 2015).

# Impact of Frequency and Intensity of Cigar Smoking on All-Cause Mortality

A paucity of studies have examined the impact of frequency (Christensen et al., 2018; Inoue-Choi et al., 2019) or intensity (Kahn, 1966; NCI, 1998) of cigar smoking or the impact of depth of inhalation on risk of mortality (NCI, 1998). Mortality risk increased significantly with more frequent cigar smoking (daily versus nondaily) (Christensen et al., 2018; Inoue-Choi et al., 2019) and increasing number of cigars smoked per day (Kahn, 1966; NCI, 1998). Overall, daily (RRs, 95 percent CI: 1.22–1.49), but not nondaily (RRs, 95 percent CI: 1.04–1.12) cigar smoking was associated with significantly increased risk of all-cause mortality among current primary cigar smokers (Christensen et al., 2018; Corrigendum, 2019; Inoue-Choi et al., 2019). In NLMS, primary nondaily cigar smokers and daily cigar smokers had RRs of mortality of 1.12 (95 percent CI: 0.82–1.53) and

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1.22 (95 percent CI: 1.04–1.44), respectively, compared with never-tobacco users (Christensen et al., 2018).

Compared with never-tobacco users, current primary cigar smokers who smoked 1–2, 3–4, and  $\geq$ 5 cigars/day had RRs of mortality of 1.02 (95 percent CI: 0.97–1.07), 1.08 (95 percent CI: 1.02–1.15), and 1.17 (95 percent CI: 1.10–1.24), respectively (NCI, 1998). Likewise, among secondary cigar smokers, smoking  $\geq$ 3 cigars per day was associated with significantly increased risk of all-cause mortality (RRs, 95 percent CI: 1.17–1.18) (NCI, 1998).

## Impact of Depth of Inhalation of Cigar Smoke on All-Cause Mortality

Only one study has examined the impact of inhalation depth on risk of mortality among cigar smokers (NCI, 1998). Among current primary cigar smokers in CPS-I, greater depth of inhalation was associated with significantly increased risk of all-cause mortality (IRRs [95 percent CI] were 1.04 [1.00–1.08], 1.19 [1.09–1.30], and 1.60 [1.38–1.84] for none, slight, and moderate-deep inhalation, respectively, compared to neversmokers) (NCI, 1998). Associations of inhalation depth and mortality were slightly reduced among secondary cigar smokers (IRRs [95 percent CI] were 1.04 [0.97–1.11], 1.16 [1.04–1.29], and 1.33 [1.16–1.51] for none, slight, and moderate-deep inhalation, respectively, compared to neversmokers) (NCI, 1998).

## **All-Cause Mortality Summary**

Cigar use in general is associated with increased risk of all-cause mortality compared to never-tobacco use, with generally lower risk than that observed in cigarette smoking and higher risk than in pipe smoking. The risk for all-cause mortality with cigar smoking increases with daily cigar smoking, additional number of cigars smoked per day, and greater depth of inhalation.

Cigar use in studies of all-cause mortality do not distinguish premium from nonpremium cigars. That is, these studies may include premium cigars but also other large cigars, little cigars, or cigarillos. Studies that distinguish premium from nonpremium cigar use as well as studies that distinguish primary and secondary cigar smokers would better isolate the effects of premium cigar smoking. Information on frequency and intensity of cigar smoking, the depth of inhalation of cigar smoke, and the number of years smoking cigars would inform potential dose–response relationship and modifying factors. Most studies are conducted in predominately white male populations; the lack of studies that include women and racial and ethnic minority populations is a research gap.

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## CARDIOVASCULAR DISEASE

Cigarette smoking is a major cause of CVD, including coronary heart disease, stroke, and aortic aneurysm (Barua et al., 2018; HHS, 2010). The risk is nonlinear, meaning that it increases sharply with smoking a few cigarettes per day. Smoking 5 cigarettes per day has 50 percent or more of the risk compared to smoking 20 per day (Inoue-Choi et al., 2020). Most of the epidemiologic studies of cigar use and CVD were performed many years ago, and none provide data by the type of cigar smoked.<sup>4</sup> Some studies report risk by the number of cigars smoked per day but not for nondaily smokers. Several studies provide data on primary versus secondary cigar smokers, and several provide data on self-reported depth of inhalation. Many from the British Regional Heart Study and other studies present data on a combined group of pipe and cigar smokers but not cigar smokers alone.

The committee's review located two studies of the acute cardiovascular effects of cigar smoking. Vlachopoulos et al. (2004) examined the effects of smoking one premium cigar (Cohiba) compared to sham smoking in 12 young healthy cigarette smokers who had abstained from tobacco use for 12 hours. The cigar was smoked over 1 hour, producing an increase in expired CO of 12 ppm, an average increase in heart rate of 5 bpm, and increase in systolic blood pressure of 10 mmHg. Arterial stiffness measured using carotid-femoral pulse wave velocity (more stiffness produces higher velocity) was increased by cigar smoking. These effects are similar to those produced by cigarette smoking. The effect peaked at 60 minutes and declined toward baseline over the next 60 minutes. Arterial stiffness increased by 15 percent with cigar smoking, compared to prior studies showing an increase of 26 percent with active and 21 percent with passive cigarette smoking. These physiological effects are likely due to the sympathomimetic effects of nicotine and endothelial dysfunction known to be produced by smoke inhalation. Claus et al. (2018) studied 42 large cigar smokers who were instructed to smoke their cigar as desired for 60 minutes. Plasma nicotine levels increased to a level similar to that seen after cigarette smoking. Maximal increase in heart rate averaged 6.5 bpm (SD 10.1), systolic blood pressure 12.3 mmHg (14.5), and diastolic blood pressure 8.2 mmHg (7.0). These studies support that idea that inhaling smoke from any combusted tobacco product can produce the same pathophysiological effect, depending on dose and duration of use.

The 1998 NCI monograph reviewed the association between cigar use and CVD through 1997, including unpublished data from CPS-I (NCI,

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<sup>&</sup>lt;sup>4</sup> Studies that primarily looked at pipe smokers or combined pipe and cigar smokers in the analysis were not included in this review (for example, Wannamethee et al., 2005).

1998). There was generally a slight (and often nonsignificant) increased risk of coronary heart disease in primary and secondary cigar users, with variability across studies. There was a trend for increased risk based on the number of cigars smoked per day for primary cigar smokers (1–2 versus 3–4 versus 5+ per day) and for depth of inhalation (none versus slight versus moderate-deep); the risk in all cases was less than that of cigarette smoking.

Data from the CPS-I study found no increased risk of stroke death in either primary or secondary cigar smokers, regardless of the number of cigars smoked per day or the depth of inhalation. , CPS-I found a significant increase in risk of aortic aneurysm deaths for both primary and secondary cigar smokers, with no clear dose–response or relationship to depth of inhalation.

Chang et al. reviewed coronary heart disease mortality (Chang et al., 2015). This analysis included published data from CPS-I and CPS-II. The authors overall found a slight and generally nonsignificant increased risk in cigar-only smokers, with the exception of CPS-II, in which those age 30–74 who inhaled moderately deeply or had smoked for 25 or more years had a significant HR of approximately 1.4.

Several studies not included in previous reviews, or that are particularly informative (for example, large sample size) are summarized here. Wald and Watt (1997) used a prospective cohort study of British men 35-64 years old to examine the cause of death over the following 11-18 years and compared primary to secondary cigar smokers (those who had switched to cigars from cigarettes). The type of cigar was not reported. They also measured carboxyhemoglobin levels and found that secondary cigar smokers had higher levels than primary smokers (1.0 percent versus 0.9 percent), with both being much lower than that of cigarette smokers (4.6 percent). These data indicate that smoke inhalation on average was much lower in cigar than cigarette smokers. However, some cigar smokers reported moderate to deep inhalation and had carboxyhemoglobin levels similar to those in cigarette smokers. Ischemic heart disease mortality data were presented only for combined cigar and pipe smokers. Primary cigar/pipe users had no higher mortality than lifelong nonsmokers, while secondary cigar/pipe users had a slight but not significant increase in mortality risk (RR 1.29; 95 percent CI: 0.88-1.99). The relative mortality of current cigarette smokers compared to never-smokers was 2.27 (1.81-2.84).

Iribarren et al. (1999) conducted a prospective cohort study in the Kaiser Health system in California of 17,774 men 30–85, followed for 25 years. The group included 1,546 men who currently smoked cigars but never smoked cigarettes. No data were available on type of cigar, but it

was estimated that 21 percent smoked large cigars.<sup>5</sup> CVD, both nonfatal and fatal, was determined from hospital discharge diagnoses. In a multivariate analysis, cigar smoking was associated with a significantly increased risk of coronary heart disease compared to never-smokers (RR: 1.27; 1.12–1.45). Risk estimates for cigar smoking and ischemic stroke, hemorrhagic stroke, and peripheral arterial disease were nonsignificant, although the case numbers were relatively small. Compared to neversmokers, cigar smokers who used fewer than 5 per day had a lower RR for coronary heart disease (1.20; 1.03–1.40) compared to those who smoked more than 5 (RR: 1.56; 1.21–2.01). The study could not distinguish occasional versus daily cigar smokers.

The CPS-II was another prospective cohort study of 121,278 male primary cigar smokers, over age 30 who smoked at least one cigar per day (Jacobs et al., 1999). They were followed between 1982 and 1991, during which time 2,508 deaths occurred. In a multivariable analysis, the IRR for coronary heart disease mortality was 1.30 (1.05–1.62) for current cigar smokers aged 30–74 but was not significantly increased for those 75 or older. Analysis by amount smoked found a significant increase in mortality for those smoking two or more cigars daily, but no increase among those smoking one cigar per day. Analysis by duration found an increase in mortality for those who had smoked for 25 or more years but not for less than 25 years. The mortality risk was also higher among those who reported inhaling compared to those who did not.

Christensen et al. (2018) identified the causes of death based on ICD-10 codes, including circulatory, cardiovascular, and cerebrovascular causes. The age-adjusted risk of circulatory death was significantly increased in former (HR: 1.50; 1.23–1.82) and current (HR: 1.42; 1.12–1.81) cigar smokers compared to never-tobacco users, but these effects became nonsignificant in multivariable analysis controlling for sex, race and ethnicity, education, and survey year. The age-adjusted risk of cardiovascular death was significantly increased in former (HR: 1.56; 1.25–1.94) but not current (HR: 1.24; 0.94–1.62) cigar smokers, with no significant risk after multivariable analysis. No significant increased risk was found for cerebrovascular disease, but the number of deaths was small and considered to be too low to make a robust analysis of daily versus nondaily use (Christensen et al., 2018).

Rostron et al. (2019) studied morbidity associated with current primary cigar smokers age 35 or more using NHIS data between 2000 and 2015. Current use was defined as every day or some days. Health condi-

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<sup>&</sup>lt;sup>5</sup> The study authors reported that, based on a previous study using this dataset in 1998 in a smaller group of men (examined between 1979 and 1985), 70 percent had smoked for at least 10 years, and 21 percent smoked large cigars (see Iribarren et al., 1998).

tions were based on self-report or ever having a heart condition (angina, coronary heart disease, heart attack, other heart disease, or stroke). Current primary cigar smoking was not associated with an increased risk of heart attack or stroke. However, former primary cigar smoking was associated with an increased risk of heart conditions (APV: 1.33; 1.03–1.72) and stroke (APV: 2.42; 1.57–3.75) compared to never-smokers. The authors speculate that former cigar use might be explained by smoking cessation in response to disease onset.

Inoue-Choi et al. (2019) used NHIS data from 1991 to 2010 to examine tobacco-related mortality. The analysis included 1,592 exclusive cigar users, but cigar type was not determined. The risk of coronary heart disease mortality was more strongly associated for daily (HR: 1.32; 0.69–2.50) than nondaily (HR: 1.21; 0.57–2.56) cigar smokers compared to neversmokers. For cerebrovascular disease death, neither daily nor nondaily cigar use was associated with increased risk compared to never-tobacco users. A limitation of this study was the relatively small number of deaths (Corrigendum, 2019; Inoue-Choi et al., 2019).

## **CVD Summary**

Cigar smoke is similar to cigarette smoke and would be expected to produce similar cardiovascular toxicity if the extent of exposure is similar. Smoking a single premium cigar has been shown to produce similar acute cardiovascular effects as smoking a cigarette. The effects of long-term cigar use are expected to depend on depth of inhalation and frequency of product use. The studies measuring CO levels suggest that cigar smokers on average inhale much less smoke than cigarette smokers and that secondary cigar smokers inhale more than primary cigar smokers.

Unfortunately, epidemiologic studies to date generally do not report the type of cigar smoked, and the few that did reported on percent of large cigars but did not differentiate premium cigars from other large cigars. Overall, primary cigar smoking appears to be associated with a small but significant increased risk of cardiovascular morbidity and mortality. Cardiovascular risk is generally higher in secondary cigar smokers but still much less than continuing cigarette smokers. There is evidence that the number of cigars smoked per day and depth of inhalation are related to cardiovascular risk. Data are limited on the risks of nondaily cigar smoking, and the available data suggest that the associated cardiovascular risk is low.

Based on what is known about premium cigar product characteristics and the biological mechanism of CVD risk, that risk is likely to be significant if a person smokes premium cigars daily, although generally less than that of cigarette smoking. If a person inhales premium cigar smoke,

the risk would be greater. Exposure to secondhand cigarette smoke by nonsmokers increases the risk of coronary heart disease in general and also of acute coronary events and stroke (Vanker et al., 2017). While it was not studied explicitly, based on such evidence, one would predict that even occasional cigar use would present a similar risk, particularly in individuals with underlying CVD.

A major research need is assessment of the type of cigar, frequency of use, and inhalation when studying disease risk. In addition, cardiovascular risk needs to be assessed in people with existing vascular disease, as this population would be especially vulnerable to adverse effects of acute short-term smoke or nicotine exposure.

## LUNG CANCER AND RESPIRATORY DISEASE

## Lung Cancer

Cigarette smoking is the main lung cancer risk factor, increasing the risk of incidence and mortality for all major lung cancer histological types. Current and former smokers have considerably higher risks than neversmokers. Lung cancer risk increases as a function of cigarette smoking duration, intensity (usually measured as cigarettes per day), and cumulative exposure (usually measured as pack-years) and decreases as a function of years since quitting (Hecht, 2012; HHS, 2014; Rachet et al., 2004; Remen et al., 2018; Tammemägi et al., 2013).

Cigar use has also been shown to be associated with lung cancer risk, with higher intensity and longer durations associated with higher risk. Most epidemiological studies evaluating the relationship between cigar use and lung cancer have focused on overall cigar use, with no distinction by type. Some studies have evaluated the risk of exclusive cigar use, with others considering cigar and cigarette smoking or cigar and pipe use combined. The literature search found no studies evaluating the specific lung cancer risks from premium cigar use.

Studies of the association between cigar use and lung cancer through 1997 were previously reviewed (NCI, 1998). The evidence was sufficient to conclude that a causal relationship exists between regular cigar use and lung cancer but that the risk was lower than for regular cigarette smokers. It also concluded that lung cancer mortality risk increased as a function of the number of cigars smoked per day and with the depth of inhalation. No consideration was given to variations of risk by cigar type or between different lung cancer histologies.

Recent studies not covered in the 1998 review are summarized here. Boffetta et al. (1999) conducted a case-control study of the association between cigar, cigarillo, pipe, and cigarette smoking with lung cancer

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incidence, overall and by histology, in users from seven European areas. The study found lung cancer OR for exclusive cigar and cigarillo use of 9.0 (95 percent CI: 5.8-14.1) versus nonsmokers of any tobacco product, comparable with the OR of exclusive cigarette smoking of 14.9 (95 percent CI: 12.3-18.1). The study found a dose-response relationship for duration and cumulative exposure for cigar and cigarillos, with similar dose-response relationships for all four products considered. In particular, the analysis found a 3.3 (95 percent CI: 1.8-6.0) lung cancer OR per one log-unit increase in cumulative exposure (measured as grams per day per year, with one cigar assumed to have four grams of tobacco on average) of cigars and cigarillos. For cigarette smoking, the odds of lung cancer were also estimated to increase by 3.3 (95 percent CI: 3.1-3.6) per one log-unit increase in cigarette pack-years. An effect was also reported for inhalation of cigar and cigarillo smoke. The authors concluded that the lower overall risk of lung cancer among smokers of cigars and cigarillos compared with cigarette smokers might be due to the lower levels of consumption (intensity) of cigar users. With regards to lung cancer histological type, the risk of squamous cell carcinoma increased along with cumulative consumption of either cigars or cigarillos. Among heavy smokers, the risk of small cell carcinoma but was higher than for adenocarcinoma.

Shapiro et al. (2000) conducted a longitudinal study of the relationship between cigar use (measured at baseline) and cancer mortality in CPS-II that did not differentiate cigars by type and excluded those who ever smoked cigarettes or pipes. Current cigar smoking at baseline was associated with increased risk of lung cancer death, with an IRR of 5.1 (95 percent CI: 4.0–6.6). Former cigar smokers were also found to have a higher risk of lung cancer with an IRR of 1.6 (95 percent CI: 1.2–2.4) versus never-users. Strong dose response relationships by intensity (cigars per day) and duration (25 years or more) were found. Lung cancer mortality risks were considerably higher for cigar users reporting inhalation (IRR: 11.3; 95 percent CI: 7.9–16.1 versus never-users), than for those not reporting inhalation (IRR: 3.3; 95 percent CI: 2.3–4.7 versus never-users). Current cigar smokers at baseline reporting 1–2 cigars per day did not have statistically significant higher risks than never cigar smokers (IRR: 1.3; 95 percent CI: 0.7–2.4).

McCormack et al. (2010) evaluated the association of cigar and pipe smoking with lung cancer incidence in the prospective European Prospective Investigation into Cancer and Nutrition (EPIC) cohort (pooled data from eight cohort centers). Exclusive current cigar smokers were found to have a lung cancer incidence HR of 3.9 (p < 0.05) relative to never-smokers. For comparison, exclusive cigarette smokers were found to have an HR of 32 (p < 0.05). Ever exclusive cigar use was not significantly associated with lung cancer risk (HR: 2.4; 95 percent CI: 0.7–8.2),

but ever exclusive cigarette smoking was significantly associated (HR: 15.2; 95 percent CI: 10.0–23.4). Lung, upper aerodigestive tract (UADT), and bladder cancer (BC) combined risk among exclusive cigar smokers increased by depth of inhalation, duration of use, and intensity (cigars per week). Risk among former cigar users increased by the age at smoking cessation. Notably, exclusive cigar users reporting inhalation were found to have considerably higher lung, UADT, and BC risk (HR: 7.5; 95 percent CI: 3.0–18.8] versus never-smokers), than those reporting no inhalation (HR: 1.8; 95 percent CI: 0.7–4.6]). The authors concluded that the lower cancer risk of cigar and pipe smokers as compared to cigarette smokers is explained by lesser degree of inhalation and lower smoking intensity (McCormack et al., 2010).

Lee et al. (2012) conducted a meta-analysis of the relationships among cigarettes, pipes, and cigars and lung cancer and found a relationship with lung cancer risk for ever exclusive cigar smoking (random-effects RR: 2.92; 95 percent CI: 2.38–3.57), current exclusive cigar smoking (RR: 4.67; 95 percent CI: 3.49–6.25), and former exclusive cigar smoking (RR: 2.85; 95 percent CI: 1.45–5.61). For comparison, the analysis found a lung cancer relationship for ever exclusive cigarette smoking (RR: 6.36; 95 percent CI: 5.33–7.59), current exclusive cigarette smoking (9.57; 95 percent CI: 7.90–11.59), and former exclusive cigarette smoking (4.22; 95 percent CI: 3.29–5.40).

Malhotra et al. (2017) evaluated the association between cigar and/ or pipe smoking and cancer incidence risk in men in a pooled analysis of five prospective cohorts from the NCI Cohort Consortium in Australia, Netherlands, and the United States (N = 524,400). The study found that ever cigar and/or pipe users were at significantly increased risk for lung cancer incidence versus never-smokers of cigarettes, cigars, and pipes. In particular, exclusive ever cigar users were found to be at higher risk of lung cancer (HR: 2.73; 95 percent CI: 2.06–3.70).

Christensen et al. (2018) evaluated the association of cigarette, cigar, and pipe use with cause-specific mortality, including lung cancer, in the NLMS (N = 357,420). Exclusive current cigar users were at high risk of lung cancer mortality (HR: 3.26; 95 percent CI: 1.86–5.71). Daily exclusive cigar users had a statistically significant higher risk of lung cancer mortality (HR: 4.18; 95 percent CI: 2.34–7.46), but nondaily exclusive cigar users did not (HR: 0.74; 95 percent CI: 0.08–7.26). In a similar study, Inoue-Choi et al. used data from the linked mortality follow-up of the NHIS to evaluate the association among exclusive cigarette, smokeless tobacco, pipe, and cigar use with overall and cause-specific mortality, including lung cancer mortality (Corrigendum, 2019; Inoue-Choi et al., 2019). For exclusive cigar users, the HR for lung cancer mortality was elevated but not statistically significant (HR: 1.87; 95 percent CI: 0.53–6.55). However,

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the authors cautioned about the interpretation of these results given the relatively small sample size of cigar users and the small number of cancer deaths observed in this group.

## Lung Cancer Summary

As noted throughout this report, cigar smoke is similar to cigarette smoke and would be expected to produce similar lung cancer risks if the magnitude of exposure is similar. Like cigarette smoking, cigar smoking has been shown in multiple epidemiological studies to result in considerable lung cancer incidence and mortality risk and to have strong dose– response relationships with intensity, duration, and cumulative exposure. Risk for former cigar smokers is highest for those quitting use at older ages. The lung cancer risk from cigar use is considerably higher for users who report inhalation.

Limited information is available regarding the risks by specific cigar types, with only one study reporting risks for cigars versus cigarillos. The literature search found no studies reporting specific risks for premium cigar users. However, based on the cigar literature, it is expected that daily or frequent long-term use of premium cigars would result in considerable lung cancer risk.

A major research need is the consideration of type of cigar, including premium cigars, as well as the frequency of use, duration, intensity, cumulative exposure, and pattern of inhalation when studying the associations with lung cancer. In addition, the existing literature does not estimate the associations between cigar use and specific lung cancer histological types.

## **Other Respiratory Diseases**

Despite several studies examining the relationship of cigar use with lung cancer, only a few have studied their impact on other respiratory diseases. The literature on the relationship between cigar use and chronic obstructive pulmonary disease (COPD) was reviewed through 1997 (NCI, 1998). Based on two studies, the authors concluded that while the association between cigar and COPD risk is less striking than that for cigarette smoking, the studies reviewed support the conclusion that cigar smoking can cause COPD in users who inhale deeply. The 1998 review also concluded that the reduced inhalation of tobacco smoke by cigar users probably explains the lower risks of COPD and lung cancer among cigar smokers compared to cigarette smokers (NCI, 1998).

The committee's literature search found only four studies published after 1997 reporting on the association between cigar use and COPD. A few additional studies evaluated the association of cigar use with asthma

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and respiratory symptoms, such as wheezing. None of these studies evaluated risks specific for premium cigar users.

Jimenez Ruiz et al. (2002) evaluated the prevalence of COPD in different tobacco use groups in Spain using a cross-sectional, nationally representative sample. Data from 4,035 individuals aged 40–69 were included, dividing the sample into noncurrent smokers, current exclusive cigar smokers, current exclusive cigarette smokers, dual smokers, current exclusive cigar smokers who used to smoke cigarettes, and current cigarette smokers who used to smoke cigars. The analysis found that all current use groups had statistically significantly higher prevalence of COPD (diagnosed through spirometry) and respiratory symptoms (cough and expectoration) versus noncurrent smokers. However, the prevalence of COPD and respiratory symptoms was higher in those reporting either current cigarette smoking, exclusively or dual, or in cigar smokers who used to smoke cigar use.

Mannino et al. (2000) examined the prevalence of COPD or asthma (obstructive lung disease), low lung function, and respiratory symptoms by tobacco use group in the National Health and Nutrition Examination Surveys (NHANES) from 1988 to 1994. Respondents were classified as never-smokers, current cigarette smokers, former cigarette smokers, or pipe or cigar smokers. Low lung function was defined as a forced expiratory volume in 1-second forced vital capacity (FEV1/FVC) of less than 0.7 and a forced expiratory volume in 1 second (FEV1) less than 80 percent of the predicted value. The study found an age-adjusted prevalence of obstructive lung disease of 12.5 percent among current cigarette smokers, 9.4 percent among former cigarette smokers, 3.1 percent among pipe or cigar smokers, and 5.8 percent among never-smokers.

Christensen et al. (2018) evaluated the association of cigarette, cigar, and pipe use with cause-specific mortality, including COPD, in NLMS (N = 357,420) and found a borderline nonsignificant association between current exclusive cigar use overall and COPD (HR: 2.44; 95 percent CI: 0.98–6.05) but a significant association between current exclusive daily cigar use and COPD (HR: 3.29; 95 percent CI: 1.33–8.17).

Rodriguez et al. (2010) studied the association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction in the Multi-Ethnic Study of Atherosclerosis. Participants reporting a history of pipe, cigar, or cigarette use were classified as exclusive ever users of pipes or cigars combined, exclusive ever users of cigarettes, or ever users of both products. Lung function, measured as FEV1 or FEV1/FVC, decreased among participants with a history of pipe or cigar smoking only, cigarette smoking only, and pipe or cigar and cigarette smoking, compared to never-smokers. However, the decrement was modest and not statistically significant among the 55 participants who smoked pipes or cigars only.

The odds of airflow obstruction increased in all tobacco use groups compared with never-smokers: pipes or cigars only (OR: 2.31; 95 percent CI: 1.04–5.11), cigarettes only (OR: 2.01; 95 percent CI: 1.31–3.08), and pipes or cigars and cigarettes (OR: 3.43; 95 percent CI: 1.75–6.71). Greater cigaryears (product of number of years smoked or duration times cigars per day) were associated with a decrement in lung function, which was statistically significant for FEV1/FVC ratio; -0.2 (-0.3, -0.05) decrease in FEV1/ FVC ratio per 10 cigar-years (duration of use times number of cigars per day). The authors concluded that pipe and cigar smoking measurably increase the risk of COPD.

Three studies evaluated associations between cigar and other tobacco product use with asthma. Jones et al. (2006) compared the prevalence of tobacco use among high school students with and without self-reported asthma in the 2003 Youth Risk Behavior Survey and found that those with current asthma used cigarettes at higher rates than those without asthma, but the rate of cigar use was similar between those with and without current asthma (OR: 1.0; 95 percent CI: 0.9-1.2). Among students with current asthma, those who had an asthma episode or attack were significantly more likely than those who had not to report lifetime daily cigarette use (OR: 1.5; 95 percent CI: 1.1–2.1), current frequent cigarette use (OR: 1.6; 95 percent CI: 1.04-2.6), and current cigar use (OR: 1.6; 95 percent CI: 1.03-2.6). Lappas et al. (2016) compared the immediate effects of cigar smoking on respiratory mechanics and exhaled biomarkers between young smokers with and without mild asthma. Participants with mild asthma were recruited from an outpatient lung function clinic. The results suggest that cigar smoking has immediate effects on pulmonary function, affecting exhaled CO, multi-frequency respiratory system impedance, and other outcomes, with mild asthma being associated with a higher increase of peripheral airway resistance (frequency dependence of resistance) after cigar smoking. Veldhuis et al. (2021) evaluated the association of selfreported asthma, sexual identity, and inhaled substance use, including cigar use, among U.S. adolescents and found that cigarettes, cigars, and electronic vapor products were all associated with asthma in both female (cigar relative risk ratio [RRR] 1.58; 95 percent CI: 1.28-1.96) and male (cigar RRR of 1.35; 95 percent CI: 1.14-1.62) adolescents. Similar risks were estimated for all tobacco products.

Schneller et al. (2020) evaluated the association between different tobacco product use and self-reported wheezing symptoms among U.S. adults from the PATH study. Significant higher odds of ever had wheezing or whistling in the chest at any time in the past were observed among current cigarette (aOR: 2.62; 95 percent CI: 2.35–2.91), electronic nicotine delivery systems (ENDS) (1.49; 95 percent CI: 1.14–1.95), and poly-tobacco (2.67; 95 percent CI: 2.26–3.16) users compared with noncurrent users. However, no significant association was found for cigar use.

## **Other Respiratory Diseases Summary**

Cigar smoking in general, particularly for those who inhale, increases the risk of COPD and reduced lung function. Higher risks have been found for those reporting longer and more intense use. The association of cigar smoking with asthma or asthma exacerbation is less clear, with some studies reporting an association and others not. Limited sample sizes, inconsistency in the outcomes studied, and combination of cigar users with other tobacco product users (e.g., cigar or pipe smokers) make it difficult to reach a conclusion.

No information is available regarding the risk of COPD, lung function, asthma, and respiratory symptoms by specific cigar types. The literature search found no studies reporting specific risks for premium cigar users.

Similar to the other health effects reviewed thus far in this chapter, a major research gap is that published studies do not consider type of cigar and the frequency of use, duration, intensity, cumulative exposure, and pattern of inhalation when studying the associations with respiratory diseases. Moreover, additional studies of relevant respiratory diseases, such as COPD and asthma, are needed.

## PERIODONTAL DISEASES AND CANCERS OF THE ORAL CAVITY, HEAD, AND NECK

While many premium cigar smokers may not inhale as much smoke as do smokers of cigarettes and other types of cigars, they do take smoke into their oral cavity and often hold it over long periods. Smoke constituents will therefore interact with tissues in the mouth and pharynx, and may, by swallowing, interact with esophageal tissues.

## Premium Cigars and Periodontal Diseases

## Anatomy of the Periodontium

The periodontium includes hard and soft tissue structures supporting the teeth: gingiva, cementum covering the roots, periodontal ligament attaching those root surfaces to the alveolar bone under each tooth, and that bone (Fiorellini, 2019). The gingiva covers the other periodontal structures, and is comprised of free gingiva, interdental gingiva, and attached gingiva. The attached gingiva extends from the bottom of the gingival sulcus to the mucogingival junction, where it is contiguous with the mucous membrane of the lip, cheek, and floor of the mouth. The free gingiva extends from the base of the gingival sulcus to the gingival margin, and the interdental gingiva fills the space between the teeth (Fiorellini, 2019).

A healthy gingival margin is positioned approximately 1.5–2.0 mm coronal to the cemento-enamel junction (CEJ, where the enamel on the tooth crown meets the root) (Lindhe, 2015); the sulcus probing depth is  $\leq$ 3 mm, and does not bleed when probed (Do, 2019). The sulcus base is formed by junctional epithelium, which joins the gingival connective tissue to the tooth surface. Healthy gingiva should be pink, well adapted to the teeth, stippled on the surface, and tightly bound to the alveolar bone and tooth roots (Do, 2019).

## Periodontitis

"Periodontitis is a chronic multifactorial inflammatory disease associated with dysbiotic plaque biofilms and characterized by progressive destruction of the tooth-supporting apparatus" (Papapanou et al., 2018, pg. 1). Primary features of peritonitis include: presence of periodontal pocketing, gingival bleeding, and the loss of periodontal tissue support (manifested through clinical attachment loss and radiographically assessed alveolar bone loss) (Papapanou et al., 2018). Periodontitis is considered a major public health problem due to its high prevalence "and because it may lead to tooth loss and disability, negatively affect chewing function and aesthetics, be a source of social inequality, and impair quality of life" (Papapanou et al., 2018, pg. 1). In addition, periodontal inflammation is associated several chronic conditions, including CVD, diabetes and its management, chronic kidney disease, rheumatoid arthritis, and pregnancy complications (Bui et al., 2019; Hajishengallis and Chavakis, 2021; Kapellas et al., 2019; Liccardo et al., 2019; Mankia et al., 2019; Martinez-Herrera et al., 2017; Moliner-Sánchez et al., 2020; Rodríguez-Lozano et al., 2019; Sanz et al., 2018).

## Mechanisms of Tobacco-Smoke-Caused Periodontal Disease

No studies are specific to the biological mechanisms of periodontitis associated with cigar use. Multiple lines of investigation exist on the biologic mechanisms involved in periodontitis due to cigarette smoking, although smoking-related periodontal pathogenesis is not yet fully understood. To the extent that smoke from combusted premium cigars contains similar agents to mainstream cigarette smoke, the mechanisms associated with cigar-associated periodontitis are likely to be similar to those involved in cigarette-related periodontitis.

Oral microorganisms have been established as major factors in the pathogenesis of periodontitis for more than half a century. The oral cavity is a complex ecosystem that can harbor hundreds of bacterial species as well as other microbes that normally act as symbiotic communities with

the host (Lasserre et al., 2018). Periodontal disease and health are more likely to be associated with qualitative or quantitative shifts in microbiome within periodontal biofilms rather than the presence or absence of specific pathogenic bacteria. It is hypothesized that soft tissue and alveolar bone destruction involves both toxins and proteases produced by the bacteria and hyperresponsiveness and reactivity of immune system components, including the production of cytokines and prostaglandins (HHS, 2004). Multiple studies have found that cigarette smoking affects the composition of the oral microflora (Apatzidou et al., 2005; Hanioka et al., 2000; Jiang et al., 2020; Kubota et al., 2011; Moon et al., 2015; van Winkelhoff et al., 2001). It also affects humoral and cell-mediated immune responses, which may increase susceptibility to periodontitis (Loos et al., 2004; Palmer et al., 2005; Ryder, 2007), and appears to alter the periodontal inflammatory response (Dietrich et al., 2004).

Based on findings from animal studies, it was hypothesized that the peripheral vasoconstrictive effect of nicotine reduces gingival blood flow and thereby impairs the delivery of oxygen and nutrients to the tissue (Clarke and Shephard, 1984). However, subsequent evidence from human studies does not support that hypothesis (Silva, 2021). A comprehensive review by Silva (2021) does suggest that chronic tobacco exposure causes long-term microvascular dysfunction, which may play a role in the progression of periodontitis. It has long been observed that smokers tend to exhibit less gingival bleeding than nonsmokers, even when controlling for bacterial plaque levels (Bergström and Boström, 2001; Dietrich et al., 2004; Rivera-Hidalgo, 2003). However, this decrease may be more related to suppression of an inflammatory response than to reduced gingival blood flow (Silva, 2021).

Nicotine can be stored in and released from periodontal fibroblasts and may affect their morphology and ability to attach to root surfaces (Hanes et al., 1991; James et al., 1999; Raulin et al., 1988; Tanur et al., 2000). Thus, it is possible that smoking impairs the ability of periodontal tissues to repair damaged junctional epithelium (HHS, 2004). Substantial evidence indicates that smoking impairs wound healing and compromises outcomes following surgical or nonsurgical periodontal therapy (Ah et al., 1994; Boström et al., 1998; Grossi et al., 1996; Grossi et al., 1997; Kaldahl et al., 1996; Kinane and Radvar, 1997; Machtei et al., 1998; Newman et al., 1994; Palmer et al., 1999; Papantonopoulos, 1999; Preber and Bergström, 1990; Preber et al., 1995; Renvert et al., 1998; Rosenberg and Cutler, 1994; Söder et al., 1999; Tonetti et al., 1995; Trombelli and Scabbia, 1997). Although the exact mechanisms are not yet known, the various factors produce increased tissue destruction and diminished healing response, with a net effect of periodontal tissue breakdown.

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#### Human Studies

The evidence is strong and consistent that cigarette smoking is a major cause of periodontitis. The 2004 Surgeon General's Report on Smoking and Health concluded that the evidence supported a causal relationship (HHS, 2004). Similarly, a 2006 systematic review of more than 100 observational studies concluded that there is strong evidence to suggest that smoking negatively interferes with a healthy periodontal condition (Bergström, 2006). Consistent evidence has continued to accumulate since that time (Warnakulasuriya et al., 2010).

Compared with the large body of literature on the effects of cigarette smoking on periodontal health, very few observational studies have addressed cigar smoking. An extensive literature search identified just three human studies on cigars and periodontitis, and these did not contain specific information on premium cigars. All three studies were conducted among adults in the United States, and each used a different outcome measure.

Krall et al. (Krall et al., 1999) examined radiographic alveolar bone loss among participants in the Veterans Affairs Dental Longitudinal Study, a prospective cohort study of men aged 21–75 and in good medical health at baseline. Participants received comprehensive oral examinations every 3 years and were followed for up to 23 years. The percentage of alveolar sites that experienced radiographically apparent bone loss was twice as much among men who exclusively smoked cigars (type not specified) than among nonsmokers (16 percent versus 8 percent, p < .05), and was identical to the mean number of alveolar sites with bone loss among cigarette smokers (16 percent). Compared with nonsmokers, exclusive cigar smokers also experienced significantly higher rates of tooth loss (RR: 1.3; 95 percent CI: 1.2–1.5), adjusted for age, education, number of teeth at baseline, and percentage of periodontal sites with moderate-to-severe clinical or radiographic periodontal disease at baseline.

Albandar et al. (Albandar et al., 2000) conducted a cross-sectional study on the association between cigar, pipe, or cigarette smoking and periodontitis among participants in the Baltimore Longitudinal Study of Aging. The measure of exposure included current or former users of cigars (type not reported) or pipes, and detailed analysis was limited to white men. Among the 54 white men who were current or former cigar and/or pipe smokers, 7 (13 percent) were also current cigarette smokers and 22 (41 percent) were former cigarette smokers. The study found a significantly higher prevalence of moderate or severe periodontitis among current/former cigar/pipe smokers than among nonsmokers (17.6 percent versus 6.1 percent; p = .006), adjusted for age, sex, and race. Cigar/pipe smokers also had a significantly higher mean number of missing

teeth: (4.0 versus 1.9; p = .0006). The analyses for cigar/pipe smoking did not exclude or control for cigarette smoking.

Vora and Chaffee (2019) analyzed cross-sectional data on adults from the first wave (2013–2014) of PATH. The outcomes in that study were based on participants' self-report in response to two questions: "Have you ever been told by a dentist, dental hygienist, or other health professional that you have gum disease?" and "Have you ever had treatment for [gum disease, your gums] such as scaling and root planing, sometimes called deep cleaning." Cigar types included traditional cigars, cigarillos, and filtered cigars (results combined). In multivariable modeling that included age, sex, race/ethnicity, educational attainment, employment, use of dental services, and history of diabetes, current exclusive cigar smokers were more likely than adults who never used tobacco to report a diagnosis of gingival disease (OR: 1.9; 95 percent CI: 1.4–2.7) or treatment for it (OR: 1.5; 95 percent CI: 1.2–2.0). The strength of association between current cigar use and self-reported gum disease diagnosis or treatment was similar to those for current cigarette use (ORs: 2.2 and 1.5, respectively).

These three epidemiologic studies on cigar smoking consistently found more prevalent or incident periodontitis among cigar users than among nonsmokers. However, none of those studies were specific to premium cigars. One (Albandar et al., 2000) combined current and former use of cigars or pipes and did not exclude cigarette smoking in its measure of exposure, and one (Vora and Chaffee, 2019) used an outcome measure based on self-report, which may have low sensitivity compared with clinically determined disease status (Blicher et al., 2005; Gilbert and Nuttall, 1999; Yamamoto et al., 2009).

# Periodontal Diseases Summary

Very few human studies have estimated the risk of periodontitis associated with cigar smoking, and none explicitly studied premium cigars. However, three epidemiologic studies consistently found elevated odds of periodontitis compared with nonsmokers. Those findings are consistent with the relatively large body of literature on cigarette smoking and periodontitis, which is sufficient to reach a strong conclusion that cigarette smoking is a cause. Similarly, no known mechanistic studies exist specific to cigars in general or premium cigars in particular. However, the evidence is substantial that cigarette smoking is associated with changes in the oral microbial profile, causes disruption to humoral and cell-mediated immune function, degrades bone and soft tissue integrity, and impairs tissue repair. To the extent that combustion of premium cigars produces many of the same toxic agents as in mainstream cigarette

smoke, the various biologic mechanisms are likely involved in cigar-associated periodontitis.

### Cancers of the Oral Cavity, Head, and Neck

#### Mechanism

The major established pathways of cancer causation by cigarette smoking involves the exposure to carcinogens, the formation of covalent bonds between the carcinogens and DNA (DNA adduct formation), and the resulting accumulation of permanent somatic mutations in critical genes, which lead to clonal outgrowth and, through accumulation of additional mutations, to development of cancer (HHS, 2010).

### Human Studies

Seven case-control studies that investigated the association between cancers of the oral cavity and pharynx and cigar use have been published since the late 1980s (Blot et al., 1988; Franceschi et al., 1992; Franceschi et al., 1990; Garrote et al., 2001; Merletti et al., 1989; Schlecht et al., 1999; Spitz et al., 1988). Five were included in a narrative review (NCI, 1998). Two were conducted in the United States, three in Italy, one in Cuba, and one in Brazil. None of the seven specifically reported data on premium cigars; four (Blot et al., 1988; Franceschi et al., 1992; Franceschi et al., 1990; Garrote et al., 2001) combined use of cigars or pipes in their analyses; and two also included cancers of the larynx among the cancer outcomes in the main analysis (Schlecht et al., 1999; Spitz et al., 1988). Most studies explicitly controlled for cigarette smoking either through exclusion of concurrent cigarette smokers or by adjustment in multivariable modeling, but control for smoking was not clear in one of the studies (Spitz et al., 1988). All seven studies found a significant positive association between cigar use and cancers of the oral cavity or pharynx, with aOR estimates of 1.9-21.9. One study reported a dose-dependent association among current cigar smokers (Garrote et al., 2001) and another found that the odds of UADT cancers declined with the number of years since quitting cigar use (Schlecht et al., 1999).

A recent systematic review and meta-analysis of 13,935 cases and 18,691 controls from 13 case-control studies conducted in multiple regions of the world examined the association between cigar use (type not specified) and cancers of the head and neck, including of the oral cavity, oro-pharynx, hypopharynx, larynx, and other nonspecified sites (Wyss et al., 2013). Among persons who had never smoked cigarettes, those who had ever used cigars were at elevated risk compared with those who never

used cigars (OR: 2.54; 95 percent CI: 1.93–3.34). Among cigar smokers who never smoked cigarettes, the odds of head and neck cancer significantly increased with the number of cigars per day, duration of cigar use, and cumulative cigar-years (p for trend <.0001 for all three). In site-specific analysis among persons who never smoked cigarettes, cigar use was associated with increased odds of cancer of the oropharynx (OR: 2.31; 95 percent CI: 1.54–3.45) and all other cancer sites.

Two large U.S. prospective studies estimated the risk for death due to cancers of the oral cavity or pharynx associated with cigar use at baseline. Shanks and Burns reported findings from CPS-I (NCI, 1998). CPS-I collected baseline data in 1959 and tracked cause-specific mortality for up to 13 years; it conducted cigar analyses for white men and classified users as either primary cigar smokers (those who never used cigarettes or pipes) or secondary cigar smokers (those who had formerly used cigarettes or pipes but only used cigars at the time of the baseline data collection). Overall, white men who were primary cigar smokers at baseline had an age-adjusted IRR for death due to oral or pharyngeal cancer of 7.92 (95 percent CI: 5.12–11.69) relative to never-smokers and secondary cigar smokers had an age-adjusted IRR of 6.58 (95 percent CI: 2.83–12.97). Analysis of CPS-I data also revealed a dose-dependent risk among primary cigar smokers (IRR: 2.12; 95 percent CI: 0.43-6.18 among men who smoked 1-2 cigars per day to IRR: 15.94; 95 percent CI: 8.71-26.75 for men who smoked 5 or more per day). A similar pattern was reported in secondary cigar smokers (IRR: 4.39–13.73, despite no data for men who smoked 3-4 cigars per day). That study also provided RR estimates by reported depth of inhalation. The risk of mortality due to cancer of the oral cavity or pharynx among primary cigar smokers increased consistently with reported depth of inhalation (IRR: 6.98; 95 percent CI: 4.13-11.03 among men who reportedly did not inhale to IRR 27.88; 95 percent CI: 5.60-81.46 among those who reported moderate to deep inhalation). The pattern was identical among secondary cigar smokers.

CPS-II was a prospective cohort study that enrolled 1.2 million men and women in 1982 and tracked cause-specific mortality for up to 12 years (Shapiro et al., 2000). Similar to CPS-I, analyses of mortality among cigar smokers were limited to men. In CPS-II the mortality IRR for cancers of the oral cavity or pharynx was 4.0 (95 percent CI: 1.5–10.3) among current cigar smokers and 2.4 (95 percent CI: 0.8–7.3) among former cigar smokers. The IRR estimates were higher among men who reported inhalation of cigar smoke (IRR: 6.5; 95 percent CI: 1.4–29.2) than among those who reportedly did not inhale (IRR: 3.2; 95 percent CI: 0.9–11.0). The data were too sparse for detailed analysis by number of cigars per day.

Iribarren et al. (1999) examined UADT cancers in exclusive cigar smokers (cigar type not reported). Among men who had never smoked

cigarettes and did not currently smoke a pipe, those who currently smoked cigars at baseline experienced an age-adjusted incidence rate of UADT cancers of 2.0 per 10,000 person-years. Compared with men who did not smoke cigars, the adjusted relative risk was 2.02 (95 percent CI: 1.01–4.06). The association was stronger when analysis was limited to cancers of the oropharynx (adjusted RR: 2.61; 95 percent CI: 1.18–5.76).

In a recent meta-analysis, Malhotra et al. (2017) found that cigar (type not reported) and/or pipe smokers were at elevated risk for cancers of the head and neck (HR 1.51; 95 percent CI: 1.22–1.87). In a subgroup analysis that included the two cohort studies with the most detailed data on frequency and duration of tobacco use, exclusive cigar smokers with no history of cigarette smoking had an elevated risk of these cancers (HR 2.59; 95 percent CI: 1.21–5.58).

Pooled data from the EPIC study were used to investigate UADT cancer incidence rates among men who smoked cigars (type of cigar not reported) (McCormack et al., 2010). Men who ever exclusively smoked cigars had an elevated HR relative to those who never smoked (HR: 4.0; 95 percent CI: 1.7–9.4). Men who had quit cigarette smoking and became current cigar smokers had an HR for UADT cancer (HR: 8.2; 95 percent CI: 4.1–16.7) that was comparable to that observed for exclusive cigarette smokers (HR: 8.9; 95 percent CI: 3.1–6.6).

#### Cancers of the Oral Cavity, Head, and Neck Summary

Consistent data from all identified cohort and case-control studies indicate a significantly elevated risk for oral and pharyngeal cancer associated with cigar use, with evidence of a dose-dependent relation. Coupled with biologic mechanisms that likely are very similar to those involved in cigarette-related carcinogenesis, the available evidence strongly supports the conclusion that cigar use is a cause of cancer of the oral cavity and pharynx. Although none of the available studies specifically examined the risk associated with premium cigars, it is very likely that their use also increases the risk for oral and pharyngeal cancer. The level of increased risk will likely depend on the frequency of premium cigar smoking, which is generally lower than that of smoking other types of cigars.

#### **OTHER CANCERS**

Cigar use is associated with the risk of other cancers. In particular, the 1998 NCI monograph reviewed the literature on the associations between cigar use and bladder and pancreatic cancer based on the evidence through 1997 (NCI, 1998). It concluded that although a few studies suggested an association between BC risk and cigar use, several other

studies had not found evidence of such association. In contrast, the 1998 review concluded that cigar users have higher rates of pancreatic cancer with increasing risk with higher number of cigars per day, level of inhalation, and age. It also concluded that regular cigar use causes cancers of the lung, oral cavity, larynx, esophagus, and probably pancreas.

Recent studies evaluating the associations of cigar use with bladder, pancreatic, and other cancers since 1997 are discussed next (note that esophageal, bladder, and pancreatic cancer are also discussed in greater detail in the following sections).<sup>6</sup> Andreotti et al. (2017) evaluated the associations between exclusive cigar, cigarillos, and smokeless tobacco ever use with the incidence of several cancers in the prospective Agricultural Health Study (n = 84,015). They found that exclusive cigar ever use at baseline was associated with all cancers (HR: 1.51; 95 percent CI: 1.20-1.90) and smoking-related cancers7 (HR: 1.87; 95 percent CI: 1.24-2.82), but no statistical association was found with gastrointestinal cancers (HR: 1.58; 95 percent CI: 0.84-2.98). The study also found a positive association with urinary cancer (bladder, kidney, and ureter cancers combined) (HR: 2.50; 95 percent CI: 1.27-4.93). Only 76 total cancers in exclusive ever cigar users were available for the study, precluding site-specific analyses. The study found that dual cigarette and cigarillo use is associated with higher risks of overall, smoking-related, and lung cancers than exclusive cigarette smoking but that dual cigar and cigarette smoking have similar risks as exclusive cigarette smoking.

Engeland et al. (1996) evaluated the associations of smoking habits, including cigar smoking, and the incidence of cancers other than lung among 26,000 Norwegian men and women recruited in 1965 and followed through 1993. The cancers studied were urinary, bladder, kidney, pancreas, upper digestive and respiratory tract (head and neck and esophageal cancer combined), uterine, cervix, stomach, colon, rectum, breast, corpus uteri, ovary, and prostate, and leukemia. No association was found between cigar use and any of the studied cancers.

Malhotra et al. (2017) evaluated the association between cigar and/or pipe smoking and cancer incidence risk in men and found that ever cigar and/or pipe users were at significantly increased risk for head and neck cancer, lung cancer, and liver cancer versus never-smokers of cigarettes, cigars, and pipes. The risk of smoking-related cancers combined and of all cancers combined was also found to be significantly higher in ever cigar

<sup>&</sup>lt;sup>6</sup> Two studies were not included in the review: Efird et al. (2004) (methods say ever cigar, but table 2 suggests current cigar; excluded due to inconsistency); Sasco et al. (2004) (just one paragraph on other tobacco products).

<sup>&</sup>lt;sup>7</sup> The smoking-related cancers in the study included bladder, colon, cervix, esophagus, kidney, larynx, lip, liver, lung, myeloid leukemia, nasal and sinus, oral cavity, pancreas, pharynx, rectum, stomach, tongue, ureter, and uterus.

and/or pipe smokers. Exclusive ever cigar smokers were found to be at higher risk of head and neck cancer (HR: 1.40; 95 percent CI: 0.98–2.00), lung cancer (HR: 2.73; 95 percent CI: 2.06–3.60), smoking-related cancers (HR: 1.47; 95 percent CI: 1.34–1.61), and all cancers combined (HR: 1.07; 95 percent CI: 1.02–1.16).

McCormack et al. (2010) evaluated the association of cigar and pipe smoking in the prospective EPIC cohort. The cancers evaluated included lung, UADT, bladder, liver, stomach, pancreas, kidney, colorectal; and lung, UADT, and bladder combined; and all these tobacco-related cancers combined. Exclusive current cigar smokers were found to have higher risk compared to never-smokers of lung (HR: 3.9; p < 0.05); UADT (HR: 3.5; p < 0.05); lung, UADT, and bladder combined (HR: 2.6; p < 0.05); and all tobacco-related cancers combined (HR: 1.6; p < 0.05). Other cancers were not associated with exclusive current cigar use or had no cases among exclusive current cigar users to measure any association (pancreatic). Ever exclusive cigar use was found to be significantly associated with UADT risk (HR: 4.0; 95 percent CI: 1.7-9.4), lung, UADT, and bladder cancers combined (HR: 2.2; 95 percent CI: 1.3-3.8), and all tobacco-related cancers combined (HR: 1.3; 95 percent CI: 1.0-1.8). Other cancers were not associated with ever exclusive cigar. Lung, UADT, and bladder cancer combined risk among exclusive cigar smokers increased by depth of inhalation, duration of use, and intensity (cigars per week). Risk among former cigar users increased by the age at smoking cessation (see study description in the lung cancer section for additional results).

As explained previously, Shapiro et al. (2000) conducted a prospective study of the relationship between cigar use (baseline) and cancer mortality in the CPS-II. In addition to the previously noted increased risk of death from cancers of the lung and oral cavity/pharynx, the study found that current cigar smoking at baseline was associated with an increased risk of death from cancers of the larynx (IRR: 10.3; 95 percent CI: 2.6–41.0). However, no significant associations were found for overall current cigar smoking and esophagus, pancreas, and bladder mortality cancer risk. As with lung and oral cavity/pharynx, cancer mortality risks were considerably higher for cigar users reporting inhalation versus never-users: larynx (IRR: 39.0; 8.4–180.1), pancreas (IRR: 2.7; 95 percent CI: 1.5–4.8), and bladder (IRR: 3.6; 95 percent CI: 1.3–9.9). No association was found for cigar smokers reporting inhalation and esophagus cancer mortality.

As noted earlier, Christensen et al. (2018) evaluated the association of cigarette, cigar, and pipe use with cause-specific mortality, including tobacco-related cancers (such as bladder, esophagus, larynx, lung, oral cavity, and pancreas) in the NLMS (n = 357,420). Exclusive current cigar users had an increased risk of tobacco-related cancer mortality (HR: 1.61; 95 percent CI: 1.11–2.32). Exclusive daily cigar users were found to have

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higher risk of tobacco-related cancer mortality (HR: 1.80; 95 percent CI: 1.20–2.69), but not exclusive nondaily cigar smokers (HR: 1.08; 95 percent CI: 0.45–2.61).

Two studies evaluated the relationship between cigar use and non-Hodgkin's lymphoma (NHL). Bracci et al. (2005) addressed the associations between tobacco use, including past-year cigar use, and NHL in a case-control study of HIV-negative NHL patients and population controls from the San Francisco Bay area (N = 1,593 total patients, N = 2,515 total controls). Among men, the study found no associations between cigar use and overall NHL (OR: 1.3; 95 percent CI: 0.54-3.0) but an association with follicular NHL (OR: 2.8; 95 percent CI: 1.1-7.2). Neither female cases nor controls reported exclusive cigar use. Fernberg et al. (2006) considered the associations between tobacco use, including cigar smoking, and the risk of malignant lymphomas in a cohort of 386,000 Swedish construction workers recruited at clinics from 1971 and 1992 and followed through 2000. Smoking cigarettes, pipes, or cigars was not associated with NHL or Hodgkin's disease. In particular, the study found that smoking one or more than one cigar per day was not related to a higher risk of NHL (IRR: 0.86; 95 percent CI: 0.58-1.27).

Sorahan et al. (1997) evaluated the association between parental tobacco use, including current cigar use among fathers, and childhood cancers in children from the Oxford Survey of Childhood Cancers study (2,587 cancer cases and 2,587 controls). No associations were found between paternal cigar use and childhood cancer (RR: 0.98; 95 percent CI: 0.69–1.40).

# **Esophageal Cancer**

The association between cigarette smoking and esophageal cancer is well established. The risk among current cigarette smokers may be up to 7.5 times higher than nonsmokers (HHS, 2014). Furthermore, many studies have reported a dose–response relationship and a reduction in mortality after quitting cigarettes. In 1998, NCI concluded that cigar use also caused esophageal cancer and, in fact, had similar mortality rates to cigarette use (NCI, 1998). Since this review, few new studies have explored this association, and no studies specifically examined the effect of premium cigars. Presented here are summaries of the results of NCI 1998 and three more recent studies identified in the literature review.

Based on data from the CPS-I, the NCI monograph reported that cigar smokers who have never smoked cigarettes (primary cigar users) have an increased risk of developing and dying of esophageal cancer when compared with nonsmokers (NCI, 1998). This association with mortality was replicated across four other prospective cohort studies and six

case-control studies (with a range in IRR of 2.0-6.7). Three of these studies (one case-control and two prospective) combined cigar and pipe use. Furthermore, the association between cigar use and esophageal cancer remained regardless of inhalation. As noted, unlike cigarette smokers, cigar smokers are less likely to inhale, resulting in different patterns of smoke exposure. The NCI monograph noted that this could contribute to the differences in mortality ratios by cause of death observed between cigar and cigarette users. Esophageal and oral cancers have similar mortality ratios for both, while cigarette users have higher mortality ratios for coronary heart disease, COPD, lung cancer, and laryngeal cancer. The association observed between cigar use and esophageal cancer is further supported by a dose-response relationship and biological evidence of carcinogenic agents in cigars affecting risk of esophageal cancer in both rats and humans. Finally, the NCI monograph noted that despite few data on occasional cigar smokers, the risks of esophageal cancer and other causes of death are likely to be greater than in those with no tobacco exposure and less than in regular users.

In 2000, Shapiro and colleagues analyzed data from CPS-II and found a positive, but not significant, association between cigar smoking at baseline and esophageal cancer (IRR 1.8; 95 percent CI: 0.9–3.7). Shapiro and colleagues also investigated cigars per day, inhalation, and years individuals had smoked. No associations were significant, but there was a greater mortality IRR for those who smoked longer than 25 years compared to those who did not (2.2 versus 0.9). Although no associations were significant, current cigar smokers registered only nine esophageal cancer deaths. Many studies included in reviews on this topic suffered from having a small number of esophageal cancer cases, making it difficult to detect true associations.

In 2015, Chang and colleagues undertook a systematic review to identify prospective cohort studies published before June of 2014. They did not identify new U.S. studies compared to the 1998 monograph other than the Shapiro study discussed above. This has further exposed the lack of research on cigars and esophageal cancer.

The last paper identified in the review was a 2017 meta-analysis of five prospective cohort studies. Cohorts were identified in Australia, Netherlands, and the United States (Malhotra et al., 2017). The investigators examined self-reported ever cigar use and predominant cigar use (most tobacco exposure resulting from cigars rather than cigarettes) with esophageal cancer mortality. They found no significant association for ever cigar use (HR: 1.01; 95 percent CI: 0.56–1.84) nor for exclusive cigar (HR: 1.39; 95 percent CI: 0.35–5.47) or predominant cigar users (HR: 1.45l; 95 percent CI: 0.37–5.73). Again, this study had very few cases, with only 12 cases for ever cigar use.

#### Esophageal Cancer Summary

Since the 1998 NCI monograph, few papers have been published on the relationship between cigars and esophageal cancer, and no papers from the literature search specifically investigated premium cigars (or the papers did not specify cigar type). While the NCI monograph established enough evidence to support a causal conclusion, many unanswered questions remain, as discussed in this section. Furthermore, of the two primary relevant studies published since the monograph, the results show insignificant association between cigar use and esophageal cancer mortality. While the risks in these studies are not significant (most likely due to small numbers of cases), based on the earlier literature, data from cigarettes, and biological plausibility, the committee concludes that cigar use is associated with esophageal cancer risk. More information is needed on infrequent cigar users, race and other sociodemographic factors, and information by country and region.

#### **Bladder Cancer**

In the United States, BC is the sixth most common cancer diagnosis and the eighth leading cause of cancer mortality (Saginala et al., 2020). Tobacco smoking has been identified as a major risk factor, accounting for 50–65 percent of all U.S. cases (HHS, 2014; IARC, 2004; Saginala et al., 2020). No epidemiologic studies have examined the association of premium cigars with BC, though several studies have examined risk associated with cigar use overall. This section provides an overview of the evidence from epidemiologic studies examining BC risk with primary cigar smoking and secondary cigar smoking. To isolate the association between cigar smoking and BC, studies that classified cigar smoking status in combination with pipe smoking (i.e., exposure defined as "cigar and/or pipe smoking") were excluded.<sup>8</sup>

The 1998 NCI monograph identified nine studies published between 1966 and 1992 that examined the association of cigar smoking with BC (NCI, 1998). Findings from this review were mixed, with some studies showing increased risk and others finding no association (NCI, 1998). Risk estimates (ORs or IRRs) were 0.94–2.50 for primary cigar smoking and 1.90–3.69 for cigarette smokers compared to never-smokers. Analyses of

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<sup>&</sup>lt;sup>8</sup> The following studies identified in the literature search were excluded and not discussed in the review: Boffetta et al., 2008 (review article that only discussed one study of cigar use that study was discussed separately); Pramod et al., 2020 (review article that only briefly discussed three studies on cigar use—these studies are discussed separately; Zeegers et al., 2002 (pipe and cigar combined); Zeegers et al., 2004 (review article that discussed the same articles from NCI monograph and articles that combined pipe and cigar smoking).

data from 442,455 men in CPS-I found that compared to never-smokers, the age-standardized IRRs (95 percent CI) for BC mortality were 1.38 (0.89–2.04) for primary cigar smokers, 1.23 (0.56–2.33) for secondary cigar smokers, 3.17 (2.83–3.54) for cigarette smokers, and 2.48 (1.42–4.03) for dual users of cigars and cigarettes.

Shapiro and colleagues examined the association between cigar smoking and death from tobacco-related cancers, including BC, using CPS-II data (Shapiro et al., 2000). Neither current nor former cigar smoking was associated with death from BC in the overall study population (IRR: 1.0; 95 percent CI: 0.4–2.3 for current cigar-only smokers and 1.3; 95 percent CI: 0.7–2.5 for former cigar-only smokers compared to never-smokers). However, mortality from BC was increased, although not significantly, for current cigar smokers who reported smoking ≥3 cigars/day (IRR: 1.9; 95 percent CI: 0.8–4.4) (Shapiro et al., 2000). Note that the number of deaths from BC in this study was low—94 in never-smokers, 10 in former smokers, and 6 in current smokers.

A pooled analysis of data from six case-control studies (2,279 BC cases and 5,268 controls) from Denmark, France, Germany, and Spain was conducted to assess the association between cigar, pipe, and cigarette smoking and BC risk in European men (Pitard et al., 2001). After adjustment for age, center, and occupational exposure, the OR (95 percent CI) for BC was 2.3 (1.6–3.5) for primary cigar smoking, 1.9 (1.2–3.1) for primary pipe smoking, and 3.5 (2.9–4.2) for primary cigarette smoking compared to never-smokers.

A prospective study of 102,395 in the EPIC cohort examined the effects on cancer incidence of exclusive cigar and pipe smoking, and in combination with cigarettes (McCormack et al., 2010). Compared to never-smokers, the HRs (95 percent CI) for BC were 1.5 (0.6–3.5) for ever exclusive cigars smokers, 1.7 (0.9–3.4) for ever exclusive pipe smokers, and 2.9 (2.3–3.7) for ever exclusive cigarette smokers.

Cumberbatch et al. (2016) conducted a meta-analysis of studies published through August 2013 that examined the impact of tobacco exposure on BC incidence and mortality. The authors reported increased BC incidence among cigar smokers compared to never-smokers (RR: 1.62; 95 percent CI: 1.18–2.22). Relative to other tobacco products, the risk of incident BC was similar for pipe smokers (RR: 1.49; 95 percent CI: 1.18–1.88) but lower than the risk for cigarette smokers (RR: 3.37; 95 percent CI: 3.01–3.78). Cigar smoking also had a nonsignificant higher risk of death from BC, but BC mortality was less extensively reported in the literature.

The aforementioned Chang et al. (2015) systematic review found that mortality ratios for bladder cancer was 0.94–1.9 for current cigar smoking.

Al-Zalabani et al. (2016) conducted a systematic review and metaanalysis of articles published between 1995 and 2015 that examined modi-

fiable risk factors of primary BC, including cigar smoking. Using data from six studies, the authors reported increased risk of BC incidence among cigar smokers compared to never-smokers (RR: 2.3; 95 percent CI: 1.6–3.5). Relative to other tobacco products, the risk of incident BC was higher for primary cigar smokers than for primary pipe smokers (RR: 1.90; 95 percent CI: 1.2–3.1) and former cigarette smokers (RR: 1.83; 95 percent CI: 1.52–2.14) but lower than the corresponding risk for current cigarette smokers (RR: 3.14; 95 percent CI: 2.53–3.75).

In a pooled analysis of data from five prospective cohorts in the NCI Cohort Consortium Malhotra et al (2017) examined the association between exclusive cigar and/or pipe smoking with BC incidence among men. Compared to never-smokers, HRs were 1.14 (95 percent CI: 0.88–1.48) for ever cigar smokers and 1.40 (1.07–1.84) for ever pipe smokers.

In the prospective study by Inoue-Choi et al. (Corrigendum, 2019; 2019) described above, the authors found that compared to never-tobacco users, HRs for BC mortality were 5.68 (95 percent CI: 0.74–43.69) for current exclusive cigar smokers, 4.65 (95 percent CI: 2.65–8.17) for current exclusive cigarette smokers, and 6.90 (95 percent CI: 1.06–45.14) for current exclusive smokeless tobacco users.

# Impact of Intensity and Duration of Cigar Smoking on Bladder Cancer

A paucity of studies have examined the impact of intensity or duration of cigar smoking on risk of BC. Among studies that examined the impact of duration (Boffetta, 2008; Pitard et al., 2001; Shapiro et al., 2000), the risk increased with increasing duration of cigar smoking. For example, Pitard et al. found the OR for BC was 1.4 (95 percent CI: 0.8–2.6) for 1–29 years, 2.7 (95 percent CI: 1.3–5.7) for 30–39 years, and 3.8 (95 percent CI: 2.1–7.1) for ≥40 years of smoking among primary cigar smokers compared to never-smokers (*p* value for trend <0.001) (Pitard et al., 2001).

The risk of BC has been shown to increase with the number of cigars smoked per day (McCormack et al., 2010; NCI, 1998; Pitard et al., 2001). In CPS-I, this trend was observed among primary but not secondary cigar smokers (NCI, 1998). Compared to never-smokers, the IRRs for BC mortality among primary cigar smokers were 0.78 (95 percent CI: 0.29–1.71) for 1–2, 1.68 (95 percent CI: 0.77–3.18) for 3–4, and 2.03 (95 percent CI: 0.97–3.73) for ≥5 cigars per day. Among secondary cigar smokers, the IRRs for BC were 1.02 (95 percent CI: 0.20–2.97) for 1–2, 2.36 (95 percent CI: 0.76–5.50) for 3–4, and 0.32 (95 percent CI: 0.00–1.80) for ≥5 cigars per day (NCI, 1998). Pitard and colleagues found that, compared to neversmokers, the ORs for BC were 1.3 (95 percent CI: 0.4–4.0) for 0.1–1.5 and 1.9 (95 percent CI: 0.8–4.4) for >1.5 cigars per day (Pitard et al., 2001).

Differences in inhalation for cigars and other combustible tobacco products may contribute to the differences in cancer risk (Chang et al., 2015; McCormack et al., 2010; NCI, 1998). In CPS-I, most primary cigar smokers did not inhale (78.4 percent) and <1 percent inhaled deeply (self-report), compared to 58.0 percent of secondary cigar smokers and 5.9 percent of cigarette-only smokers who did not inhale and 2.2 percent and 24.8 percent who inhaled deeply, respectively (NCI, 1998). Among participants in CPS-I, BC risk did not differ by level of inhalation for primary or secondary cigar smokers (NCI, 1998). Among primary cigar smokers, the IRRs compared to never-smokers were 1.57 (95 percent CI: 1.00–2.36) for those who did not inhale and 1.52 (95 percent CI: 0.02–8.44) for moderate-deep inhalation. Among secondary cigar smokers, the IRRs were 0.77 (95 percent CI: 0.21-1.98), 2.87 (95 percent CI: 0.58-8.40), and 1.45 (95 percent CI: 0.16–5.25) comparing no inhalation, slight inhalation, and moderate-deep inhalation to never-smokers, respectively. However, among participants in CPS-II, risk of mortality due to BC was increased for current cigar smokers who reported inhaling cigar smoke (IRR 3.6; 95 percent CI: 1.3–9.9) but not for those who did not (IRR 0.5; 95 percent CI: 0.1–2.1) (Shapiro et al., 2000).

#### Bladder Cancer Summary

Cigar smoking overall is associated with increased risk of BC compared to never-tobacco use, with risk generally lower than risk observed among cigarette smokers. No studies have examined risk of BC with premium cigar use (or the studies did not specify cigar type). The risk increases with increasing number of cigars smoked per day, longer duration of smoking, and possibly greater depth of inhalation. The research gaps for BC and cigars, and premium cigars especially, are the same as those for other health effects previously reviewed in this chapter.

#### Pancreatic Cancer

In 1998, the NCI monograph concluded there was some evidence for the effect of cigars on pancreatic cancer but not enough to determine causation (NCI, 1998). At the time, only five studies had been published: three case-control and two cohort studies. Additional studies have been published now showing a relationship between cigars and pancreatic cancer—three were case-control studies (Alguacil and Silverman, 2004; Hassan et al., 2007; Tranah et al., 2011). Only the Hassan study captured primary cigar use; Alguacil et al. examined combined cigar and other tobacco smokers (excluding cigarettes); and Tranah et al. examined cigar

and pipe smokers who also smoked cigarettes (as well as 16 cases and 73 controls who were cigar and/or pipe smokers who did not smoke cigarettes). These three studies all had small case numbers, and none found significant associations. However, all associations were positive, and the Hassan results came close to significance: the OR for cigar use among noncigarette smokers was 2.2 (95 percent CI: 0.99-4.7). A larger study by Bertuccio and colleagues pooled 11 case-control studies and was sufficiently powered to find a significant association of 1.62 (95 percent CI: 1.15–2.29) (Bertuccio et al., 2011). However, exposures were classified differently for cigar use among the various studies. For example, while all studies used primary cigar smoking, some had ever smokers and some regular or current smokers. In a meta-analysis by Iodice et al. (2008), the risk of pancreatic cancer among cigar smokers was 1.53 (95 percent CI: 1.02-2.28). However, these studies showed evidence of heterogeneity, which suggests potential for bias. Ultimately, there is growing evidence for an association between cigars and pancreatic cancer.

# **Other Cancers Summary**

Studies of the associations between cancers others than lung, head and neck, and oral cavity cancer have been limited by the small samples of cigar users in epidemiological studies and the corresponding relatively small numbers of cancer cases available for analysis. However, the available evidence suggest that cigar use is associated with increased risk of all cancers, smoking-related cancers, pancreatic cancer, and probably urinary tract cancers, including bladder, with higher risks with increased intensity or frequency of use and level of inhalation.

No information is available regarding risks by specific cigar type, with only one study reporting risks for cigars versus cigarillos. The literature search found no studies reporting specific risks for premium cigar users. However, based on the cigar literature, it is expected that daily or frequent long-term use of premium cigars would result in higher risk of these cancers.

Future studies need to evaluate the associations between cigar use and the incidence and/or mortality risks of pancreatic, esophageal, bladder, and urinary cancers, accounting for frequency of use, duration, intensity, cumulative exposure and pattern of inhalation.

# **OTHER HEALTH CONDITIONS**

The committee identified several studies that investigated lesserknown and understudied potential health effects: skin health (contact dermatitis), diabetes, eye health (lens opacification), hepatitis C, fertility,

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and the health of cigar factory workers. Few studies examined primary cigar smoking. There appears to be some evidence that there are health effects for cigar factory workers.

# Contact Dermatitis

Bonamonte and colleagues reviewed literature on tobacco exposure and contact dermatitis (Bonamonte et al., 2016). Despite a clear pattern between cigar manufacturing and contact dermatitis, the association with cigar smoking is unclear. The authors reported an association with smoking and contact dermatitis, but studies supporting this conclusion examined cigarettes rather than cigars. The connection to cigar smoking specifically and contact dermatitis is understudied, but it may exist, based on the association found with cigarette smoking.

#### Diabetes

The committee found no studies on exclusive cigar use and diabetes but identified one study on combined cigar/pipe smoking. While the role of cigars cannot be definitively determined using this combined cohort, the data are presented to indicate concern. Future studies need to examine exclusive cigar use and diabetes. Cigarette smoking is associated with an increased risk of type 2 diabetes. In a study by Wanamethee and colleagues, diabetes incidence was examined in primary cigar/pipe smokers (never-cigarette smokers who smoked cigars/pipes) and secondary cigar/pipe smokers (former cigarette smokers who smoked cigars/ pipes) (Wannamethee et al., 2001). The reference group of never-smokers was defined as never-cigarette smokers who did not currently smoke cigars/pipes. They found no substantial association for primary pipe/ cigar smokers. However, their reference group included individuals who were former cigar smokers, which may have attenuated a true positive significant association. They did find an association for secondary cigar/ pipe smokers who switched from using cigarettes to pipe/cigars. Assessing the association between cigar smoking and diabetes is problematic, as cigar and pipe smoker were combined. Thus, more evidence is needed.

# Eye Health

In a study of risk factors associated with lens opacification in Iceland, Arnarsson and colleagues found that pipe and/or cigar had a significant effect (OR: 2.5; 95 percent CI: 1.2–5.1) (Arnarsson et al., 2002). However, it is unclear how cigar smoking was defined, and it was combined with pipe use. Thus, nothing can be concluded regarding any possible association between cigar use and eye health.

# Factory Workers

As mentioned, in Bonamonte's (2016) review, multiple studies reported contact dermatitis, particularly on the hands, in cigar workers. In an assessment of airborne microbes, endotoxins, and total dust, Reiman and colleagues found that cigar factories had higher concentrations of airborne microbes than cigarette factories (Reiman and Uitti, 2000). They also found that endotoxin exposure in cigar factories was higher than the recommended limit. In a study on respiratory health in cigar workers, Uitti and colleagues did not find substantial evidence of respiratory ill health in cigar workers. However, they noted possible episodes of allergic alveolitis (Uitti et al., 1998). Research is limited on the impact of cigars manufacturing on factory workers, and more evidence is needed.

# HEALTH EFFECTS: SUMMARY AND CONCLUSIONS

Tobacco smoking is associated with increased risk of mortality, CVD, respiratory disease, cancer, and other adverse health outcomes. Health risk associated with tobacco use, including use of premium cigars, may be determined by smoking behaviors, including smoking frequency, intensity, duration of use, and depth of inhalation. At the time of the review, no epidemiologic studies have examined the association of premium cigars with health outcomes; however, several epidemiologic studies have examined the health effects of cigar use in general, which may include premium cigars. Additionally, premium cigar smoke contains many hazardous and potentially hazardous constituents that have been associated with increased risk of adverse health outcomes. Based on the findings from epidemiologic studies evaluating the health effects of cigar use in general, as well as biological plausibility, the absence of any important threats to validity, generalizability of study inferences, and the smoking behaviors of premium cigar users, the committee concludes:

Conclusion 5-3: There is **strongly suggestive evidence** that the health risks of **premium cigar use** (overall mortality; cardiovascular disease; lung, bladder, and head/neck cancer; chronic obstructive pulmonary disease; and periodontal disease) depend on frequency, intensity, duration of use, and depth of inhalation.

Conclusion 5-4: There is **insufficient evidence** to determine if occasional or **nondaily exclusive cigar use in general** is associated with increased health risks.

Conclusion 5-5: There is **strongly suggestive evidence** that health consequences of **premium cigar smoking overall** are likely to be less than

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those smoking other types of cigars because the majority of premium cigar smokers are nondaily or occasional users and because they are less likely to inhale the smoke.

Conclusion 5-6: There is **strongly suggestive evidence** that many of the health risks of **daily exclusive cigar use in general** (overall mortality; cardiovascular disease; lung, bladder, and head/neck cancer; chronic obstructive pulmonary disease; and periodontal disease) are significantly higher than those of never-smokers and lower than those of daily cigarette smokers.

Conclusion 5-7: There is **moderately suggestive evidence** that the health risks among **primary cigar users in general** (those who were never established cigarette users) are generally lower than among **secondary cigar users** (those who were former users of cigarettes) because secondary cigar users may be more likely to inhale the smoke. Likewise, **concurrent users of premium cigars** and other combustible tobacco products would experience greater health risks than those smoking only premium cigars.

Conclusion 5-8: There is **insufficient evidence** to draw conclusions on the health effects of **premium cigars** on

- Youth or young adults,
- Racialized and ethnic populations,
- Pregnancy,
- Those with underlying medical conditions,
- People with occupational exposures to premium cigars (e.g., cigar lounges, manufacturing), and
- Health effects compared to other cigar types.

# DIFFERENCES BY SOCIODEMOGRAPHIC CHARACTERISTICS

Very few studies on the health effects of cigars examine different sociodemographic characteristics. Most studies did not examine differences by sex or were conducted only among male populations, given the relatively low rates of cigar use among women. Regarding overall mortality, two studies (Inoue-Choi et al., 2019; Lange et al., 1992) that included women considered differences by sex; in both studies, associations of cigar smoking with all-cause mortality were stronger among women. Among the studies that included nonwhite populations, most studies accounted for race and ethnicity as a confounder by either using it as a covariate in multivariable models or matching cases and controls based on race and ethnicity (see, for example, Hartge et al., 1985; Inoue-Choi et al., 2019; Malhotra et al., 2017; Morrison et al., 1984; Rodriguez et al.,

2010). No studies were identified that examined potential differences by race and ethnicity in the association of cigar smoking and health risks.

# POTENTIAL HEALTH IMPLICATIONS OF FLAVORINGS IN PREMIUM CIGARS

In the research questions provided by FDA and NIH, the committee was asked what the impact of adding flavors to premium cigars would be (see also Chapter 2). Commonly marketed flavors in tobacco products, including cigars, are fruits/candy (grapes, mango, melon, strawberry, apple, peach, berry), crème/butter, cinnamon, cheesecake, coffee/ tea/chocolate, alcoholic beverages, and nonidentifiable varieties (e.g., "tropical," "cosmopolitan"). Some of the chemicals in these flavorings have known respiratory toxicity (e.g., diacetyl, cinnamaldehyde). Many of these chemicals are included on FDA's list of additives shown to be "generally recognized as safe" under conditions of intended use (FDA, 2019); however, this designation applies to consumption and/or topical use, and the criteria do not include an examination of inhalation risks. In fact, the flavor chemical profile for flavored tobacco products is similar to that for candy (e.g., Swisher Sweet grape small cigars versus Kool-Aid grape mix), and flavored tobacco products may also have higher levels of some flavor ingredients per serving (Brown et al., 2014).

Different flavoring chemicals used in cigars may differentially influence toxicity in the production of oxidative stress, DNA damage, epithelial barrier dysfunction, and inflammatory responses with varying intensity and duration of exposure. Limited information is available on their adverse respiratory health effects even from manufacturer to manufacturer within the same class of flavorings. A significant concern exists regarding the ingredient purity and the general lack of oversight in manufacturing or marketing/communication (Kaur et al., 2018). Common flavorings have potential respiratory effects and have been shown to further enhance inhalation toxicity of tobacco smoke (Kaur et al., 2018; Paumgartten et al., 2017; Roemer et al., 2012).

Flavors in tobacco mask harsh taste, reduce throat irritation, and make smoke easier to inhale, which increases carcinogen exposure, nicotine intake, and addiction potential (Kostygina et al., 2016). Cigar flavors have been shown to increase the appeal of cigar smoking by masking the harshness and smell of tobacco (Delnevo et al., 2015). By doing so, flavorings may also make it easier for young and novice smokers to initiate tobacco use (King et al., 2013; Villanti et al., 2019; Villanti et al., 2021). A study based in the Southeastern United States found that flavored cigarillos were mood-enhancing and flavors made cigar products more palatable (Sterling et al., 2015).

Flavors may also influence smokers' perceptions of potential health risks associated with smoking tobacco products. Promoting sweet flavorings that alter cigar's sensory effects may explain the misperceptions of cigars as less harmful relative to cigarettes (Malone et al., 2001; Nyman et al., 2002; Sterling et al., 2013; Sterling et al., 2016; Villanti et al., 2021).

# Summary and Conclusion

Although there is lack of direct evidence on the potential health effects of flavored premium cigars (as added flavors are excluded in most definitions of premium cigars), based on the extensive literature on the effects of flavors on other types of cigars and other tobacco products, strong evidence suggests that adding characterizing flavors (not inherent to the tobacco itself) to premium cigars would have important implications for the product's impact on public health. Adding flavors to premium cigars may increase these cigars' popularity, since flavored tobacco products in general have greater appeal to nonusers. Flavors used in other tobacco products have been shown to affect users of those products, for example by influencing patterns of product use. As has been documented for other types of tobacco products, flavored products are generally used more frequently, which leads to increased nicotine intake, addiction potential, and exposure to harmful and potentially harmful chemicals. Based on the findings from flavored cigars in general and other flavored tobacco products, as well as biological plausibility, the absence of any important threats to validity, and generalizability of study inferences, the committee concludes:

Conclusion 5-9: Based on the extensive literature on the effects of flavors on cigars and other tobacco products, there is **moderately suggestive evidence** that **adding characterizing flavors** (that is, flavors added to the product that are not inherent to the tobacco itself) **to premium cigars** could result in a greater appeal to nonusers and lead to more frequent use with potentially increased nicotine intake, increased addiction potential, and increased exposure to harmful and potentially harmful constituents present in premium cigar smoke.

# HEALTH EFFECTS OF SECONDHAND CIGAR SMOKE

Combusted tobacco product use produces smoke that is released into the environment, which presents a risk to health. Secondhand tobacco smoke (SHS) exposure is a well-established cause of disease in nonsmokers; associated diseases include lung cancer, coronary heart disease, stroke, asthma and other respiratory diseases, and reproductive prob-

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lems, including low birth weight and increased risk of sudden infant death syndrome (HHS, 2006; Vanker et al., 2017). The vast majority of SHS health effects studies are based on nonsmokers living with cigarette smokers who smoke in the home. Children are particularly susceptible to SHS harms. While the committee did not identify studies of disease risk in nonsmokers who live with cigar users who smoke indoors, the risks are likely to be similar to that of secondhand cigarette smoke for similar levels of exposure.

SHS consists of a combination of emissions related to passive burning of the tobacco (sidestream smoke) and exhaled mainstream smoke. For cigar smokers, exhaled smoke may contribute a smaller percentage to overall SHS due to small puff volumes in premium cigar smokers who do not inhale. The constituents of SHS from cigars are qualitatively similar to secondhand cigarette smoke. Particulate matter in smoke is an important toxicant, which contributes to CVD and pulmonary disease and possibly other diseases. Inhaled particulates cause oxidative stress and inflammation and affect autonomic nervous system function, which can promote disease.

A few studies have examined indoor air SHS from different types of cigars by measuring airborne particulates, CO, and PAH concentrations. The air concentrations depend on emission rates of particular substances from the cigar, the number of smokers, duration of smoking, size of the room, and ventilation. Studies generated SHS using smoking machines, volunteer smokers, or sampled real-life cigar social events. Large and premium cigars are smoked for much longer than cigarettes, so the peak concentrations of particles and CO are higher after smoking. However, if multiple cigarettes are smoked during the day, the cumulative exposure could be higher.

Particulate emissions in one small study averaged 0.2–0.7 mg/min for cigars compared to 0.7–0.9 mg/min for cigarettes (Klepeis et al., 2003). One premium cigar was tested in this study with an emission rate of 0.35 mg/min. Mass-normalized emissions were lower for cigars than cigarettes: 3.3–5.2 versus 7.0–7.6 mg/gram smoked. The premium cigar studied yielded 3.7 mg/g smoked. The particle size distribution was similar for cigarettes and cigars, with most of the particles between 0.02 and 2 uM. In another study, volunteers smoked one cigar (Italian Toscanello)<sup>9</sup> over 30 minutes or three cigarettes, one per hour, in a test room with measurement of particle concentrations over 200 minutes (Protano et al., 2017). The peak particle concentration was substantially higher for cigar

<sup>&</sup>lt;sup>9</sup> This is likely a premium-like rather than premium cigar—it is not clear if it is long filler (or shredded tobacco), and some might be machine made. This is a borderline product, like Acid cigars.

compared to cigarette smoking, and the cumulative predicted lung particle deposition for children was also higher with cigar smoking.

Klepeis et al. (1999) measured air concentrations of CO, particulates (PM 2.5), and PAH from different cigars in three environments. In a vacant office on different occasions, five different cigars were machine-smoked (for 7 to 40 minutes, depending on the cigar) with measurement of CO levels over time. The emissions included both mainstream and sidestream smoke. One premium cigar was studied (Todo El Mundo<sup>10</sup> or Ashton); it was smoked for 28 minutes and generated a peak CO concentration of 15 ppm, with an average emission rate of 42 mg/min or 82 mg/gram smoked. Other smaller cigars generally generated similar peak CO concentrations, while having higher emission rates per gram tobacco smoked. In a residence, volunteer smokers smoked a large cigar (Santona, 13.2g,<sup>11</sup> Paul Garmirian, 15.4 g<sup>12</sup>) or a Marlboro cigarette. The cigars were smoked for 1.3 and 1.5 hours and compared to one cigarette. One cigar generated a peak CO concentration of 3 ppm, with an average emission rate of 14 mg/min or 130 mg/gram smoked. The other cigar generated a peak respirable suspended particle concentration of 0.35 mg/m3, with an average emission rate of 0.98 mg/min or 8.2 mg/gram smoked. The cigarette generated a peak respirable suspended particle concentration of 0.16 mg/ m3, with an average emission rate of 1.9 mg/min or 43 mg/gram smoked. Finally, the investigators sampled CO concentrations in two large cigar social events with a high degree of ventilation due to open doors and windows. Indoor CO concentrations were 5–11 ppm, averaging around 6 ppm. The contribution of cigar smoking was similar to that measured on the freeway driving to the events.

### Secondhand Smoke Summary and Conclusion

The limitations of this review are the small number of studies and that few premium cigars were tested. Nonetheless, it seems clear that concentrations of secondhand cigar smoke can be similar to or greater than that from cigarettes. The emission rates appear to be lower for cigars, but cigars are smoked for much longer periods. It is likely that the health effects of indoor premium cigar and cigarette smoking would be similar for a similar duration and intensity of exposure. These could include increased risk of heart attack, respiratory symptoms, more severe respiratory infections in adults, lung cancer, lower respiratory tract infection,

<sup>&</sup>lt;sup>10</sup> The study says "equivalent for Ashton" and that "a Todo El Mundo cigar of similar size to the Ashton was used for measurement of physical characteristics."

<sup>&</sup>lt;sup>11</sup>Given this cigar's obscurity and size, it was likely a premium cigar.

<sup>&</sup>lt;sup>12</sup> This cigar meets the committee's definition of premium.

and otitis media in children. Evidence is lacking about the extent of secondhand exposure to premium cigar smoke. Of particular concern with respect to harms from secondhand smoke exposure are workers in venues where premium cigars are commonly smoked, such as cigar lounges.

Conclusion 5-10: There is **sufficient evidence** that **premium cigars** generate considerable levels of secondhand smoke; however, there are **insufficient data** on the health risks associated specifically with exposure to **premium cigar secondhand smoke**. It is plausible that since the constituents emitted from premium cigars are similar to constituents from other tobacco products, the health risk might be the same, but the extent of secondhand premium cigar exposure is unknown.

# ADDICTION POTENTIAL

# Background

Tobacco addiction is a pathological pattern of compulsive use despite negative consequences. Addiction involves a constellation of symptoms clinically referred to as "tobacco use disorder" or "tobacco dependence," involving tolerance, withdrawal, craving, loss of control over use, neglect of other life activities, and others (APA, 2013; HHS, 2008). Addiction is believed to be the primary driver that maintains regular tobacco use, interferes with quitting, and perpetuates chronic use (HHS, 2008). Thus, the greater the inherent addictiveness of a tobacco product, the more likely users will experience high levels and durations of exposure to its toxins, and, in turn, risk of adverse health effects. In addition, the symptoms of tobacco use disorder interfere with quality of life and results in significant distress and impairment of social or occupational functioning (APA, 2013; Hughes, 2006), making it an important disease outcome.

# **Research Questions and Approach to Evidence Review**

The research questions addressed in this section were (1) are premium cigars addictive and (2) is their addiction potential different than that of other cigar products and other noncigar tobacco products, and what is the reason for the presence or absence of cross-product differences in addictiveness? Because of the absence of direct empirical evidence for premium cigars, two approaches were taken. First, the committee examined biological plausibility. This involved reviewing the extent to which premium cigar characteristics relevant to addictiveness (e.g., nicotine delivery and sensory features) paralleled the profile of features known to make a tobacco product addictive. Second, the committee reviewed

empirical literature indicative of the addictiveness of nonpremium cigars and evaluated the certainty to which making inference generalizations to from nonpremium cigars was possible. Newly calculated comparisons of tobacco dependence between premium cigar users and users of other tobacco products commissioned for this report were also reviewed (Jeon and Mok, 2022). The methodology to approaching evaluating the biological plausibility and indirect empirical literature follows.

# Empirical Evidence and Biologic Plausibility on Addictiveness of Premium Cigars and Other Tobacco Products

# Determining Biological Plausibility

Risk of tobacco dependence onset, duration, and severity is a function of the inherent addictiveness of the product and by the extent of exposure to it (i.e., chronicity, frequency, and quantity of use). That is, the extent to which increasing tobacco product use translates into successive increases in risk of addiction is augmented for products with high addictiveness. Nicotine is the principal addictive constituent in tobacco smoke that underlies tobacco dependence (Benowitz, 2010). Nicotine activates the brain's reward system and other neurocircuitry, causing pleasure and desirable (i.e., reinforcing) effects (HHS, 2014). Chronic nicotine exposure causes neuroadaptations that underlie addiction and the dependence syndrome (HHS, 2014). Tobacco and nicotine products that produce rapid spikes in blood nicotine in the form of "boluses" that are delivered quickly to the brain have a high potential for addiction, including inhalable products with efficient pulmonary delivery (e.g., combustible cigarettes, e-cigarettes) (Benowitz, 2010). Products that deliver appreciable levels of nicotine via the oral mucosa at a slower rate with no pulmonary delivery can also be addictive (e.g., smokeless tobacco), albeit less so than conventional cigarettes. Therapeutic nicotine products that deliver nicotine more slowly via nonpulmonary routes are minimally addictive (e.g., Le Houezec, 2003)

Nicotine is necessary but not sufficient to cause addiction. Nicotine has direct reinforcing effects but also acts as a reinforcement-enhancer that augments the rewarding effects of nonpharmacological stimuli, including those associated with the tobacco self-administration sequence (e.g., taste, smell, sight of smoke clouds, hand-to-mouth movement, airway sensations) (Chaudhri et al., 2006). Repeated pharmacological exposure to nicotine in concert with these other pleasant cues synergistically increase the reinforcing effects of tobacco product use (Chaudhri et al., 2006). Thus, nicotine and tobacco products that provide more opportunities to provide high-intensity sensations and other pleasant stimuli in concert with self-

administration are likely to be more addictive (e.g., inhalable or flavored products). Tobacco products involving hand-to-mouth movements that can provide pleasant tastes and other oral sensations without stimulating the airways are also addictive (e.g., smokeless tobacco), albeit to a lesser extent than inhalable products. By contrast, nicotine products with very few stimulus opportunities (e.g., transdermal patch) are minimally addictive.

Given this conceptual premise, any tobacco product that delivers higher amounts of nicotine to the blood and does so quickly and in concert with a greater variety of pleasant sensations is likely to have a higher addiction potential. Therefore, the committee's review of biological plausibility involved examining features of premium cigars likely to indicate the impact of their blood nicotine and sensory stimuli. The committee also integrated studies of the effect of nonpremium large cigars and other cigars on nicotine yield with this. Inferences regarding whether premium cigars are addictive involved considering comparisons of nicotine yield and sensory profile to other tobacco products with known addictiveness.

# Evaluating Experimental Research on Addiction Potential

Abuse liability/addiction potential assessment refers to a host of experimental and quasi-experimental research paradigms designed to examine the effect of exposure to a tobacco product on intermediate end points that are proxy outcomes indicative of addictiveness and likely to correlate with risk of dependence (Carter et al., 2009). These studies can involve controlled exposure to a certain "dosage" of a cigar (e.g., number of puffs) or restricted duration of ad libitum use (e.g., up to 10 minutes with as many puffs as desired). The outcomes include measures of the product's "abuse liability," including the subjective pleasant effects, ability to suppress smoking urge or withdrawal symptoms (two elements of tobacco dependence), willingness to expend effort or money to obtain more of the product, and amount used under unconstrained conditions. Experimentally assigning participants to exposure to one cigar product versus another (or between cigars and other tobacco products) using randomized between-subject or within-subject crossover designs, allows for causal inferences about the relative abuse liability. These studies' ecological validity is challenged by several factors, including the existing use preferences of the population tested (e.g., whether the sample includes nonsmokers of cigars) and possibility that the experimental product may differ from the participant's preferred product. Abuse liability studies can provide inferences about whether a product is addictive based on if use changes and outcome pre- versus post-smoking (e.g., withdrawal or urge). Differences in the effects of a particular cigar product relative

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to other tobacco products with known addictiveness can also address whether it is addictive and its comparative addictiveness. If the effects of a cigar product on abuse liability indexes are similar to those caused by use of another tobacco product with known addictiveness, it can be inferred that the cigar is indeed addictive.

### Evaluating Observational Epidemiologic Research on Tobacco Dependence

Observational research studies of dependence involve administering questionnaire or interview measures of tobacco dependence symptoms to populations of users of the product. A key metric of a product's dependence potential is the overall prevalence of experiencing dependence, speed of acquisition of dependence symptoms, or mean number or severity of dependence symptoms in a population. To address the question of whether premium cigars are addictive, estimates of whether the prevalence or severity of tobacco dependence symptoms among users of premium cigars are nonnegligible (i.e., different than zero) were made. This included a review of estimates in other (nonpremium) cigars for comparison.

To address that question and also their comparative addiction potential to other products, dependence symptom metrics were compared between populations of cigar users and users of other tobacco products. This approach was also used to compare premium to nonpremium cigar users. Sampling and selection biases and poly-tobacco use are important considerations. These types of population-wide estimates are influenced by the overall frequency, quantity, and chronicity of use in the respective population. Use levels are due to the product's inherent dependence potential (i.e., addictiveness) but also many other factors (e.g., price, ease of access, marketing, cultural trends). Some cigars might be more difficult for users to access due to their higher cost or due to lower accessibility (e.g., sold only in specialty shops). Because individuals might not be able to access certain cigar types on a regular basis, their ability to develop dependence symptoms from their use may be lower. By contrast, combustible cigarettes and certain types of mass-market cigars might be more widely available and provide ample opportunity for individuals to become frequent users and develop dependence symptoms. For these reasons, cross-population comparisons in overall prevalence or severity of dependence symptoms between users of premium cigar versus other tobacco products provide only a proxy for differences in the addiction potential between premium cigars and other tobacco products.

Other observational methods involve examining the association of frequency, quantity, and chronicity of use with dependence risk or severity. The magnitude of association between product exposure and dependence

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may also provide an estimate of its addiction potential. This approach is likely to provide a stronger estimate of inherent addictiveness, over and above factors that contribute to variation in exposure. However, reverse causality and criterion contamination (some measures of dependence include frequency of use as symptom indicator) affect these designs, necessitating scrutiny of temporal precedence and the outcome construct.

An important consideration is that epidemiologic studies need to be limited to exclusive users of a single tobacco product so that the tobacco dependence symptoms reported by the user can be ascribed to that product. Tobacco dependence symptoms among poly-tobacco product users cannot be differentiated to a specific product. This approach reduces the generalizability of the results to the overall population of users, which includes high proportions of poly-tobacco product users (Kasza et al., 2017). In a PATH study, poly users are 2–3 times more likely than singleproduct users to report higher levels of nicotine dependence and could presumably have greater vulnerability to tobacco dependence than exclusive users (Strong et al., 2017). Consequently, the analyses may be underestimates of the level of dependence of premium cigar (and other tobacco product) users.

### **Results of the Evidence Review**

# Biologic Plausibility

Given the above considerations, the rate of blood nicotine delivery and extent of pleasant sensory cues experienced during self-administration of premium cigars will provide information regarding their dependence potential. As noted in Chapter 2, premium cigar smoke emissions from a puffing machine contain nicotine at levels that appear to be at least equivalent to nicotine in smoke in nonpremium cigars and other combustible tobacco products (e.g., conventional cigarettes) (Fant and Henningfield, 1998), although direct comparisons are complicated because of differences in the methodologies used to create machine-generated puffs of different cigars and cigarette products. An important consideration for nicotine effects is the rate of systemic absorption. This is influenced by the pH of the smoke, the extent of inhalation into the lungs, and the pattern of puffing. At lower pH, the nicotine molecule is more highly protonated, while at higher pH, it exists more in the unprotonated form. Unprotonated nicotine permeates cell membranes more easily, so smoke with alkaline pH facilitates nicotine absorption across the oral mucosa. Premium cigar smokers anecdotally report holding cigar smoke in their mouths, which could be a source of oral nicotine absorption. As discussed in Chapter 2, large cigars, including premium cigars, tend to be more

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alkaline than combustible cigarettes (Fant and Henningfield, 1998; Henningfield et al., 1999; NCI, 1998).

Conventional cigarette smokers are more likely to inhale and to inhale more smoke more deeply than cigar smokers do, particularly cigar smokers with no history of conventional cigarette smoking (Fant and Henningfield, 1998; NCI, 1998; Wald and Watt, 1997). However, studies involving objective indexes of inhalation (e.g., CO; lung imaging) suggest users of large cigars do inhale smoke, including noncigarette smokers and including those who self-report not inhaling (Claus et al., 2018; McDonald et al., 2002; Pickworth et al., 2017b; Rosenberry et al., 2018). Objective inhalation exposure studies suggest large cigars exhibit inhalational exposure that is at least equivalent to other cigar products. Research on the nicotine yield of large cigars indicates blood nicotine boosts similar in magnitude to conventional cigarettes and sometimes larger than other cigar products (Claus et al., 2018; Pickworth et al., 2017b; Rosenberry et al., 2018). Despite no rigorous research on inhalation patterns or nicotine yield from premium cigars, one would expect similar inhalation and nicotine yield relative to nonpremium large cigars. No specific studies exist on the pharmacokinetics of blood nicotine from premium cigar use.

Premium cigars, like other cigar products, provide the sensations and stimuli shown to be important to the dependence potential of tobacco products (e.g., hand-to-mouth movements, taste, smells, airway sensations). They do not have characterizing flavors, per this report's definition of the product class (see Chapter 1), and flavors are known to increase the addictiveness of other tobacco products (e.g., menthol-flavored cigarettes, non-tobacco-flavored e-cigarettes) (see Chapter 3; Goldenson et al., 2019; Wickham, 2015). One nationally representative study found that premium cigar smokers were less likely to report that "they come in flavors I like" than users of other cigar types, although close to half (48.6 percent) of premium cigar users reported this as a reason they use cigars (Corey et al., 2018). However, premium cigars do have distinctive tastes related to tobacco blends, curing processes, and sometimes infusions with various volatile chemicals, as discussed earlier in this chapter. Given these results and the similar features of premium cigars to other tobacco products that are addictive, there is reason to believe that premium cigars have sensory aspects to contribute to their addiction potential. Given the absence of added characterizing flavors in premium cigars, their sensory profile may not be equivalent to nonpremium cigar and other noncigar products that are available in characterizing flavors. Their absence of flavors could reduce the sensory-related addictiveness versus explicitly flavored products.

In summary, some research indicates that nonpremium cigars, in particular large cigars that are similar in size and other characteristics

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(no filter), might have nicotine levels similar to other cigar products and potentially conventional cigarettes. Furthermore, premium cigar and nonflavored cigar products may have similar sets of sensorimotor characteristics that contribute to addiction potential. For these reasons, it is biologically plausible that premium cigars can be addiction promoting, provided the user has sufficient extent of level exposure (i.e., chronicity x frequency x quantity of use represents the totality of exposure).

# Experimental Addiction Potential Assessment of Cigars

The literature search identified seven total abuse liability studies of cigars, three of which examined large cigars and none of which examined premium cigars separately.

Large cigar addiction potential studies Claus et al. (2018) studied adult, exclusive cigar users (N = 77) who smoked their own-brand product ad libitum for up to one hour. In the overall sample, smoking urge and withdrawal symptoms were significantly reduced by smoking, and the magnitude of tobacco withdrawal and urge suppression did not differ across people who used small cigars versus cigarillos versus large cigars. A group of four articles used partially overlapping samples of dual users of conventional cigarettes and cigars. Each of these articles applied the similar study design of ad libitum smoking of either a single experimenterprovided unflavored cigar or their own-brand cigarettes (Koszowski et al., 2015; Pickworth et al., 2017a; Pickworth et al., 2017b; Rosenberry et al., 2018). Two of them studied large cigars. Pickworth et al. (2017b) studied dual users of cigarettes and cigars and made comparisons across groups who typically smoked either large or small cigars or cigarillos. After ad libitum smoking of a respective study product from the cigar class they typically smoked (Phillies Blunt [large cigar], Black and Mild [cigarillo], Winchesters [little cigar]), smoking urge was reduced from pre- to postsmoking for each cigar group. Ratings of product appeal and sensory effects had no group differences, although little cigars were rated significantly lower than cigarillos and large cigars on satisfaction. Rosenberry et al. (2018) studied dual users of cigarettes and large cigars (n = 17, 94percent men, 77 percent African American) who smoked ad libitum either their usual cigarette brand or a study-provided large cigar (Phillies Blunt) in two laboratory sessions using the same design as above. Smoking cigarettes and large cigars each significantly reduced the urge to smoke from pre- to post-smoking. The cigars and cigarettes had no significant differences in the magnitude of urge suppression or subjective product appeal or satisfaction.

**Studies of other cigar products** Pickworth et al. (2017b) found that dual users of cigarettes and little cigars reported lower product liking and satisfaction but not psychological reward, after ad libitum smoking Winchester little cigars versus their own-brand cigarette. Koszowski et al. (2015) studied dual cigarette and cigarillo users and found no differences in psychological reward, satisfaction, and liking or withdrawal suppression after ad libitum smoking of Black & Milds versus their own-brand cigarettes, but each product significantly reduced several indexes of tobacco withdrawal symptoms.

Bono et al. (2020) conducted a study of 25 current users of cigarettes with no significant history of cigar use. At each session, participants took two directed 10-puff bouts (separated by 60 minutes) of a different tobacco product: own-brand cigarettes or one of four flavored plastic-tipped Black & Mild (nonpremium) cigars (apple, cream, wine, and original). A variety of post-smoking abuse liability assessments was measured, including the drug purchase task, cross-price purchase task, and multiple-choice procedure. Across the outcomes, the results showed that, in general, all cigars had lower abuse liability than cigarettes, but some evidence indicated that apple and wine flavors had lower abuse liability than cream or original flavors.

Cunningham et al. (2019) studied 48 adult cigarette users who also smoke little cigars or cigarillos who completed four ad libitum sessions that differed by tobacco product smoked: usual brand cigarette and unflavored, cherry, or menthol little cigars. Own-brand cigarettes provided stronger smoking urge and withdrawal suppression than all three little cigar flavors. There was consistent evidence of a graded effect, whereby subjective abuse liability indexes (i.e., withdrawal suppression, satisfaction, product liking) were highest for cherry little cigars, with unflavored little cigars in the middle, and menthol little cigars having the lowest levels.

# Observational Empirical Research on Cigar Dependence Symptoms

The literature search identified no studies that collected tobacco dependence data in users of premium cigars. The search yielded nine studies of cigars defined broadly, which did not distinguish type. Given that the overall base rate of premium cigar use is very low (less than 1 percent prevalence in adults; see Chapter 3) and the different demographic and behavioral profile of premium and nonpremium cigar smokers (Chapter 3), there is a low certainty that the population of all cigar smokers is representative of premium cigar smokers.

**Overall prevalence or mean severity of cigar dependence** Several studies report the prevalence and mean severity of cigar dependence among exclusive U.S. adult cigar users (Gomez et al., 2020; Rostron et al., 2016; Strong et al., 2017) and exclusive youth cigar users (Apelberg et al., 2014), with 2.3–3.8 percent experiencing dependence symptoms of some sort. One small study with nonrepresentative sampling of 42 large cigar smokers with no past 6-month use of any other tobacco product found levels of dependence symptoms approximately 15 percent higher than the minimal score (and 85 percent below the maximum score) (Claus et al., 2018). For instance, participants reported a mean of 2.1 (SD: 2.1) symptoms of dependence out of 10 possible symptoms (Claus et al., 2018).

In the committee-commissioned analysis of U.S. adults in PATH (see Appendix D), the prevalence and severity of experiencing tobacco dependence symptoms was examined on 16 items scaled for cross-product comparisons (Strong et al., 2017). The measure included items from the Wisconsin Inventory of Smoking Dependence Motives (11 items), the Nicotine Dependence Syndrome Scale (4 items), and the Diagnostic and Statistical Manual criteria (1 item). The scale's construct domains spanned "automaticity," "craving," "loss of control," "tolerance," "negative reinforcement," "cognitive enhancement," "affiliative attachment," and "withdrawal." In addition to reporting the prevalence of any level of symptoms across the 16 items, a 0–100 score was scaled such that 100 represented the maximum possible severity across all items and 0 the lowest. Comparisons were made between exclusive current users of seven different products, including premium cigars.

The results of the commissioned analysis showed exclusive premium cigar users' reports of one or more tobacco dependence symptoms was 43–60 percent across waves (see Table 5-1) (Jeon and Mok, 2022). The mean severity of tobacco dependence symptoms on a 0–100 score for exclusive premium cigar users was 10–17 across PATH waves.

**Differences between cigar and noncigar tobacco dependence** Observational studies also indicate that the dependence symptom prevalence and mean severity in the U.S. overall adult and adolescent population of individuals that exclusively use cigars is lower than exclusive cigarette users (Apelberg et al., 2014; Gomez et al., 2020; Odani et al., 2020; Rostron et al., 2016; Strong et al., 2017; Sung et al., 2018). Comparisons of dependence symptoms between exclusive users of cigars versus exclusive users of hookah, pipes, smokeless tobacco, or e-cigarettes yielded mixed results. Some studies find higher prevalence of dependence symptoms in cigar users compared to users of noncigar products, although many found no differences, and others found lower prevalence than for other products, with variations in findings across the different products and

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		Nonpremium		Filtered	<u>.</u>	Smokeless			
	cigars	cigars	Cigarillos	cigars	Cigarettes	tobacco	Hookah		
Mean Tobacco Dependence Symptom Level Score (95% CI)									
Wave 1	7.8 (6.4–9.1)	13.1 (10.4– 15.9)	22.4 (20.1– 24.8)	35.2 (30.7– 39.6)	52.4 (51.8– 53.0)	45.4 (44.1– 46.6)	8.1 (7.4–8.8)		
Wave 2	7.1 (5.7–8.5)	12.9 (10.2– 15.6)	21.2 (19.1– 23.3)	31.5 (27.6– 35.3)	49.6 (48.9– 50.3)	42.9 (41.8– 43.9)	4.9 (3.8–6.0)		
Wave 3	6.0 (4.3–7.7)	16.9 (8.0–25.8)	17.1 (13.8– 20.4)	36.3 (27.1– 45.4)	50.6 (50.1– 51.0)	44.1 (42.4– 45.9)	5.2 (4.1–6.3)		
Wave 4	6.6 (5.4–7.8)	10.4 (7.3–13.4)	20.3 (17.4– 23.2)	36.6 (29.2– 43.9)	51.1 (50.6– 51.5)	44.0 (41.9– 46.0)	6.8 (5.1–8.6)		
Wave 5	4.8 (4.0–5.6)	16.7 (9.4–23.9)	20.2 (17.9– 22.4)	34.7 (27.6– 41.8)	51.4 (50.7– 52.2)	45.7 (44.4– 47.1)	7.6 (6.3–8.9)		
Percenta	age of repo	ort 1+ symp	toms (95% (	CI)					
Wave 1	59.6 (52.9– 65.8)	63.8 (51.4– 74.6)	76.5 (71.9– 80.5)	92.5 (89.5– 94.7)	96.1 (95.6– 96.4)	95.6 (94.3– 96.6)	63.0 (60.8– 65.1)		
Wave 2	59.7 (50.6– 68.2)	67.8 (54.4– 78.8)	78.6 (71.3– 84.4)	87.3 (80.4– 92.1)	95.2 (94.6– 95.6)	94.0 (90.8– 96.1)	50.1 (45.1– 55.2)		
Wave 3	49.1 (39.1– 59.3)	64.0 (53.6– 73.3)	70.8 (62.6– 77.9)	81.7 (72.5– 88.3)	94.5 (93.6– 95.2)	91.1 (88.9– 93.0)	44.3 (36.4– 52.4)		
Wave 4	46.9 (41.5– 52.4)	46.6 (34.8– 58.7)	73.0 (69.0– 76.6)	85.6 (76.0– 91.8)	95.2 (94.7– 95.6)	94.7 (93.4– 95.8)	47.5 (43.4– 47.5)		
Wave 5	43.3 (36.1– 50.9)	54.2 (41.7– 66.1)	75.5 (67.2– 82.3)	87.2 (77.0– 93.2)	94.7 (93.9– 95.4)	95.8 (93.7– 97.2)	48.4 (42.8– 54.1)		

**TABLE 5-1** Tobacco dependence among current established exclusive users of four cigar types, cigarette smokers, users of smokeless tobacco and hookah in U.S. PATH adults

SOURCE: Jeon and Mok, 2022.

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dependence indicators (Apelberg et al., 2014; Gomez et al., 2020; Odani et al., 2020; Rostron et al., 2016; Strong et al., 2017; Sung et al., 2018). One study also found that U.S. adult cigar users who reported using a cigar product with flavors had higher odds of early morning smoking, which is an index of dependence, than those who did not (Odani et al., 2020). One reason for the mixed findings could be because the types of cigars that the user groups smoked varied in each study (e.g., large or little filtered cigars). Users of certain types of cigars might have higher dependence levels, given variation in use frequency and inhalation patterns across different cigar types.

Several studies found that U.S. poly users of cigars and other tobacco products have higher prevalence and severity of dependence compared to exclusive cigar users (Rostron et al., 2016; Strong et al., 2015; Sung et al., 2018). None of these studies differentiated dependence symptoms associated with use of different tobacco products (e.g., asked about symptoms related to tobacco use more generally).

In this report's commissioned analysis of PATH, exclusive premium cigar users had a prevalence and mean severity of tobacco dependence symptoms that was substantially lower than that of exclusive cigarette or smokeless tobacco users across waves (see Table 5-1) (Jeon and Mok, 2022) but comparable to that of exclusive hookah users.

Differences in mean dependence across different types of cigar products The only published comparison of dependence symptoms across users of different cigar types was in a convenience sample of 77 participants in a clinical research study (Claus et al., 2018): large cigar smokers reported lower levels of nicotine dependence and baseline nicotine withdrawal than little cigar smokers but did not differ from cigarillo smokers (Claus et al., 2018). In this report's commissioned PATH analysis, exclusive premium cigar users had a substantially lower prevalence and mean severity of tobacco dependence symptoms than exclusive filtered cigar users (see Table 5-1) (Jeon and Mok, 2022). Exclusive premium cigar users had dependence symptom prevalence and severity that was moderately lower than that of exclusive cigarillo users and slightly lower than that of exclusive nonpremium traditional cigar users.

As described in Chapter 3, premium cigar smokers smoke at lower frequencies and quantities than users of other cigars and cigarettes. None of the reviewed studies has comprehensively adjusted for differences in use frequency, use quantity, and other possible factors that may affect dependence vulnerability (e.g., mental health) (Dierker and Donny, 2008). Consequently, differences in dependence between users of premium cigars, nonpremium cigars, and other tobacco products may be due to one or more of these factors. Hence, it is difficult to rule out the possibility that

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the substantial differences in use frequency of cigarettes and premium cigars are entirely driven by external factors rather than the product's inherent addictiveness (e.g., availability, price, culture).

Association between use exposure and dependence of cigars Crosssectional studies have found significant associations of frequency of cigar use with prevalence and severity of dependence in U.S. youth and adults (Gomez et al., 2020; Strong et al., 2017). In a study of youth, the association of frequency of cigar use and dependence was weaker than the association of cigarette use frequency and dependence (Gomez et al., 2020). However, in a study of adults, the magnitude of association of daily compared to nondaily use with dependence for cigar use was not different than the association of daily use and dependence for cigarettes (Strong et al., 2017). No longitudinal studies of cigars assessed use frequency prior to dependence outcomes.

The commissioned PATH analysis calculated the associations between the level of tobacco product use exposure (assessed as past 30-day use frequency) and severity of tobacco dependence for each product using the 0-100 scale (see Table 5-2) (Jeon and Mok, 2022). For Waves 1-3, the strength of association of multiple indicators of past 30-day use frequency (daily versus nondaily, number of days, and 6+ versus <6 days) with dependence was comparable between exclusive premium cigar users and exclusive hookah users, and for some exposure metrics, it was comparable between exclusive premium cigar users and exclusive users of other noncigarette tobacco products. For Waves 4-5, the difference in dependence severity between users of <6 days versus 6+ days in the past 30 days were also comparable between exclusive premium cigar users and exclusive users of other products (except for cigarettes and smokeless tobacco, which produced stronger associations; see Table 5-2). For Waves 4-5, associations of number of days used and daily versus nondaily use with dependence severity were not statistically significant and produced wide confidence intervals, potentially due to the small number of daily exclusive premium cigar users (Jeon and Mok, 2022). However, in general, all waves had few daily exclusive cigar users and exclusive hookah users, suggesting the need for caution in interpreting this result. For all products, the number of exclusive users in <6 days vs. 6+ days groups was sufficient to produce reliable estimates. For that comparison, the data suggest significant associations between use frequency and dependence for each product; the magnitude of association for premium cigars was comparable to that of hookah and less than cigarettes and smokeless tobacco (Jeon and Mok, 2022).

In summary, the prevalence and severity of tobacco dependence among exclusive premium cigar users (and traditional cigar users, includ-

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**TABLE 5-2** Association of past-30-day use frequency and tobacco dependence among current established exclusive users of four cigar types, cigarette smokers, users of smokeless tobacco and hookah, PATH Study

	Premium cigars	Nonpremi- um cigars	Cigarillos	Filtered cigars	Ciga- rettes	Smokeless tobacco	Hookah		
Difference between daily vs. nondaily users of respective product in dependence sever- ity (95% CI)									
Wave 1	26.9 (21.3– 32.6)	20.1 (10.0–30.2)	21.9 (15.0– 28.9)	32.3 (24.2– 40.5)	37.6 (36.6– 38.5)	27.2 (24.7– 29.7)	19.1 (14.5– 23.8)		
Wave 2	15.6 (6.1–25.1)	24.2 (15.0–33.5)	20.5 (15.2– 25.7)	22.3 (15.7– 28.9)	35.8 (34.9– 36.7)	30.2 (27.3– 33.1)	27.0 (13.9– 40.0)		
Wave 3	25.9 (8.2–43.7)	24.3 (5.0–43.7)	17.5 (9.7–25.2)	25.7 (17.0– 34.5)	36.7 (35.6– 37.8)	34.2 (32.2– 36.3)	16.2 (1.1–31.2)		
Wave 4	13.5 (-4.7– 31.6)	20.8 (8.0–33.6)	24.1 (18.9– 29.3)	17.1 (4.4–29.9)	36.6 (35.7– 37.5)	27.6 (23.8– 31.4)	40.4 (34.3– 46.5)		
Wave 5	9.4 (-2.8– 21.6)	13.8 (0.8–26.8)	19.9 (13.1– 26.7)	42.9 (34.9– 50.9)	36.6 (35.7– 37.5)	28.3 (25.3– 31.4)	28.8 (19.5– 38.0)		

Linear association between number of days used of respective product and dependence severity, B (95% CI). Note: "times" used for hookah

Wave 1	0.9	0.7	0.9	1.1	1.8	1.4	0.0
	(0.7–1.1)	(0.4–1.0)	(0.7–1.1)	(0.7–1.4)	(1.8–1.9)	(1.2–1.5)	(0.0–0.0)
Wave 2	0.5	0.9	0.9	0.7	1.8	1.4	0.0
	(0.3–0.8)	(0.6–1.2)	(0.8–1.0)	(0.4–1.1)	(1.7–1.8)	(1.3–1.6)	(0.0–0.2)
Wave 3	0.6	1.5	0.6	0.9	1.7	1.5	0.5
	(0.2–0.9)	(0.8–2.3)	(0.4–0.9)	(0.5–1.3)	(1.7–1.8)	(1.4–1.7)	(0.2–0.9)
Wave 4	0.6	0.7	09	0.6	1.7	1.3	0.2
	(0.0–1.1)	(0.3–1.1)	(0.7–1.0)	(0.2–1.1)	(1.6–1.7)	(1.1–1.6)	(-0.1–0.5)
Wave 5	0.3	0.8	0.7	1.5	1.7	1.5	0.6
	(0.0–0.7)	(0.4–1.2)	(0.5–0.9)	(1.2–1.8)	(1.7–1.8)	(1.3–1.7)	(0.4–0.7)

Difference between <6 days vs. 6+ days used of respective product for dependence severity, B (95% CI)

# Note: "times" used for hookah

Wave 1	14.6 (10.2– 19.0)	13.1 (5.9–20.2)	20.0 (15.8– 24.2)	20.9 (11.1– 30.7)	43.4 (42.0– 44.8)	31.1 (26.6– 35.6)	9.1 (5.3–13.0)
Wave 2	9.0 (2.6–15.3)	16.1 (7.9–24.4)	20.1 (17.7– 22.6)	13.9 (4.0–23.8)	41.4 (39.7– 43.1)	35.5 (31.0– 40.1)	2.9 (0.7–5.1)

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	Premium cigars	Nonpremi- um cigars	Cigarillos	Filtered cigars	Ciga- rettes	Smokeless tobacco	Hookah
Wave 3	11.4 (6.5–16.4)	25.4 (3.8–47.0)	14.3 (8.8–19.8)	18.9 (9.5–28.2)	38.8 (36.3– 41.2)	35.1 (30.6– 39.7)	12.0 (8.8–15.3)
Wave 4	12.6 (4.0–21.2)	15.7 (7.0–24.3)	17.1 (13.0– 21.1)	13.9 (-2.6– 30.5)	39.2 (37.6– 40.7)	29.6 (23.9– 35.4)	13.8 (1.9–25.7)
Wave 5	5.9 (1.2–10.6)	10.9 (0.3–21.5)	17.6 (13.4– 21.8)	30.9 (22.6– 39.1)	42.3 (40.5– 44.1)	32.5 (29.1– 35.9)	10.2 (3.4–17.0)

 TABLE 5-2
 Continued

NOTE: Exclusive users of each of the products presented. Dependence scale is a 16-item measure derived from Strong et al. 2017. See Appendix D for further detail on the methods and data analysis.

SOURCE: Jeon and Mok, 2022.

ing premium/nonpremium users) is modest. The extent of dependence in these populations is substantially lower than among exclusive users of cigarettes and several other addictive tobacco products but comparable to hookah users. The association of level of exposure and dependence severity similarly is substantially smaller than that for cigarettes and on par with that for hookah.

#### Addiction Potential Summary and Conclusion

Two studies show that users of premium or large cigars have low population-wide prevalence and severity of dependence symptoms but at levels that are not negligible. The prevalence evidence estimates only modestly altered the committee's conclusion regarding the addiction potential of premium cigars because these estimates are confounded with ease of accessing premium cigars versus other tobacco products and preexisting dependence vulnerability. Premium cigars are more difficult to access than other tobacco products because of their high cost and limited availability (e.g., at specialty retailers). Consequently, only a subset of the population can become frequent users of premium cigars and have sufficient opportunity to develop dependence symptoms from their use, which might reduce the population-wide prevalence and severity of premium cigar dependence symptoms. Furthermore, in comparison to users of other tobacco products, premium cigar users have disproportionately fewer pre-existing risk factors for nicotine dependence (e.g., low socioeconomic status, mental health problems, comorbid substance use; see Chapter 3). In addition to the population prevalence estimates, several

well-designed abuse liability/addiction potential studies of large cigars with similar characteristics to premium cigars consistently show that abuse liability outcomes are significantly increased from pre- to post-cigar administration and that the effects of large cigar administration on abuse liability outcomes do not differ from other addictive tobacco products. A strong biological plausibility exists that premium cigars possess the features (i.e., rate/amount of nicotine delivery, pleasant stimuli) liable to make them as addictive as other tobacco products with known addiction potential (e.g., smokeless tobacco). Therefore, there is moderately suggestive evidence that premium cigars can be addictive.

One moderate-quality study shows that users of premium cigars have lower prevalence or severity of dependence symptoms than cigarette users; another low-quality study shows lower dependence in cigar users compared to cigarette users. One abuse liability study found no differences between large cigars and cigarettes, but studies of other (nonlarge) cigar products find lower abuse liability compared to cigarettes. Premium cigars possess features (i.e., rate/amount of nicotine delivery, pleasant stimuli) that make them less likely to be addictive than cigarettes, particularly cigarettes with characterizing flavors. Overall, there is moderately suggestive evidence that premium cigars are less addictive than cigarettes.

The commissioned PATH analyses showed that prevalence and severity of tobacco dependence among exclusive premium cigar users (and traditional cigar users, including premium/nonpremium users) is modest (Jeon and Mok, 2022). The extent of dependence in these populations is substantially lower than among exclusive users of cigarettes and several other addictive tobacco products but comparable to hookah users. The association of level of exposure and dependence severity similarly is substantially smaller than that for cigarettes and on par with that for hookah.

Gaps in the literature include the absence of longitudinal data on trajectories of dependence for premium cigar users to provide information on the speed of dependence acquisition, as is research that compares the prevalence and severity of dependence across different demographic groups, which can provide insight into the role of premium cigars in health disparities. Research with detailed assessment of premium and nonpremium cigar use patterns, including inhalation behaviors, in epidemiologic studies of dependence would provide useful information about the inherent addictiveness of cigar products. Controlled abuse liability studies of premium and nonpremium cigars with different product characteristics (e.g., flavors, pH, size) is lacking and would be useful for

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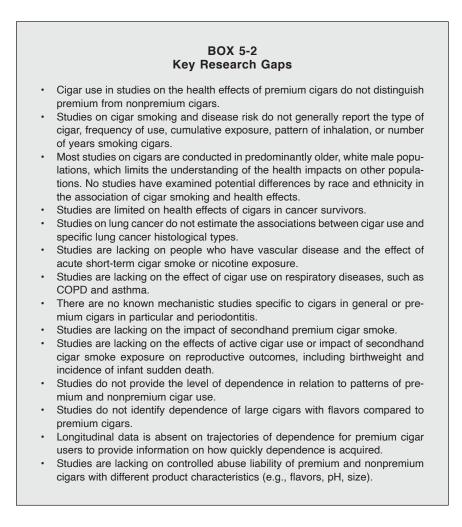
informing regulation of cigar products, particularly research isolating the impact of flavors.

Conclusion 5-11: There is **moderately suggestive evidence** to support the biological plausibility that **regular cigar smoking in general** can be addictive. It is likely that this is also true for **premium cigar** smoking, based on nicotine delivery characteristics, abuse liability studies, and epidemiological data. The magnitude of **premium cigar** dependence appears to be less than that of cigarette smoking and smokeless tobacco use dependence. The extent of addiction is likely to depend on the patterns of use.

# **RESEARCH GAPS**

As noted in the chapter opening, premium cigars' potential adverse health effects need to be viewed in the context of harms of combusted tobacco smoking broadly, and the mechanisms of tobacco smoke toxicity and biomarkers of toxicant exposure are applicable to understanding the potential harms of premium cigars. However, the committee identified key research gaps in the health effects literature for premium cigars specifically (see Box 5-2) and provides two recommendations to address these gaps (see Recommendations 4 and 8 in Chapter 6).

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# **Chapter 5 Annex**

## **Health Effects Evidence Tables**

These tables provide descriptive and methodological information on the studies cited in Chapter 5 that studied primary cigar smokers for all-cause mortality, cardiovascular disease [CVD], lung cancer and respiratory illness, oral health and head/neck cancer, and other cancers. The findings and results are discussed in the chapter proper (see Chapter 5 reference list for full citations).

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Iortali	
All-Cause <b>N</b>	
5A-1 /	
ILE	

TABLE 5A-1 A	A-1 All-Cau	ll-Cause Mortality	7				
Reference	Study design and study Sample size period (e. (number of enrollmer exclusive cigar and follov users in study) up years)	, tô	Operationally Confounders defined or adjusted outcomes factors	Confounders or adjusted factors	Results	Cigar use definition	Other cigar use characteristics: inhalation, duration, intensity
Chang (2015). PMID: 25907101	Seven studies System contained review primary cigar review smoking: Best Study J (1966), with riod: St 196 cigar Study Publish smoker deaths, before Kahn (1966), 2014 w with 1,532 conduc deaths, Cole Studies (1974), with 33 conduc deaths, Cas- in diffe tensen (1987), periods with 131 fell with deaths, Lange (1994), with 511 deaths, Ben-Shlomo (1994), with 141 deaths, and Shanks (1998) with 5,216 deaths.	atic Pe- red ere s but hin 000.	All-cause and cause-specific mortality as- sociated with cigar use	All studies adjusted for age	Primary cigar smoking associ- ated with all-cause mortal- ity based on two studies for primary cigar smoking. Among significant mortality ratios, the estimates were 1.1–1.8.		Current Intensity (cigars cigar use. per day), inhala- Cigar type tion (none, slight, umspecified moderate-deep), and and varied by duration (less than or study. greater than 25 years)

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Intensity (daily ver- sus nondaily use)	Daily versus non- daily users; number of days smoked last 30 days	continued
Current or former use of any cigar (little cigar, cigarillos, large cigar)	Former, current rent, current nondaily, nondaily, previous- daily users of any cigar	
Adjusted for Increased all-cause mortality age, sex, race/ among current primary cigar ethnicity, edu- smokers compared to never- cation, and tobacco users (HR: 1.20; 95 survey year vaca attenuated among former was attenuated among former primary cigar smokers (HR: 1.11; 95 percent CI: 0.99–1.25)	Adjusted for Increased risk of mortality sex, education among current primary cigar level, race or smokers, though findings not ethnicity, and statistically significant (HR: survey year 1.22; 95% CI: 0.93–1.60). Daily (1991, 1992, but not nondaily cigar smoking but not nondaily cigar smoking was associated with significant- ly increased risk of all-cause mortality among current primary cigar smoking was lower than observed for cigarettes; it increased sig- nificantly with more frequent cigar smoking (daily versus nondaily).	
Adjusted for age, sex, race/ ethnicity, edu- cation, and survey year	Adjusted for sex, education level, race or ethnicity, and survey year (1991, 1992, 1998, 2000, 2005, and 2010)	
All-cause and cause-specific mortality risk	All-cause and cause-specific mortality	
Prospective cohort Study Pe- riod: Partici- pants were identified in 1985,1992, 1995, 1998, 2000, 2001, 2003, 2006, and 2010 and fol- lowed to 2011	Prospective cohort Study Pe- riod: Partici- parts were 1991, 1992, 1998, 2000, 2005, and followed to 2015	
N = 3,537 Prospe exclusive cigar cohort smokers with 427 deaths Study from all-cause riod: P mortality pants 1 1995, 1 1095, 1 1005, 2 1005, 2 2000, 2 200, 2 2000,	Inoue-Choi N = 165,335 (2019). adults; 1,595 exclusive cigar 31321380 users users	
Christian- sen (2018). PMID: 29459935	Inoue-Choi (2019). 31321380 31321380	

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	Confounders or adjusted factors Results Age, race/ Increased risk of mortal- ethnicity, ity among current primary marital status, cigar smokers, not statistically educational significant (IRR: 1.02; 95% CI: attainment, 0.86–1.23). family in- come, region of residence, and survey year
	Confounders or adjusted factors Age, race/ ethnicity, educational attainment, family in- come, region of residence, and survey year
	Operationally Confounders defined or adjusted outcomes factors Mortality as- Age, race/ sociated with ethnicity, cigar use marital status educational attainment, family in- come, region of residence, and survey year
ed	Study design and study period (e.g., enrollment and follow- up years) Pooled analysis from the Integrated Public Use Micro- data Series for NHIS surveys Study Period:
TABLE 5A-1 Continued	StudyStudydesignand studySample sizeperiod (e.,(number of(number of <t< td=""></t<>
TABLE 5∕	Reference Rodu and Plurphan- swat (2021), 33413424 33413424

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

inhalation, duration,

intensity Lack

definition

Cigar use

Other cigar use characteristics: of information about

smokers de-

fined as

Never cigar

frequency and duration of consumption current smokers and

for

at least 50

never smoked

the number of years

their lifetime. Current cigar

cigars in

for former smok-

smokers had

smoked at

since quitting

deficiencies by distin-

between exclusive cigar smokers and

and smoked every day or some days at

the time of

the survey.

Former

guishing

Participants were identified in 1987,

1991, 1992, 1998, 2000, 2005, and 2010 and

ers. Study partially accounted for these

east 50 cigars

those with a cigarette

smoking history.

cigar smokers

nad smoked

at least 50

ollowed to

2015

cigars but did

not

smoke at the time of the survey. Cigar type not specified.	Ever cigar Cigars smoked smokers per day in the past month
smoke at the time c the surve Cigar typ specified.	Ever ciga smokers
	Prospective Cause-specific Age (in 5-year Compared to never smokers, study mortality groups primary cigar smoking was of age at risk, associated with increased all- Study 30–69 years), cause mortality (IRR: 1.27; 95% sex, education CI: 1.11–1.46) 1996–2002 to completed, 2017. alcohol completed, and BMI
	Cause-spe mortality
	Prospective study Study Period: 1996–2002 to 2017.
	Thomson et $N = 109,395$ , al. (2020). 2,535 primary PMID: cigar smokers 32446350 (Cuba)
	Thomson et al. (2020). PMID: 32446350

(CVD)
Disease
ovascular
Cardi
<b>TABLE 5A-2</b>

Reference	Sample Size (Number of Exclusive Cigar Users in Study)	<del>u</del>	Confounders or Adjusted Factors Results	Results	Cigar use defi- nition	Other cigar use characteristics: in- halation, duration, intensity
Chang (2015). PMID: 25907101	Seven stud- ies contained primary cigar smoking: Best (1966), with 196 cigar smoker deaths, Kahn (1966), with 1,532 deaths, Cole (1974), with 33 deaths, Cole (1974), with 33 deaths, Castensen (1987), with 131 deaths, Ben- Shlomo (1994), with 141 deaths, and Shanks (1998) with 5,216 deaths	Systematic All-cause and All studies ad- review cause-specific justed for age mortality as- Study sociated with Period: sincluding published cigar use, including published coronary hefore and aortic included. aneurysm Studies 2014 were and aortic included. aneurysm Studies 1954-2000.	All studies ad- justed for age	Slight and generally Current cigar Intensity (cigars nonsignificant increased risk in cigar-only smokers, with the exception of CPS-II with the exception of CPS-II varied by study, moderate-deep), and duration (le than or greater moderately deeply or had significant HR of approximately 1.4.	Current cigar use. Cigar type unspecified and varied by study.	Current cigar use. Cigar type per day), inhala- unspecified and tion (none, slight, varied by study, moderate-deep), and duration (less than or greater than 25 years)

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Intensity (dauy versus nondaily use)
current or former use of any cigar (little cigar, cigarillos, large cigar)
Identified Adjusted for age, Age-adjusted risk of circula - Current or cause of death sex, race/ethnic- tory death was significantly former use of based on ity education, increased in former (HR: any cigar (littl ICD-10 codes, and survey year 1.50; 1.23–1.82) and cur- cigar, cigar (littl including circulatory) rent (HR: 1.42; 1.12–1.81) arge cigar) circulatory, rent (HR: 1.42; 1.12–1.81) arge cigar) cigar smokers compared to rent cular, and circulator serve-eff- fects became nonsignificant in multivariable analysis controlling for sex, race and ethnicity, education, and survey year. Age-adjusted risk of CVD death was significantly increased in former (HR: 1.56; 1.25–1.94) but not current (HR: 1.24; 0.94–1.62) cigar smokers, with no significant risk after multivariable analysis. No significant increased risk was found for cerebrovas- cular disease (small number of deaths was too low to make a robust analysis of daily
Adjusted for age, sex, race/ethnic- ity, education, and survey year
Identitied cause of death based on ICD-10 codes, including circulatory, cardiovas- cular, and cerebrovascu- lar causes.
Prospective Identified cohort cause of de Based on Feriod: including Partici- including in 1985, circulatory in 1985, cerebrovas 1992, 1995, lar causes. 1998, 2000, 2001, 2003, 2001, 2003, 2001, and followed to 2011 2011
N = 3,53/ Prospect exclusive cigar cohort use, with 2,398 former users and Study 608 current non-Period: daily and 531 Partici- daily. Seventy- pants we two CVD deaths identifice in former cigar in 1985, users, 53 in cur- 1998, 200 rent. 1998, 200 rent. 2001, 200 2006, and followed followed
Christian- sen (2018). 29459935 29459935

versus nondaily use.

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Other cigar use characteristics: in- halation, duration, intensity	None.
Cigar use defi- nition	No data were available on type of cigar, but it was esti- mated that 21% smoked large cigars. The study could not distinguish oc- casional versus daily cigar smokers.
Results	Age adjusted for all study out- ates included in multivariate incidence of can- ers. CVD, and ers. TVD, and ers. CVD, and ers. Froke, hemorrhagic stroke, hemorrhagic stroke, and peripheral arte- following: age, rial disease were nonsig- nificant (case numbers were tory of diabetes tory of diabetes erection mellitus, ersonumption, ersposure, as compared to those who smoked five or more (1.56; with no expo- sure. Multivari- ate analyses of cardiovascular outcomes also
Confounders or Adjusted Factors Results	Age adjusted for all study out- comes; Covari- ates included in multivariate analyses of the incidence of can- cer, CVD, and COPD were the following; age, race, BMI, his- tory of diabetes mellitus, current alcohol consumption, recent or past occupational exposure, as compared with no expo- sure. Multivari- ate analyses of cardiovascular outcomes also
Study Design and Period (e.g., enrollment Operation- and follow- ally Defined up years) Outcomes	CVD, both nonfatal and fatal, was determined from hospital discharge diagnoses.
	Prospective CVD, both cohort monfatal an fatal, was Kaiser determined Health from hospit system in discharge California; diagnoses. Baseline 1964–1973 with 25-year follow-up
Sample Size (Number of Exclusive Cigar Users in Study)	N = 17,774 men 30–85 years old, followed for 25 years; 1,546 male cur- rent cigar users (never smoked cigarettes)
Reference	al. (1999)

TABLE 5A-2 Continued

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	Statistical power was limited so du- ration, frequency, and inhalation patterns could not be measured precisely.	continued
	Current cigar smokers had never smoked cigarettes, and the majority smoked at least daily. Cigar type not speci- fied.	
		those who did not.
included educa- tional attain- ment), systolic blood pressure, and total serum cho- lesterol level (but not occupational exposure)	Adjusted for age, race, marital status, education, alcohol use, BMI, exercise level, self-reported hypertension, environmental tobacco smoke exposure at home, fat intake, vegetable and citrus fruit intake, and use of aspirin, multivi- tamin, vitamin C, E, and A supple- ments	
	Prospective Death from cohort coronary heart disease Study Pe- riod: 1982 to1991	
	N = 121,278 men, 2,508 deaths	
	Jacobs 1999 PMID: 10665889	
included tional att ment), systolic b pressure, total seru lesterol le not occur	999     N = 121,278     Prospective     Death from       99     men, 2,508     cohort     coronary       99     deaths     study Pe-     heart disease       51udy Pe-     riod: 1982     riod: 1982       101991     to1991     to1991	

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in- ion,	·> Ø
Other cigar use characteristics: in- halation, duration, intensity	Daily versus nondaily users; number of days smoked last 30 days
Other cig character halation, intensity	Daily numba smoke days
Cigar use defi- nition	Former, current, Daily versus current daily, nondaily use current non- daily, nondaily, smoked last previous-daily days users of any cigar
Results	Adjusted for sex, Risk of coronary heart education level disease mortality was ( <high school,<br="">high school, some college or associated degree, college, or associated degree, college, or associated degree, college, i.32,0.69–2.30) but not for nondaily cigar smokers (HR: 1.21;0.57–2.56) com- graduate or pro- graduate or pro- hispanic on- hispanic on- hispanic other, this category.) and missing), and survey year (1991, 1992, 1998, 2000, 2005, and 2010)</high>
Confounders or Adjusted Factors Results	Adjusted for sex, education level ( <high school,<br="">ingh school, some college or associated degree, college, graduate or pro- fessional school, and missing), race or ethnicity (non-Hispanic white, non- Hispanic Non- Hispanic Non- Hispanic other, and missing), and survey year (1991, 1992, 1998, 2000, 2005, and 2010)</high>
Confounders or Adjusted Factor	Adjusted for sex education level ( <high school,<br="">some college or associated degree, college, graduate or pro- fessional school, and missing), and missing), race or ethnicity (non-Hispanic white, non- Hispanic Non- Hispanic Non- Hispanic other, and missing), and survey year (1991, 1992, 1998 2000, 2005, and 2010)</high>
Study Design and Period (e.g., enrollment Operation- and follow- ally Defined up years) Outcomes	Prospective All-cause and cohort cause-specific mortality, in- Study cluding coro- Period: nary heart pants were enrolled in 1991, 1992, 1998, 2000, 2005, and 2010 and followed to 2015
Study Design and Period (e.g., enrollment and follow- up years)	Prospective cohort Study Period: Partici- pants were enrolled in 1991, 1992, 1998, 2000, 2005, and followed to 2015
Sample Size (Number of Exclusive Cigar Users in Study)	N = 165,335 adults; 1,595 exclusive cigar users
Reference	Inoue-Choi (2019). 31321380 31321380

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None. Timing of cessation also was not assessed.	
Current smoker None. Timing of defined as ev- cessation also wa ery day or some not assessed.	days. Former defined as hav- ing smoked at least 50 cigars but currently not smoking at all. Never use defined as having smoked <50 cigars. Type of cigar not specified.
Angina, coro- Adjusted for sex, 1) Current primary cigar Current smoker nary heart age, race/ethnic- smoking was not associated defined as ev- disease, heart ity, education, with an increased risk of ery day or some	heart attack or stroke. days. Former 2) However, former primary defined as hav- cigar smoking was associ- ated with an increased risk least 50 cigars of heart conditions (APV: 1.33; 95% CI: 1.03–1.72) not smoking and stroke (APV: 2.42; 95% at all. Never CI: 1.57–3.75) compared to never smokers. c50 cigars. Type of cigar not specified.
Angina, coro- Adjusted for sex, nary heart age, race/ethnic- disease, heart ity, education,	alcohol use, and BMI
Angina, coro- nary heart disease, heart	attack, other alcol heart disease, BMI or stroke
Cross- Sectional	Study Pe- riod: 2000, 2005, 2010, and 2015
Approximately Cross- 30,000 Sectiona respondents	each year
Rostron (2019) PMID:	30815336

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Reference	Sample Size (Number of Exclusive Cigar Users in Study)	Study Design and Period (e.g., enrollment and follow- up years)	Study Design and Period (e.g., enrollment Operation- and follow- ally Defined up years) Outcomes	Confounders or Adjusted Factors Results	Results	Cigar use defi- nition	Other cigar use characteristics: in- halation, duration, intensity
Wald (1997) PMID: 9224127	Wald (1997) <i>N</i> = 21,520 men PMID: 9224127		Risk of dy- ing from lung cancer, ischemic heart disease, ob- structive lung disease.	Adjusted for age at entry of the study	Adjusted for age 1) Carboxyhemoglobin Compared at entry of the levels: secondary cigar primary to study than primary smokers (1.0% cigar smokers versus 0.9%), with both (those who being much lower than that had switched of cigarette smokers (4.6%). to cigars from Some cigar smokers who reported moderate to deep Cigar tobacco inhalation and had carboxy- consumption hemoglobin levels similar and containing 2 g 2) Ischemic heart disease and one large mortality data were pre- cigar and pipe smokers. cigar was not Primary cigar/pipe users.	Compared primary to secondary cigar smokers (those who had switched to cigars from cigar tobacco consumption defined as one small cigar containing 2 g and one large cigar contain- ing 5 g. Type of cigar was not reported.	None

TABLE 5A-2 Continued

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had no higher mortality than lifelong nonsmokers, while secondary cigar / pipe users had a slight but not significant increase in mortality risk (1.29; 95% CI: 0.88–1.99). Current cigarette smokers' relative mortality compared to never smokers was 2.27 (95% CI: 1.81–2.84).

Illness	
<i>cespiratory</i>	
Other <b>R</b>	
and	
Cancer and	
Lung	
BLE 5A-3	

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Former, current, Daily versus non- current daily, daily users; number and current of days smoked last nondaily users 30 days of any cigar
Adjusted for 1) Adjusted HR for lung sex, education cancer for former cigar level ( <high (95%="" 0.28="" ci:<br="" smokers:="">school, high 0.04–2.03), school, some 2) 1.87 (95% CI: 0.53–6.55 college or for current daily cigar graduate or 3) 1.50 (95% CI: 0.22–10.09) gree, college, 3) 1.50 (95% CI: 0.43–10.20) gree, college or for current daily cigar professional 4) 2.10 (95% CI: 0.43–10.20) school, and for current mondaily cigar missing), race smokers or ethnicity (non-Hispanic white, non-Hispanic white, non-Hispanic white, non-Hispanic white, non-Hispanic other, and missing), and survey year (1991, 1992, 1998, 2000, 2005, and 2010)</high>
Prospective Lung cancer cohort Study Pe- riod: Partici- pants were pants were pants were pants were pants and 1991, 1992, 1998, 2000, 2005, and 2010 and followed to 2015.
Inoue-Choi N = 165,335 2019. PMID: adults; 1,595 31321380 exclusive cig users

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continued

Reference	Sample Size (Number of Exclusive Cigar Users in Study)	Study Design and Period (e.g., enroll- ment and follow-up years)	Operation- ally Defined Outcomes	Confounders or Adjusted Factors	Results	Cigar use defi- nition	Other cigar use characteristics: inhalation, duration, intensity
Lee (2012). PMID: 22943444	Fifteen effects from studies were pooled	Meta-anal- ysis Study Period: Papers pub- lished before 1999 were included.	Lung cancer	Results were entered with greatest number of potential confounders for which results were available	<ol> <li>Random-effects relative risk of lung cancer for ever smoking cigars: 2.95 (95% CI: 1.91–4.56),</li> <li>CI: 1.91–4.56),</li> <li>cI: 1.91–4.56),</li> <li>cI: 1.91–4.57)</li> <li>e.25), 3) ex-smokers: 2.85 (95% CI: 1.45–5.61)</li> </ol>	Ever, current, and former use of any cigar	None
McCor- mack. (2010). PMID: 20162568	N = 1,451 exclusive cigar users with 22 lung cancer cases	Prospective cohort Study Period: 1991–1998 to 2003–2006	Lung cancer	Adjusted for BMI, alcohol history, and educa- tional level, stratified by country	<ol> <li>For lung cancer, the Exclusive adjusted HR among current cigar and pipe exclusive cigar smokers smoking and was significant at 3.9 and in combination 2.4 (95% CI: 0.7–8.2) among with cigarettes every cigar smokers.</li> <li>Lung cancer combined with upper aerodigestive tract and bladder cancers were assessed by inhalation, duration, cigars per week, and cigar size. For more information, see the entry for this study in the other cancers section.</li> </ol>	Exclusive cigar and pipe smoking and in combination with cigarettes	Inhalation, duration, cigars per week, cigar size

TABLE 5A-3 Continued

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Inhalation	None
Exclusive cur- rent smoker of any cigar	Current, exclusive cigar users were those who had ever smoked a cigar (tradi- tional cigars, cigarillos, or filtered cigars), had smoked at least one cigar product fairly regularly, smoked every days at Wave 3
Other respira-Not adjusted.1) 10.8% of exclusive cigarExclusive cur-tory illnesses:Reportedsmokers have COPD, 10.8%rent smoker ofCOPD andpercentageshave hemoptosis, andany cigarrespiratorysolely.10.8% reported a chroniccoughsymptoms2) 71.4% of cigar smokersreported never inhaling	<ol> <li>For cigar users who never smoked, the adjusted OR for indicating "ever had wheezing or whistling in chest at any time in the past" was 0.90 (95% CI: 0.51-1.58),</li> <li>for indicating "in the past 12 months, had wheez- ing or whistling in the chest" was 0.80 (95% CI: 0.38-1.69),</li> <li>for indicating "in the past 12 months, chest has sounded wheezy during or after exercize" was 1.02 (95% CI: 0.56-1.86)</li> </ol>
Not adjusted. Reported percentages solely.	Adjusted for age, gender, race/ethnici- ty, BML, insur- ance, asthma, and second- hand smoke exposure
Other respira- tory illnesses: COPD and respiratory symptoms	Other respira- Adjusted for tory illnesses: age, gender, wheezing race/ethnici- symptoms ty, BML insur ance, asthma, and second- hand smoke exposure
Cross-sec- tional Study Pe- riod: October 1997	<ul> <li>(44 cases Cross-sec- zing tional</li> <li>cases Study Pe- nonths, riod: October</li> <li>ases 2015-October</li> <li>g after 2016</li> </ul>
Jimenez- N = 37 cigar Cross-sec- Ruiz (2002). smokers (4 tional 1 PMID: cases of COPD, 12435319 hemoptosis, and Study Pe- coughing) riod: October 1 1996–April 1997	N = 266 (44 cases of wheezing ever, 25 cases wheezing in past 12 months, and 25 cases wheezing after exercise)
Jimenez- Ruiz (2002). PMID: 12435319	Schmeller (2020). PMID: 33320256

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Other cigar use char- acteristics: inhalation, duration, intensity	Never smoked Did not assess dura- cigarettes and tion of cigar smoking; did not cur- rently smoke a casional cigar smokers pipe; cigar type (those who smoked a not specified few each month) or sporadic cigar smokers (those who smokers (those who smokers in the study group
Cigar use defi- nition	Never smoked cigarettes and did not cur- rently smoke a pipe; cigar type not specified
Results	Age, race, BMI, diabetes1) Cancer of the orophar- Never smokedBMI, diabetesynx: Current exclusive cigarBMI, diabetesynx: Current exclusive cigarstatus, alcoholsmoking: age-adjusted rate: (adjusted RR: 2.61; 95% CI: 1.18–5.76)consumption,2.0 per 10,000 person-years (adjusted RR: 2.61; 95% CI: pipe; cigar type not specified hazardous2) UADT cancer: Current chemicals or2) UADT cancer: Current ing: age-adjusted rate: 2.4 per 10,000 person-years (adjusted RR: 2.02; 95% CI: 1.01-4.06)
Confounders or Adjusted Factors	Age, race, BMI, diabetes status, alcohol consumption, occupational exposure to hazardous chemicals or substances
Operation- ally Defined Outcomes	Cancers of upper aerodigestive tract (UADT; oropharynx, nose, larynx, and esopha- gus)
Study Design and Period (e.g., enroll- ment and follow-up years)	Prospec- tive cohort study Study Period: 1971–1996
Study Design and Per Sample Size (e.g., en (Number of ment ar Exclusive Cigar follow Users in Study) years)	ribarren et N = 17,774, 1546 Prospec- al. (1999). exclusive current tive cohort of upper exclusive current tive cohort of upper igar smokers study aerodiges (0362820 Study orophary Period: nose, lary 1971–1996 and esopi gus)
Reference	Iribarren et al. (1999). 10362820

Table 5A-4 Oral Health and Head/Neck Cancer

Ever and exclu- None sive use of any cigar
Adjusted for age at enroll- ment, BMI. included the two cohort race/ethnic- try, SES, race/ ethnicity, and duration of tobacco use, exclusive cigar smok- amily history of cigarette smoking had an elevated risk of head and neck cancer (HR: 2.59; 95% CI: 1.21–5.58)
Adjusted for age at enroll- ment, BMI, in ment, BMI, race/ethnic- sity, SES, race/ ethnicity, alcohol use, family history of cancer of cancer
Cancers of head and neck
Pooled analysis of five prospec- tive cohort studies from the NCI Cohort Consor- tium Study Period: Five stud- ies with different dates (and median duration of follow-up): 1996 (17.3), 1996-01-994 (18.6), 1996-01-994 (18.6), 1996-01-904 (19.5), 1995-2001 (12.5)
N = 6,622 cigar smokers across five studies
Malhotra (2017). PMID: 28972007

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TABLE 5,	TABLE 5A-4 Continued	d					
Reference	Sample Size (Number of Exclusive Cigar Users in Study)	Study Design and Period (e.g., enroll- ment and follow-up years)	Operation- ally Defined Outcomes	Confounders or Adjusted Factors	Results	Cigar use defi- nition	Other cigar use char- acteristics: inhalation, duration, intensity
McCormack (2010). PMID: 20162568	McCormack N = 1,451 exclu- (2010). sive cigar users, PMID: 33 for UADT, and 620 all tobacco-related cancers	Prospective cohort Study Period: 1991–1998 to 2003– 2006	Prospective UADT (lip, cohort UADT (lip, oral cav- ity, tonsil, Study oropharynx, Period: esophagus) 1991–1998 to 2003– 2006	Adjusted for BMI, alcohol history, and educa- tional level, stratified by country	<ol> <li>Men who ever exclusively smoked cigars had an elevated HR relative to those who never smoked (HR: 4.0; 95% CI: 1.7–9.4)</li> <li>Men who had quit ciga- rette smoking and became current cigar smokers had an HR for UADT cancer (8.2; 95% CI: 4.1–16.7) that was comparable to that observed for exclusive cigarette smokers (8.9, 95% CI: 3.1–6.6).</li> </ol>	Exclusive cigar and pipe smoking, and in combination with cigarettes	Inhalation, duration, cigars per week, cigar size
Shapiro (2000). PMID: 10675383	N = 137,555, 7,888 current and 7,868 former cigar smokers	Prospective Mortality cohort from oral. Study Pe- riod: 1982 to 1994	Mortality Age, alco from oral cav-use, and ity/pharynx use of sn or chewi tobacco	Age, alcohol use, and use of snuff or chewing tobacco	<ol> <li>Mortality IRR for cancers of the oral cavity or pharynx: 4.0 (95% CI: 1.5–10.3) among current cigar smokers and 2.4 (95% CI: 0.8–7.3) among former</li> </ol>	Ever cigar smokers	Intensity (cigars/day), inhalation (data were too sparse for detailed analysis by number of cigars per day), duration (less than 25

duration (less than 25 years or greater than or equal to 25 years)

cigar smokers 2) The IRR estimates were CI: 0.8–7.3) among former

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	Cigar-years were cal- culated by multiply- ing the frequency and duration of smoking cigars. Levels of frequency, duration, and cumulative use of tobacco were catego- rized according to previous IN- HANCE Consortium reports.
	Ever cigar smokers, un- specified cigar type.
higher among men who reported inhalation of cigar smoke (IRR: 6.5, 95% CI: 1.4–29.2) than those who did not (IRR: 3.3, 95% CI: 0.9–11.0)	Cancers of Sex, age, race, 1) Among persons who had and neck educational nevel, frequen- those who had ever used cigarettes, a smokers, u sevel, frequen- those who had ever used cigares, use, and dura- of head and neck cancer ynx; or lar- use, and dura- of head and neck cancer the second lip, salivary smoking pharynx, or smoking pharynx, or smoking process of large and neck cancer significantly increased with the number of cigar use, and cumulative cigar u
	Sex, age, race, educational level, frequen- cy of alcohol use, and dura- tion of pipe smoking
	Pooled data from 13 case-con- trol studies Study Pe- riod: within range of 1981–2007
	N = 13,935 cases, 18,691 controls; N = 171 every cigar smokers (155 controls)
	Wyss et al. (2013). 23817919 23817919

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	char- ation, ity	
	Other cigar use char- acteristics: inhalation, duration, intensity	
	Other acteris durati	None
	Cigar use defi- nition	Exclusive cigar smokers during follow-up pe- riod; cigar type unspecified.
	Results	1) Cigar smokers hadExclusive cigarhigher percentage of mesialsmokers duringand distal alveolar sitessmokers duringand distal alveolar sitesfollow-up pe-with bone loss progressionriod; cigar typethan nonsmokers $(16\%)$ umspecified.versus $8\%$ , $p < .05$ umspecified.2) Adjusted RR of tooth lossfor cigar smokers was 1.3(95% CI: 1.2-1.5) relative tononsmokers
	Confounders or Adjusted Factors	
D)	Operation- ally Defined Outcomes	Radiographic alveolar bone loss ≥40%
nader la	Study Design and Period (e.g., enroll- ment and follow-up years)	Prospective cohort Study Pe- riod: 1968 to 1991
INDLE UN-U I CHUUUIIIAI DISCASE	Sample Size ( (Number of r Exclusive Cigar f Users in Study)	N = 690 (50 cigar       Prospective       Radiographic       Age, educa- alveolar bone         smokers)       cohort       alveolar bone       tion, number         Study Pe-       loss ≥40%       of teeth at         Study Pe-       riod.       1968       percentage of         riod.       1991       alveolar sites       with moder- ate to severe         alveolar sites       of setties       percentage       of alveolar sites         of setties       alveolar sites       pone loss       at baseline, percentage         of sites with       moderate to       severe pocke       depth at
	Reference	Krall et al. (1999). PMID: 9919032

TABLE 5A-5 Periodontal Disease

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None
Current use defined as using only one product "fairly regularly": "everyday" or "some days." Cigar types included traditional and filtered cigars and cigarillos, (results com- bined)
<ol> <li>Adjusted OR of gingival disease was 1.9 (95% CI: 1.4–2.7) relative to tobacco never users</li> <li>Adjusted OR of gingival disease treatment was 1.5 (95% CI 1.2–2.0) relative to tobacco never users</li> </ol>
Self-reported Age, sex, 1) gingival dis- race/ethnic- di ease diagnosis ity, educa- 1. and treatment einon, income, no for it mistory of di history of di diabetes (9
Self-reported Age, sex, gingival dis- race/ethnic- ease diagnosis ity, educa- and treatment tion, income for it employment history of diabetes
Cross- sectional Study Period: September 2013-De- cember 2014
N = 32,223 un- weighted (1.1% of weighted sample were current estab- lished cigar smokers)
Vora and Chaffee (2019). PMID: 30922519

Reference	Sample Size (Number of Exclusive Cigar Users in Study)	Study Design and Period (e.g., enroll- ment and follow-up years)	Operation- ally Defined Outcomes	Confounders or Adjusted Factors	Results	Cigar use defi- nition	Other cigar use char- acteristics: inhalation, duration, intensity
Alguacil (2004). PMID: 14744733	N = 46 (9 cases and 37 controls)	Case con- trol Study Period: August 1986 - April 1989	Pancreatic cancer risk	Adjusted by race, gender, geographic site, and cigar smoking, smokeless tobacco, and age	1) Adjusted OR for cigar- only smokers was 1.9 (95% CI: 0.8–4.3)	Regular cigar use of any cigar	None
Andreoti (2017). PMID: 28035020	N = 433 cigar us- Prospecers with 76 cases cohort of total cancers, 24 cases of Study smoking-related Period: cancers, 10 cases 1993–19 of gastrointesti- to 2010. nal cancer, and 9 2011. cases of urinary cancer. $N = 44$ cigarillo users with 5 cases of total cancers	Prospective cohort Study Period: 1993–1997 to 2010– 2011.	3 cigar us- h 76 cases cohort and tobacco- leancers, related cancer s of Study incidence. related cancer ng-related Period: Tobacco-re- s, 10 cases 1993–1997 lated cancers rointesti- to 2010– analyzed cer, and 9 2011. were bladder, f urinary to 2010– analyzed cer, and 9 2011. were bladder, f urinary colon, cervix, N = 44 kidney, cases of larynx, lip, nncers liver, lung, myeloid l	Adjusted for age, gender, race, state of residence, education, and alcohol use.	<ol> <li>For cigar use, the ad- justed HR was 1.51 (95% CI: cigarillo use</li> <li>1.20–1.90) for total cancers,</li> <li>1.87 (95% CI: 1.24–2.82) for smoking-related cancers,</li> <li>3) 2.50 (95% CI: 1.27–4.93) for urinary cancer</li> <li>4) Other associations were not significant (gastrointes- tinal) or not available.</li> <li>5) For cigarillos, only the total cancers adjusted HR was available: 1.44 (95% CI: 0.60–3.48), which is not significant.</li> </ol>	Ever cigar and cigarillo use	None

TABLE 5A-6 Other Cancers

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	None
	Ever use of any None cigar
	1) The age-adjusted OR for NHL was 1.3 (95% CI: 0.54-3.0) 2) For follicular NHL, OR was 2.8 (95% CI: 1.1-7.2) 3) For diffuse large cell, OR was 0.42 (95% CI: 0.05-3.2)
eukemia, na- sal and sinus, oral cav- ity, pancreas, pharynx, rectum, stom- ach, tongue, ureter, and uterus	Non-Hodgkin Adjusted for lymphoma age (NHL) incidence, overall and by histology
	Case con- trol Study Period: 1988-1995
	N = 9 patients, 15 controls
	Bracci (2005). 15953976

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# Premium Cigars: Patterns of Use, Marketing, and Health Effects

Other cigar use char- acteristics: inhalation, duration, intensity	Current cigar Intensity (cigars per use; cigar type day), inhalation (none, was unspectified slight, moderate- and varied by deep), and duration (less than or greater than 25 years)
Cigar use defi- nition	Current cigar use; cigar type was unspecified and varied by study.
Results	Esophageal: 1) The adjusted IRR for cigar-only smokers in Shanks (1998) was 3.6 (95% CI: $2.17-5.62$ ), and the HR in Shapiro (2000) was 1.8 (95% CI: $0.90-3.70$ ). 2) In Shanks (1998), the IRR was $2.28$ (95% CI: $0.74-5.33$ ) for $1-2$ cigars per day, $3.93$ (95% CI: $1.43-8.55$ ) for $3-4$ cigars per day, and $5.19$ (95% CI: $1.43-8.55$ ) for $3-4$ cigars per day, and $5.19$ (95% CI: $2.23-10.22$ ) for $5$ or greater cigars per day, which is suggestive of a dose response. 3) In Shapiro (2000), the HR was 1.8 (95% CI: $0.60-5.00$ ) for $1-2$ cigars per day and 1.9 (95% CI: $0.80-4.90$ ) for 3+ cigars per day.
Confounders or Adjusted Factors	All studies adjusted for age
Operation- ally Defined Outcomes	Mortal- ity from esophageal and bladder cancer (BC)
Study Design and Period (e.g., enroll- ment and follow-up years)	Systematic review Study Period: Studies published before 2014 were included. Shanks (1998): 1959–1960 to 1972 and Shapiro (2000): 1982–1994
Sample Size (Number of Exclusive Cigar Users in Study)	Two studies con-Systematic M tained primary review it cigar smoking: Study et Shanks (1998) Study an with 19 cigar Period: ca smoker deaths Studies and Shapiro published (2000) with 9 before cigar smoker 2014 were deaths. Shanks (1998): 1959-1960 to 1972 and Shapiro (2000): 1982-1994
Reference	Chang (2015). PMID: 25907101

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an increased number of cigars ratios for BC were 0.94-1.9 for 4) In Shanks (1998), the IRR halation, and 14.84 (95% CI: 5) In Shapiro (2000), the HR 95% CI: 0.10–7.20) for inhaincreased mortality. Mortality CI: 0.02–10.58) for slight inwas 3.4 (95% CI: 1.90-5.61) for no inhalation, 1.9 (95%)was 1.6 (95% CI: 0.70-4.10) the HR for smoking cigars was 0.9 (95% CI: 0.10-6.40) ation. 6) In Shapiro (2000) and 2.2 (95% CI: 1.00–4.70) cigars affect mortality from esophageal cancer and that 2.98-43.37) for moderatefor shorter than 25 years 7) Evidence indicates that per day is associated with for no inhalation and 1 for 25 years or longer. current cigar smoking. deep inhalation.

Continued	
<b>TABLE 5A-6</b>	

ċ	Study	Decion	1701B11	Dario Dario

Other cigar use char- acteristics: inhalation, duration, intensity	Intensity (daily versus nondaily use)
Cigar use defi- nition	Current or former use of any cigar (little cigar, cigarillos, large cigar)
Results	Adjusted for 1) The adjusted HR for age, sex, race/ age, sex, race/ ethnicity, edu- 1.61 (95% CI: 1.11–2.32) for any cigar (little cation, and risk of dying from tobacco- survey year elated cancers and 3.26 (95% CI: 1.86–5.71). 2) Among daily cigar users, mortality risks from tobac- co-related cancer (HR: 1.80); 95% CI: 1.20–2.69), lung cancer (HR: 4.18); 95% CI: 2.34–7.46), and COPD (HR: 3.29; 95% CI: 1.33–8.17) were elevated and statisti- cally significant. For non- daily use, these associations were not significant.
Confounders or Adjusted Factors	Adjusted for age, sex, race/ ethnicity, edu- cation, and survey year
Operation- ally Defined Outcomes	Tobacco-re- lated cancers (bladder, esophagus, larynx, lung, oral cavity, and pancreas)
Study Design and Period (e.g., enroll- ment and follow-up years)	Prospective cohort Study Period: Partici- pants were identified in 1985, 1995, 1995, 1995, 1995, 1995, 1995, 2000, 2001, 2003, 2001, 2003, 2001, 2003, 2011.
Sample Size Number of Exclusive Cigar Users in Study)	N = 3,537 exclu- sive cigar withProspective cohortTobacco-re- lated cancers32 deaths from tobacco-related(bladder, (bladder, Period: Partici- oral cavity, pants were identified in 1985, 1992, 1995, 1998, 2000, 2001, 2003, 2001, 2003, 2011.
Reference	Christian- sen (2018). PMID: 29459935

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e.
Nor
Not specified. None
Meta-analImpact ofIf multipleBC incidence increasedysistobaccoRRs or ORsamong cigar smok-studyexposure onwere pre-ers compared to neverStudyBC incidencesented in thesmokers (RR: 1.62; 95%Period:and mortal-original thesmokers (RR: 1.62; 95%inty, renal cellauthors ex-orther tobacco products,six didedity, renal cellauthors ex-inty, renal cellauthors ex-other tobacco products,six didestmates fromsimilar for pipe smokerstween 1987as no primarythe maximallyand Augustcigar smokersbut lower than the risk for2013 inin the study)model tocigarette smokers (RR: 3.37;Europe,smoking also had a nonsig-possibleAsia, andoceaniapossiblenificant higher risk of deathOceaniathe study)that BC mortality was lessextensively reported in thefrom BC, but authors notedoceaniaconfounding.that BC mortality was less
If multiple RRs or ORs were pre- sented in the original the authors ex- tracted the es- timates from the maximally adjusted model to reduce the risk of possible unmeasured confounding.
Meta-anal- Impact of If multiply ysis to acco RRs or Of Bobacco RRs or Of Bobacco RRs or Of Period: BC incidence sented in Period: and mortal- included ity, renal cell authors es 3 studies cancer (not tracted the on BC be- reported here, timates fr tween 1987 as no primary the maxin and August cigar smokers adjusted 2013 in in the study) model to Europe, reduce the America, possible Oceania confound
Outcomes for 51,404 BC cases and 64 602 con- trols were included in the meta-analysis.
Cumber- batch (2016) PMID: 26149669

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TABLE 5,	TABLE 5A-6 Continued	þ					
Reference	S I Sample Size (Number of Exclusive Cigar Users in Study) y	tudy Design nd Period e.g., enroll- nent and ollow-up ears)	Operation- ally Defined Outcomes	Confounders or Adjusted Factors	Results	Cigar use defi- nition	Other cigar use char- acteristics: inhalation, duration, intensity
Inoue-Choi (2019). 31321380 31321380	noue-Choi N = 165,335 2019). adults; 1,595 2MID: exclusive cigar 31321380 users users	Prospective cohort Study Period: Par- ticipants were iden- tified in 1991, 1992, 1998, 2000, 2005, and 2010 and followed to 2015	BC mortality	Adjusted for sex, education level, race or ethnicity, and survey year (1991, 1992, 1998, 2000, 2005, and 2010)	Compared to never-tobacco users, HRs for BC mortal- ity were 5.68 (95% CI: 0.74–43.69) for current exclusive cigar smokers, 4.65 (2.65–8.17) for current exclusive cigarette smokers, and 6.90 (1.06–45.14) for current exclusive smokeless tobacco use.	Former, current, current daily, current non- daily, nondaily, previous-daily users of any cigar	Daily versus nondaily users; number of days smoked last 30 days

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	continued
None	
Ever and exclusive use of any cigar (exclusive cigar use was defined as 100% of lifetime tobacco consumption cigar use).	
<ol> <li>The adjusted HR for ever cigar use was 1.47 (95% CI: 1.34–1.61) for smoking-related cancers (head and neck, esophagus, lung, stomach, pancreas, liver, kidney, bladder, and colorectal) and 1.07 (95% CI: 1.02–1.16) for all can- cers. No other significant associations existed except for lung cancer.</li> <li>For exclusive cigar use, the risk of gastric cancer was 1.96 (95% CI: 0.99–3.88) and of all cancers was 1.41 (95% CI: 1.04–1.91).</li> <li>Esoplageal Cancer The adjusted HR for ever cigar use was 1.01 (95% CI: 0.56–1.84). The adjusted HR for exclusive cigar use was 1.39 (95% CI: 0.35–5.47).</li> </ol>	BC Compared to never smok- ers, HRs for incidence of BC were 1.14 (95% CI: 0.88–1.48) for ever cigar smokers only and 1.40 (95% CI: 1.07–1.84) for ever pipe smokers only.
Adjusted for age at enroll- ment, BMI, race/ethnic- ity, SES, race/ ethnicity, alcohol use, family history of cancer	
Incidence of smoking-re- lated cancers, such as head and neck, esophagus, lung, stom- i ach, liver, pancreas, kidney, and bladder	
Pooled Incidence analysis smoking- of five such as he tive cohort and neck, studies esophagu from the lung, ston NCI Cohort ach, liver, consor- pancreas, tium kidney, ar Period: Five stud- ies with different dates (and median duration of follow-up): 1996-1994 (18.6)	(9.9), 1995– 1996 (15.5), 1993–2001 (12.5)
N = 6,622 cigar smokers across five studies	
Malhotra (2017). PMID: 28972007	

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A-6 Continued	Study Design

Exclusive cigar and pipe smoking, and n combination with cigarettes	
<ol> <li>Compared to never smokers, HR of cancers of lung, UADT, and bladder</li> <li>combined was 2.2 (95% CI: 1.3–3.8) for exclusive cigar smokers. The study found no significant associations for overall current cigar smoking and esophagus, pancreas, and BC mortality risk. 2) For combined lung, UADT, and bladder can- cers, cigar size and duration of smoking trend were assessed and not significant (although the trend was close to significant with</li> </ol>	- - -
Adjusted for BMI, alcohol history, and educa- tional level, stratified by country	
Incidence of lung, UADT, bladder, liver, stomach, pan- creas, kidney, cancers, and all tobacco-re- lated cancers (lung, UADT, bladder, liver, stomach, pancreas, kidney and colorectal)	
of the terms of terms	
Mckormak (2010). PMID: 20162568	
(area)	KN = 1,451Prospective indext of exclusive cigarProspective indext of instory, bladder, liver, listory, bladder, liver, listory, bladder, liver, listory, indext acrodigestiveCompared to never smokers, HR of cancers of umg, UADT, and bladder imm, UADT, 80, exclusive cigar aerodigestive cruthment colorectal attract (UADT), 81 between tract (UADT, 81 brancers, partici- fulung, UADT, fulung, UADT, fulun

hale (7.5 versus 1.8). There did appear to be somewhat than those who did not ininhalation had higher HR 3) Those with light/deep

duration).

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acteristics: inhalation,

Other cigar use char-

cigars per week, cigar size

Inhalation, duration, duration, intensity

	Duration of smoking and time since quit- ting (for ex-smokers) was ascertained in all studies. Average daily consumption was as- certained in two stud- ies. Analysis of daily tobacco consumption was restricted to two studies.
of a pattern for cigars per week: 14+ cigars had an HR of 4.1, while smoking fewer than 7 had an HR of 2.0.	The OR for BC was 2.3 (95% Not specified. CI: 1.6–3.5) for primary cigar smoking, 1.9 (95% CI: 1.2–3.1) for primary pipe smoking, and 3.5 (95% CI: 2.9–4.2) for primary ciga- rette smoking compared to never smokers.
	Adjusted for age, center, and oc- cupational exposure
	Pooled BC risk Analysis (6 case-con- trol studies from Denmark, France, Germany, and Spain) Study Period: Reviewed stud- ies were published between 1980 and 1996
	N = 50 "pure" cigar smokers only smokers with 122 con- trols;
	Pitard (2001). PMID: 11519763

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# **Priority Research Needs**

#### **INTRODUCTION**

Cigar<sup>1</sup> products exist on a spectrum with overlapping characteristics, with no clear distinction separating "premium"<sup>2</sup> from other types. Premium cigars currently have a different pattern of use than other cigar products and therefore result in different health effects. However, premium cigars are not inherently less risky than other cigars. As discussed in Chapters 2 and 5, all cigars contain harmful and potentially harmful constituents, and the extent to which they negatively affect health largely depends on how they are used (e.g., frequency and duration, pattern of inhalation).

Since the comprehensive NCI monograph on cigars (NCI, 1998), little has changed regarding the state of knowledge on premium cigar characteristics or health effects. Some studies have expanded our knowledge about cigar characteristics or reinforced the findings and conclusions from the monograph regarding health effects. However, it identified many research gaps that still exist today, such as the lack of data to fully understand how cigars, including premium cigars, are used by consumers. To

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<sup>&</sup>lt;sup>1</sup> Note that when the terms "cigar(s)" or "cigars in general" are used in this report, they refer to all cigar types (filtered cigars, little cigars, cigarillos, and large/traditional cigars [which include premium cigars]). When discussing a specific cigar type, the type is noted in text.

<sup>&</sup>lt;sup>2</sup> Note that quotations are used at the first occurrence of the term "premium" in each chapter, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information.

advance the field, comparisons to other cigar types are needed; therefore, the committee offers priority recommendations that will advance knowledge of cigars as a whole—not only premium cigars.

Premium cigars have a small share of the cigar market compared to other types. Current evidence suggests that they are less likely to be used by youth, and most users smoke them only occasionally, rather than daily. However, these patterns of use could change due to factors that include changes in marketing, consumer awareness, or prices; taxes, or regulations of one or more tobacco products; or social shifts that result in a preference for premium cigars. A greater understanding of premium cigars' physical characteristics, patterns of use, user perceptions, tobacco industry marketing strategies, and health effects will aid comparison over time and inform regulation. The committee identified many research gaps for premium cigars, and cigars in general, as highlighted in this report. This chapter provides nine priority recommendations that the federal government<sup>3</sup> should support to advance the field, based on the report's findings, conclusions, and research gaps.

It is important to consider why the prevalence of premium cigar use is lower than for other cigars and tobacco products. Many of the characteristics that distinguish them from other cigar types are affected by tobacco control policies (see Chapter 1 for the committee's definition of a premium cigar). For example, when access to a tobacco product is restricted (due to tobacco control policies, manufacturer's decisions, or retailer and consumer preferences [e.g., manufacturers could reduce the weight and/ or price of the product]) and it is only available in limited locations, its use is generally lower. Premium cigars are not as widely available for purchase as other cigar types or tobacco products. In most definitions (see Chapter 1 Annex), including the committee's for the purpose of this report, premium cigars do not have any added flavors, and restrictions (including bans) on flavors and menthol are a proven public health strategy to decrease tobacco product use. Premium cigars are also larger than other types and can take up to 2 hours to smoke. They have a considerably higher price point than other cigar types or tobacco products, and increasing taxes and prices are also known public health strategies to decrease use. However, all combustible tobacco products are inherently harmful if used as expected (i.e., burned and smoked) (see Chapters 2 and 5). Additionally, the tobacco industry also often changes products based on regulations and consumer preferences. If one or more premium cigar characteristics change (e.g., size, weight, price, added flavor) and thus

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<sup>&</sup>lt;sup>3</sup> The committee was only asked in its statement of task to provide recommendations to federal agencies.

#### PRIORITY RESEARCH NEEDS

they become more appealing or easy to access, it is plausible that they would be used a wider population and/or more frequently by the people who already use them.

Health equity is an important consideration for all public health issues (NASEM, 2017). While premium cigar users are largely adult, white, male, and of higher socioeconomic status (SES), users of other cigar types are more likely to smoke cigarettes, be of lower SES, be female, be young, be from racialized and ethnic populations groups, and have comorbid health (including mental health) conditions (Anderson, 2011; NCI, 2008; Rising and Alexander, 2011; Yerger et al., 2007). Targeted marketing of other tobacco products increased use in these populations; it is therefore possible that premium cigar marketing efforts could shift the demographics of users. It remains critical to balance the relative importance of premium cigars compared to other cigar types and other tobacco products in health equity research and interventions, given important disparities in use of nonpremium (NCI, 2017).

### PRIORITIZATION CONSIDERATIONS

To develop its research recommendations, the committee identified key research needs in each of the areas it was tasked with exploring—product characteristics, patterns of use, marketing and perceptions, and health effects. The committee reviewed the research gaps, which can be found in each chapter, and considered the following criteria in prioritizing them:

- a) public health impact,
- b) disease burden,
- c) health equity,
- d) implementation considerations (including feasibility, cost-effectiveness, time frame, measurability, and scalability),
- e) relevance to FDA regulation,
- f) alignment with other research efforts, and
- g) whether the results would change the field's understanding of the health effects and/or patterns of use of premium cigars.

The committee ranked these needs via a voting process, informed by the above criteria. and identified four high-priority recommendations and five additional priority recommendations based on the findings, conclusions, and key research gaps identified throughout this report.

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### HIGH-PRIORITY RECOMMENDATIONS

### **Definition of Premium Cigars**

This report repeatedly points to the lack of formal definitions for not only premium cigars but also other cigar types. This has significantly hindered the research, with studies using a range of different definitions and terms (for example, cigars on the larger end of the size spectrum are referred to as "large," "traditional," and "premium," with large or traditional typically including premium). In addition, evidence is limited on consumers' awareness of each type, the terms consumers use to describe each type, and its congruency with researchers' nomenclature and operationalization of those types.

### Recommendation 1: The Food and Drug Administration, in consultation with other federal agencies, should develop formal categories and definitions for cigars to be used for research to ensure consistency among studies.

These definitions should be, in part, informed by consumers' use and experience with the products. Having standard definitions will advance research in many ways. For example, distinguishing premium cigars will help researchers: capture awareness of them in the U.S. population and knowledge of the health risks associated with their use, track patterns of use (including when new regulations are implemented), and better assess health effects over time. As discussed in Chapter 4, the term "premium" itself has connotations about the products it represents (e.g., luxury) and can influence perceptions and use. These definitions could also be used for regulatory purposes.

When developing the definition, it will be important to consider that the weights of premium cigars reviewed in this report are much higher than the typically cited threshold of 6 pounds per 1,000 units. Moreover, other cigar types also commonly meet this criterion. Because this threshold is used in many definitions of premium cigars, the weight criterion merits re-examination, as it might need to be increased to be consistent with the current marketplace.

Experience with other tobacco products (e.g., e-cigarettes) has demonstrated that as definitions are delineated, new products arise that no longer fit into existing definitions. In addition, tobacco products are also sometimes altered to meet the definition or category of another product (e.g., small and large cigar weight as a category for tax purposes is a good example of tobacco industry success in adjusting to categories defined by government agencies—see Chapter 1 for more information). Furthermore, products can change for other reasons, such as advances in technology

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#### PRIORITY RESEARCH NEEDS

(e.g., 3-D printing of biological substances), which could change both the health effects and the price of the product. Therefore, it is important that in addition to using consistent definitions for research purposes, as recommended by the committee, a series of product design criteria (e.g., length, weight, circumference, tobacco weight, tobacco type, flavors, filters) also be identified and reported consistently in all research studies so that as products evolve, they can still be characterized and compared. Lastly, these research definitions could be adapted for other purposes, such as regulation, but important factors that were not the focus of the committee's deliberations need to be taken into account, such as the response of industry and consumers to any regulatory definition.

### Strategic Planning and Data Collection

The 1998 NCI monograph identified significant gaps in data on cigar use and evaluation of cigars and made recommendations for improvement. Since that time, no coordinated federal surveillance and evaluation infrastructure has been established to support regular monitoring and tracking related to different cigar types. To conduct research on premium cigars and compare among cigar types, infrastructure to collect relevant data for cigars overall is needed.

Recommendation 2: The Department of Health and Human Services, in partnership with the Alcohol and Tobacco Tax and Trade Bureau and the Federal Trade Commission (FTC), should implement a strategic plan to develop surveillance and evaluation systems that regularly monitor patterns of use, product characteristics, and related knowledge and perceptions by cigar type. These systems should also measure exposure to cigar smoke; track health outcomes; monitor tobacco industry marketing and promotion strategies; track sales and marketing expenditures; track cigar prices by cigar type; make data available; and define other indicators of monitoring to inform public health research and practice. These efforts should include but are not limited to

- a. Agreed-upon definitions of each cigar type (see Recommendation 1), and
- b. Development of annual FTC sales and marketing expenditure reports on all cigar product types, as is done for cigarettes, smokeless tobacco, and electronic cigarettes.

Including all cigar types in this strategic plan will allow for comparisons in these areas over time—what the marketplace looks like today could change in the future. This recommendation will likely require fund-

ing from Congress; however, a similar structure is already in place for cigarettes and smokeless tobacco.<sup>4</sup> Parts of this recommendation can be implemented in the short term—for example, item b, which calls for annual FTC sales and marketing expenditure reports. Industry could be an important source for these data. This information will allow FDA to better assess how changes in polices (e.g., taxation) and regulation of premium cigars and other tobacco products could change use patterns.

This monitoring and tracking related to different cigar types would fill important information gaps on cigar use. Study participants have been classified based on relatively recent use (e.g., past 30 days) of each type of cigar, which may underestimate the total number of users, particularly for products not used daily or frequently, as is the case for premium cigars. Moreover, researchers, and the committee, relied on self-reported preferred brand data to classify large cigar users as premium or nonpremium, which may also underestimate the total users. Collecting data on the environments where premium cigars are smoked (e.g., homes, cigar lounges, outdoors), including by whom and smoking duration, will allow researchers to determine the real-life exposures to secondhand smoke, an area with a paucity of data. Given the potential seasonal and geographic variation in premium cigar use, including paradata (administrative data about the survey) could facilitate a better understanding of such potential variations and their implications for interpreting prevalence estimates.

Recommendation 3: The Department of Health and Human Services should ensure that the tobacco research it supports, including surveys such as the Population Assessment of Tobacco and Health Study, the Tobacco Use Supplement to the Current Population Survey, and the National Survey on Drug Use and Health:

- a. Measures ever use, ever regular use, and past 12-month use to better capture lifetime use of each type of cigar product.
- b. Asks participants about use of premium cigars, employing commonly used terminology (e.g., "Have you ever smoked premium cigars?") in addition to asking about brands used.
- c. Asks participants about self-reported inhalation patterns, how cigars are typically smoked (e.g., in one session or partial/relighting), and where cigars are smoked (e.g., indoors at home) to assess secondhand smoke exposure.
- d. Includes paradata (administrative data about the survey), such as survey date and geographic location in publicly available datasets to improve understanding of patterns of use and/or exposure.

<sup>&</sup>lt;sup>4</sup> See, for example, https://www.ftc.gov/reports/federal-trade-commission-cigarette-report-2020-smokeless-tobacco-report-2020 (accessed November 10, 2021).

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### **Health Effects**

Most studies on health effects do not distinguish premium from nonpremium cigars (they may include premium cigars, other large cigars, little cigars, or cigarillos). Studies that distinguish premium from nonpremium cigar use would better isolate the health effects of premium cigar smoking. Since co-use of premium cigars is more likely for alcohol than any other substance (for example, co-use of cannabis was low; see Chapter 3 for detailed analysis) and co-use of alcohol with tobacco products is directly related to cancer risk, data on alcohol use should be routinely collected.

Recommendation 4: The Food and Drug Administration (FDA), the National Institutes of Health, and other federal agencies should ensure that the research they support on the associations between cigar, including premium cigar, use and health effects

- a. Reports the frequency of use, duration, intensity, cumulative exposure, pattern of inhalation, and the number of years smoking cigars to inform potential dose-response relationship and modifying factors (e.g., co-use of alcohol, cannabis, and other substances);
- b. Distinguishes primary, secondary, and dual use cigar smokers;
- c. Examines co-use of alcohol and premium cigars;
- d. Estimate the associations between cigar use and specific lung cancer histological types;
- e. Includes questions on the type of cigar, including premium cigars, separated from large cigars and other cigar types; and
- f. Uses the definitions of cigar types provided by FDA (see Recommendation 1).

### ADDITIONAL PRIORITY RECOMMENDATIONS

### **Product Characteristics**

Methods are available to analyze harmful and potentially harmful constituents in premium cigar tobacco, but developing standardized conditions for quantifying the components of premium cigar smoke and executing studies on these components is a research priority.

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Recommendation 5: To improve knowledge of premium cigar characteristics, the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and other federal agencies should support

- a. The development of reproducible methods for machine smoking of premium cigars;
- b. Laboratory studies to measure nicotine, toxicants, and carcinogens in tobacco and smoke emitted from premium cigars;
- c. Studies to assess how the pH of premium cigar smoke affects puff topography and extent of inhalation;
- d. Comparative biomarker studies, both of toxicant exposure and of potential harm, in smokers of premium, large, and other cigar type smokers;
- e. Studies that precisely measure "real-life" puff topography and patterns of use;
- f. Studies that systematically evaluate how various premium cigar characteristics (e.g., size, shape, type of tobacco, added flavoring, sugar content, moisture, smoke pH) affect puffing topography; and
- g. Observational studies to assess patterns and intensity of secondhand smoke exposure to premium cigar smoke.

In studies of the impact of cigar pH, measurements should include nicotine absorption in premium cigar users. When studying premium cigar characteristics and users over time, the studies should examine use patterns, puffing topography, inhalation, relighting, and transitions. Studies of secondhand smoke exposure should include nonsmokers who may be regularly exposed to secondhand smoke from premium cigars (for example, employees at cigar lounges).

### Marketing and Perceptions

As noted in NCI Monograph 19, promotional activities for any tobacco product can normalize its use and increase its consumption, especially among new users (such as youth, young adults, and women) (NCI, 2008). Given the lack of research in this area for premium cigars, the committee recommends:

Recommendation 6: The Food and Drug Administration (FDA), the National Institutes of Health (NIH), and other federal agencies should conduct or fund research to determine the unique type of marketing, advertising, and promotional practices used by compa-

### PRIORITY RESEARCH NEEDS

nies that manufacture, distribute, and sell premium cigars. FDA, NIH, and other federal agencies should also identify strategies for tracking these activities, especially those that may appeal to youth.

This research should include studies to examine:

- a. The various environmental (e.g., print and online media and platforms, social events, bars, lounges, etc.) and interpersonal channels (e.g., industry representatives, peers, online users, etc.) used to promote premium cigars;
- b. Premium cigar message effects, their framing, formatting, construction, and reach to better understand how they interact with audience characteristics (e.g., age, gender, race/ethnicity, socioeconomic background) to influence behavior;
- c. Advertising and audience segmentation practices that aim to recruit new users (including smokers who do not use premium cigars) versus advertising practices that target existing premium cigar users;
- d. If manufacturers are selling premium and large cigars in the same market, whether they are differentially marketed, and, if so, how; and
- e. Consumer cognitions, perceptions, and beliefs about advertising content, and how this content influences their motivation to use premium cigars and potentially other tobacco products.

### **Addiction Potential**

Little is known about the addiction and addiction potential of premium cigars and how they compare to other cigar types. Premium cigars have nicotine levels similar to (or higher than) other cigars and conventional cigarettes. Premium and nonflavored cigars may also have similar sensorimotor characteristics that contribute to addiction potential (see Chapter 5). For these reasons, the conceptual and biological plausibility that premium cigars can be addiction promoting cannot be ruled out, given a sufficient level of exposure. However, more research is needed.

Recommendation 7: The Food and Drug Administration (FDA), the National Institutes of Health, and other federal agencies should support research that

- a. Provides data on the level of dependence in relation to patterns of premium and other cigar type use;
- b. Measures dependence on cigars and other tobacco products in dual and/or poly-tobacco users;

- c. Compares dependence on large cigars with flavors to dependence on premium cigars (which, by definition in this report, do not include flavors); and
- d. Studies the impact on dependence of reduced nicotine content in cigars, per proposed FDA policy to reduce nicotine to 0.4 mg/g for all cigarettes, to make them minimally addictive.

Regarding item d, FDA has issued an advance notice of proposed rule making that would require tobacco companies to lower the nicotine content in all cigarettes sold in the United States to levels at which they are no longer addictive (FDA, 2018). If this regulation progresses and cigars are excluded or other cigar types are included but premium cigars are not, premium cigars would provide an alternative source of nicotine for cigarette and cigar users, most likely resulting in significant changes in use patterns and undermining the aim of reducing the addictiveness of combusted tobacco products.

### **Priority Populations**

The literature about the health effects of large and premium cigars on specific populations has significant gaps; however, additional research is a high priority in certain areas.

Recommendation 8: The Food and Drug Administration, the National Institutes of Health, and other federal agencies should support research on the comparative health effects of cigar types, including premium cigars, in priority populations (as needed based on prevalence and trends), including

- a. Women, racialized and ethnic populations, sexual and gender minority groups, adolescents/young adults, and during pregnancy, including studies on the impact on nondaily users of cigars;
- b. People with vascular disease, including assessments of their cardiovascular risk, as this population would be especially vulnerable to the adverse effects of acute short-term smoke exposure;
- c. People with respiratory diseases, such as chronic obstructive pulmonary disease and asthma;
- d. Cancer survivors; and
- e. People with occupational exposures to premium cigars (e.g., in cigar lounges, manufacturing).

#### PRIORITY RESEARCH NEEDS

While it will be challenging to implement this recommendation, especially the first item (due to finding appropriate sample sizes), that does not obviate the need to obtain the best data possible for these populations over time.

### **Consumer Perceptions and Knowledge**

As discussed in Chapter 4, no research examines whether consumers distinguish premium cigars from large cigars or other cigar types, their knowledge of what premium cigars are, what defines them, or their knowledge of specific health effects.

Recommendation 9: The Food and Drug Administration, the National Institutes of Health, and other federal agencies should support research to assess consumer knowledge and awareness of premium cigars in the U.S. population. Specifically, these studies should

- a. Develop and implement specific measures that capture awareness of premium cigars as a tobacco product category, perceived risks and benefits of using premium cigars, and knowledge of the risks of premium cigar use; and
- b. Gather data regarding consumer knowledge about different cigar types and how, why, and where people start, continue, and discontinue using premium cigars (including perceived benefits and harms).

### CONCLUDING COMMENTS

The committee reviewed four premium cigar topics in this report: product characteristics, patterns of use, marketing and perceptions, and health effects. While research on premium cigars specifically is largely lacking, the committee drew conclusions in many areas based on studies on other cigar types, biological plausibility, and the absence of important threats to validity. The committee identified nine research priorities directed to federal agencies to expand the evidence for on premium cigars and cigars in general. If implemented, these recommendations will result in better understanding premium cigar use (and cigar use overall), marketing practices and consumer perceptions, and health effects over time to inform evidence-based policies, programs, and regulations.

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# Appendix A

# **Research Questions**

The Center for Tobacco Products of the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) (the report sponsors) submitted draft research questions to guide the literature review for this report. The committee statement of task (see Chapter 1) states that the draft research questions are subject to further input from stakeholders. To gather this input, the draft questions were posted to the committee website and public comments were accepted through May 6, 2021.<sup>1</sup> The preliminary list of questions from FDA and NIH is available on the project website.<sup>2</sup> The committee also held a public comment session for individuals and organizations to provide verbal feedback and asked for input from relevant organizations during one of its information-gathering meetings.<sup>3</sup> Based on this feedback, the committee updated the research questions and used those questions to guide its review of the literature. The final list of questions is below, organized by topic. While none of the preliminary questions were removed, some were combined or expanded. Notably, many of the comments submitted by stakeholders suggested questions regarding marketing and user perceptions of premium cigars. Given the connection between marketing and user perceptions (see Chapter 1 and

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<sup>&</sup>lt;sup>1</sup> All written comments submitted to the committee are available in the project public access file and from PARO@nas.edu.

<sup>&</sup>lt;sup>2</sup> See https://www.nationalacademies.org/event/04-20-2021/docs/DE4A7B81359B6E0C 08B06CACEE9033DF81528523E951 (accessed November 11, 2021).

<sup>&</sup>lt;sup>3</sup>See https://www.nationalacademies.org/event/04-20-2021/health-effects-and-patterns-of-use-of-premium-cigars-meeting-2-part-2.

Figure 1-1), the committee added several questions in this category. The committee also added to the questions on product characteristics, patterns of use, and health effects based on the input received. However, not all stakeholder suggestions were added—given the limited time for the committee's review, the committee focused on the suggestions that were most salient to its charge. As noted throughout this report, there is a paucity of data published on "premium"<sup>4</sup> cigars, which limited the committee's review for many of these questions.

### CIGAR PRODUCT CHARACTERISTICS

- 1. What is the impact of different manufacturing processes on cigars (e.g., selection and curing of leaves)?
- 2. Are the chemical constituents present in cigarette smoke similar to those that are found in premium cigars or other cigars?
- 3. How would the addition of flavors to premium cigars alter the smoke's harmful and potentially harmful constituent (HPHC) profile?
- 4. What is known about use characteristics among users of premium cigars in terms of depth of inhalation?
- 5. Due to the varying sizes of cigars, what is the most accurate way to measure exposure/emissions to HPHCs? And, what are best practices for HPHC testing in premium cigars?

### CIGAR PATTERNS OF USE

- 1. How does the cigar market break down into the various cigar types, by sales? How has the market changed in recent years? What are contributing factors to the changes?
- 2. What is the range of retail prices for premium cigars? What are the reported prices that people pay for premium cigars? How many cigars do people usually buy at a time?
- 3. What is known about the demographic and socioeconomic characteristics of users of premium cigars? What are the characteristics of users in terms of age, gender, race, ethnicity, educational attainment, and income?
- 4. What is known about use characteristics among users of premium cigars in terms of quantity of cigars used and frequency of use? How

<sup>&</sup>lt;sup>4</sup> Note that quotations are used at the first occurrence of the term "premium" in each section of the report, as there is no formally agreed upon definition of what constitutes a premium cigar, and different entities might use this term differently. See Chapter 1 for more information.

APPENDIX A

are these characteristics similar to or different from those of users of other cigar subtypes?

- 5. What is known about the use of premium cigars among different populations, such as youth, racial and ethnic minorities, individuals of low socioeconomic status, pregnant people, people with disabilities, lesbian, gay, bisexual, transgender and queer or questioning people, and people with mental illness?
- 6. How are the demographic and socioeconomic characteristics of users of premium cigars similar to or different from characteristics of users of other cigar types and other tobacco products?
- 7. What is known about co-use of premium cigars and other tobacco products? How do those who use premium cigars only (monoproduct) differ from users of premium cigars in conjunction with (dual use) other cigar subtypes and/or other tobacco products in terms of age, gender, race, ethnicity, educational attainment, income, frequency of use, and use of other addictive substances?
- 8. Regarding use of cigar products with other tobacco products, what are the impacts on of risk trajectories for youth and young adult tobacco users?
- 9. How and where do premium cigar users obtain these products? Does use vary by season?
- 10. Where do youth and young people obtain cigars (online mail-order sites, other retailers, or from other sources)?
- 11. What is known about premium cigar smokers who want to or have quit using premium cigars? Are they more or less likely to quit than users of other cigar types and other tobacco products? What methods do they use to quit?
- 12. How does current premium cigar use influence initiation or continued use of other tobacco products?
- 13. Do consumers use premium cigars as a cessation mechanism from other tobacco products?

### CIGAR MARKETING AND RISK PERCENTIONS

- 1. How do the perceived benefits and harms of premium cigars differ from those of other cigar subtypes or other tobacco products?
- 2. Are risk perceptions associated with different patterns of use (e.g., initiation of premium cigar use, greater use, dual use, or sustained use)?
- 3. How do perceptions of premium cigars vary by sociodemographic groups by sex, age, sexual orientation, race and ethnicity, geographic location, income level, and education level?

- 4. Is knowledge of the various constituents of premium cigars associated with different patterns of use (e.g., initiation of premium cigar use, greater use, dual use, or sustained use)?
- 5. Are there particular features of premium cigars, either with the product itself or in the way the products are packaged and/or marketed, that would be considered appealing or unappealing to youth?
- 6. What is the impact of coupons and price floors on premium cigar use? What types of discounts and price promotions are applied to premium cigars?
- 7. Is product marketing of premium cigars associated with different patterns of us (e.g., initiation of premium cigar use, greater use, dual use, or sustained use)?
- 8. What is the impact on use behaviors of celebrity endorsements? Is celebrity endorsement associated with different patterns of use (e.g., initiation of premium cigar use, greater use, dual use, or sustained use)?
- 9. What is the impact on use behaviors of social influencers? Do social media icons influence different patterns of use (e.g., initiation of premium cigar use, greater use, dual use, or sustained use)?

### HEALTH EFFECTS OF CIGARS

- 1. What are the acute and long-term health effects of premium cigar use in terms of circulatory, respiratory, oropharyngeal, cancer, and other health outcomes? How are these health effects similar to or different from health effects of other cigar subtypes and other combustible tobacco products?
- 2. What are the short- and long-term health effects (cancer and noncancer) of secondary and tertiary exposure to "premium" cigar smoke? How do these differ from the short- and long-term effects of secondary exposure to other subtypes of cigars and to other tobacco products? How do these differ by subgroups (e.g., youth vs. adults)?
- 3. How do the health effects of premium cigar use vary by the following factors? Inhalation; frequency and intensity of use; unique features of premium cigars (such as the construction process); amount of smoke inhaled; population subgroups and/or demographic characteristics of those who use them; concurrent use of other tobacco products; pre-existing medical conditions; other factors.
- 4. What are the adverse health effects of exposure to harmful and potentially harmful constituents, including nicotine, tobacco-specific nitrosamines, volatile organic compounds, and polyaromatic hydrocarbons?

APPENDIX A

- 5. How much of the emissions of premium cigars become secondhand smoke? Is it the same as cigarettes?
- 6. Do the chemical constituents in premium pose similar hazards as cigarettes? Other cigar types?
- 7. Are there unique chemicals/toxicants that are delivered to nonusers who are exposed to premium cigar smoke versus smoke from other cigar subtypes?
- 8. Will a multi-product user be exposed to a different HPHC smoke profile or different health impacts compared to a solely premium cigar user?
- 9. How does the pharmacokinetics of nicotine in premium cigars compare to other cigar subtypes and to other tobacco products?
- 10. How does the addition of flavors alter the smoke's harmful and potentially harmful constituent profile? How does the addition of flavors affect the health effects of premium cigars?
- 11. Are the health effects of premium cigars different for dual users, past users of other products, etc.?
- 12. What is known about the characteristics of premium cigars that cause people to start using them and continue using them? How are those characteristics similar to or different from characteristics of other cigar subtypes and other tobacco products?
- 13. What is known about the abuse or addiction potential associated with premium cigars? Do premium cigars pose different addiction or abuse potential than other tobacco products, and, if so, what is the source of that differential risk? Are differences or similarities due to products themselves or how they are used, how people initiated, or other reasons?
- 14. What is known about the subjective effects of premium cigar users after prescribed and ad libitum smoking regimens (e.g., dependence, withdrawal, liking)? How do these results compare to other cigar subtypes and to other tobacco products?
- 15. What are best practices in quantifying the long-term health risks of premium cigar use and secondary exposure to premium cigar smoking?
- 16. Are there specific biomarkers and clinical end points that should be used to assess the health effects of premium cigar use? If so, what clinical end points should be used to assess the impact of premium cigar smoke on user health? How do biomarkers and clinical end points associated with premium cigar use compare to use of other cigar subtypes?

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# Appendix B

# **Overview of Literature Search**

The committee conducted a series of searches in five databases— PubMed, Scopus, PsycINFO (ProQuest), MEDLINE (Ovid), and Embase (Ovid)— between February 2021 and March 2021 to identify all literature on premium cigars. Additional focused searches were conducted for subject- or language-specific databases, including American Chemical Society, Agricola (Ovid), LILACS, and LexisNexis. Initial search results were then expanded in June to include any relevant articles published prior to the dates included in the initial search criteria and after the initial searches were undertaken. Additional searches were run in August 2021 focusing on the use of the term "premium" for other consumer goods in specific publications.

Some 2020 and 2021 studies may not have been captured due to lags and discrepancies in database indexing. Because the last comprehensive review cigars (including premium cigars) was published in 1997, the search date range was 1996–2021. The search was limited to the English and Spanish languages but did not limit country of origin. The research questions that the committee considered informed the terms used in the search strategy (see Appendix A).

Because "premium" has been neither clearly defined nor used systematically (see Chapter 1), searches considered cigars more generally. Reviews were identified for other combustible tobacco products for comparison to premium cigars. The committee's approach was informed by published guidelines for conducting systematic reviews and the approaches taken by prior National Academies committees (CRD., 2009; Higgins, 2021;

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IOM, 2011, 2012, 2016; NASEM, 2017, 2018; NRC, 2014; OHAT, 2019; Whiting et al., 2016). However, early in its work, the committee noted the very limited literature available on premium cigars specifically and the lack of an agreed-upon definition of "premium" and therefore a lack of consistency regarding which brands are considered premium in the literature. Moreover, many publications do not distinguish "premium" from other large cigars. In addition, the study types varied considerably (e.g., laboratory, epidemiologic and toxicologic studies, and surveys). The committee adjusted its approach and framework accordingly. The following section includes the committee's search strategy to identify literature on premium cigars.

Committee members reviewed and assessed each relevant study. First, the committee identified what questions the literature addressed and then assessed the extent to which each study was able to answer each one. The committee considered study design, study results, and other potential sources of conflict of interest or bias, including multiple elements to assess internal and external validity, including the study sample, sampling methods, basic demographic information (age, gender, and race/ethnicity), and setting. Analytical methods were also considered, such as statistical tests used and their appropriateness. The quality of execution (e.g., dropout rates) was assessed as well. Finally, the committee considered the study results (including adjusted and unadjusted results where available), including the outcomes assessed and how these outcomes were operationalized.

Potential bias in the studies based on sponsorship, particularly by industry, is often a concern in in the tobacco literature, given the industry's history of manipulating evidence to support its interests. However, a range of nonscientific influences affect how investigators design, conduct, analyze, and interpret their data, including research sponsorship and source of employment (NASEM, 2018). The evidence assessment in this report focused on the quality of the research and reported results but recognized that financial interests raise concerns to varying degrees with the credibility of the findings. For completeness, the committee documented the source of research sponsorship or other external involvement in a table available as an online supplement, noting whether each study was funded by industry, government, other (university, foundation), or not stated (the committee used the template used in NASEM, 2018). The committee also notes other industry involvement, such as if industry is a source of employment.

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### SEARCH SYNTAX

### General Keyword and Mesh Term Searches

Search Strategy for General Keyword and Database Index Terms for Cigars/ Premium Cigars in Human Populations

### PubMed

(Cigar Smoking[MeSH Terms]) OR ((Tobacco Products[MeSH Terms]) AND ((cigar[Title/Abstract]) OR (cigar[Text Word])) NOT ((cigarette[Title/Abstract]) OR (cigarette[Text Word]))) OR (("hand-made"[Text Word] OR "handmade"[Text Word] OR ("hand-rolled"[Text Word] OR "handrolled"[Text Word]) OR ("roll-your-own"[Text Word] OR "RYO"[Text Word] OR "RYO."[Text Word]) AND (("cigar"[Text Word]] OR "cigars"[Text Word]) OR ("cigars"[Title/Abstract]))) AND (("cigar"[Text Word] OR "cigars"[Text Word]] OR ("cigars"[Text Word]]) OR ("cigars"[Text Word]] OR ("cigars"[Text Word]]) OR ("cigars"[Text Word]] OR "cigars"[Title/Abstract]]))

Limit: Peer-Reviewed Journal Articles, Systematic Reviews

Limit: Human

Limit: 1996 – Present

### Results: 127

((Cigar Smoking[MeSH Terms]) AND (premium[Text Word])) OR ((Tobacco Products[MeSH Terms]) AND ("premium cigars"[Text Word])) OR (("premium cigar"[Title/Abstract]) OR ("premium cigar"[Text Word])) Limits: same

### Results: 6

### Scopus

((INDEXTERMS ( *cigar* ) OR INDEXTERMS ( *cigars* ) OR AUTHKEY ( *cigar* ) OR AUTHKEY ( *cigars* ) OR INDEXTERMS ( "*cigar smoking*" ) OR AUTHKEY ( "*cigar smoking*" ) ) OR ( INDEXTERMS ( "*tobacco products*" ) OR AUTHKEY ( "*tobacco products*" ) AND TITLE-ABS-KEY-AUTH ( "*cigar*" ) OR TITLE-ABS-KEY ( "*cigars*" ) ) AND ( TITLE-ABS-KEY ( "*hand-made*" ) OR TITLE-ABS-KEY ( "*hand-made*" ) OR TITLE-ABS-KEY ( "*hand-made*" ) OR TITLE-ABS-KEY ( "*tolayour own*" ) OR TITLE-ABS-KEY ( "*hand-rolled*" ) OR TITLE-ABS-KEY ( "*roll-your-own*" ) OR TITLE-ABS-KEY ( "*roll your own*" ) OR TITLE-ABS-KEY ( "*RYO*" ) OR TITLE-ABS-KEY ( "*RYO*" ) OR TITLE-ABS-KEY ( "*roll-your-own*" ) OR TITLE-ABS-KEY ( "*large*" ) OR TITLE-ABS-KEY ( "*roll-your-own*" ) OR TITLE-ABS-KEY ( "*large*" ) UR TITLE-ABS-KEY ( "*roll-your-own*" ) OR TITLE-ABS-KEY ( "*large*" ) OR TITLE-ABS-KEY ( "*roll-your-own*" ) OR TITLE-ABS-KEY ( "*large*" ) Limit: peer-reviewed journal articles, reviews

Limit: 1996 - present

Results: 105

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### Embase

1	exp cigar/ or exp cigar smoking/	419
2	limit 1 to (human and yr="1996 -Current" and (article o article in press or "review") and (journal or trade journal))	r 249
3	Exp tobacco/ AND ("premium cigar" or "hand-made" or "hand-rolled" or "roll-your-own" or "RYO" or "handmade" or "handrolled" or "hand rolled" or "hand rolled" or "hand	156 I
4	limit 3 to (human and yr="1996 -Current" and (article o article in press or "review") and (journal or trade journal))	r 107
5	(exp cigar smoking/ or exp cigar/) and ("premium cigar" or "hand-made" or "hand-rolled" or "roll-your- own" or "RYO" or "handmade" or "handrolled" or "hand rolled" or "hand made").mp.	16
6	limit 5 to (human and yr="1996 -Current" and (article o article in press or "review") and (journal or trade journal))	r 8
7	2 or 4 or 6	352
Limi Limi Limi	t: Humans t: 1996 – Current t: article, article in press, review t: journal, trade journal <b>llts: 352</b>	
MEE	DLINE	
1	Exp cigar smoking/	43
2	limit 1 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review") and "humans only (removes records about animals)")	41
3	exp tobacco products/ and ("cigar" or "cigars").mp.	472

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4	limit 3 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review"))	416
5	exp tobacco/ and ("cigar" or "cigars").mp.	192
6	limit 5 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review"))	77
7	2 or 4 or 6	473
8	("premium cigar" or "premium" or "large cigar" or "large" or "hand-made" or "hand-rolled" or "roll- your-own" or "RYO" or "handmade" or "handrolled" or "hand rolled" or "hand made").mp.	1,522,462
9	limit 8 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review"))	647,092
10	7 and 9	63
Limit: Humans Limit: 1996 – present Limit: clinical trials, journal articles, preprints, reviews, systematic reviews <b>Results: 473 (all cigars)</b> <b>Results: 63 (premium cigar and synonyms)</b>		
PsychINFO (su("cigar" OR "cigars") OR ti("cigar" OR "cigars") OR ft("cigar" OR "cigars") OR ab("cigar" OR "cigars")) OR (su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars") (su("cigar" OR "cigars") OR ti("cigar" OR "cigars") OR ft("cigar" OR "cigars") OR ab("cigar" OR "cigars")) AND ("premium" OR "large") Limit: Humans Limit: 1996 – present Limit: Journal articles		

Results: 208 (premium cigars and synonyms)

**Results: 690 (all cigars)** 

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## LILACS

tabaco [Descriptor de asunto] and cigarro OR puro [Palabras] tobacco [Subject descriptor] and cigar [Words] cigaro OR puro [Palabras] and grande OR prima [Palabras] Limits: None due to the lack of options in the LILACS interface **Results: 133** 

# Agricola

("cigar" or "cigars").ab. and ("cigar" or "cigars").ti. **Results: 8** 

Select Search Strategies for General Keyword and Database Index Terms for Premium Cigars in Human Populations with Earlier Date Limits ( > 1996)

### PubMed

((Tobacco Products[MeSH Terms]) AND ((cigar[Title/Abstract]) OR (cigar[Text Word])) NOT (cigarette[Title/Abstract])) OR ((("handrolled"[Text Word] OR "handrolled"[Text Word] OR "roll-your-own"[Text Word] OR "RYO"[Text Word] OR "premium"[Text Word] OR "large"[Text Word]) NOT ("cigarette"[Title/Abstract] OR "cigarettes"[Title/Abstract]) AND ("cigar"[Title/Abstract] OR "cigars"[Title/Abstract]))) Limit: Peer-Reviewed Journal Articles, Systematic Reviews Limit: Human

Limit: > 1996 **Results: 6** 

### Scopus

( ALL ( "premium cigar" OR "premium cigars" OR "large cigar" OR "large cigars")) OR ((INDEXTERMS (cigar) OR INDEXTERMS (cigars ) OR ( ( AUTHKEY ( cigar ) OR AUTHKEY ( cigars ) ) AND ( TITLE-ABS-KEY (large) OR TITLE-ABS-KEY (premium))))) OR (((INDEX-TERMS ( "cigar smoking" ) OR AUTHKEY ( "cigar smoking" ) AND ( TITLE-ABS-KEY (large) OR TITLE-ABS-KEY (premium))))) OR ( INDEXTERMS ("tobacco products") OR AUTHKEY ("tobacco products") AND (TITLE-ABS-KEY (cigar) AND (TITLE-ABS-KEY (large) OR TITLE-ABS-KEY ( premium ) ) ) ) OR ( ( INDEXTERMS ( cigar ) OR INDEXTERMS ( cigars ) OR AUTHKEY ( cigar ) OR AUTHKEY ( cigars ) OR INDEXTERMS ( "cigar smoking" ) OR AUTHKEY ( "cigar smoking" )) OR ( INDEXTERMS ( "tobacco products" ) OR AUTHKEY ( "tobacco products") AND TITLE-ABS-KEY-AUTH ("cigar") OR TITLE-ABS-KEY ("cigars")) AND (TITLE-ABS-KEY ("handmade") OR TITLE-ABS-KEY ( "hand-made" ) OR TITLE-ABS-KEY ( "handrolled" ) OR TITLE-ABS-KEY ( "hand-rolled" ) OR TITLE-ABS-KEY ( "roll your own" ) OR

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TITLE-ABS-KEY ( "roll-your-own" ) OR TITLE-ABS-KEY ( "RYO" ) OR TITLE-ABS-KEY ( "R.Y.O." ) OR TITLE-ABS-KEY ( "large" ) OR TITLE-ABS-KEY ( "premium" ) ) )Limit: >1996 Limit: Article, Review Limit: > 1996 **Results: 86** 

### Embase

1	exp cigar/ or exp cigar smoking/	447
2	limit 1 to (human and yr="1883 - 1995" and (article or "review") and (journal or trade journal))	13
3	exp tobacco/	many
4	((("cigar" or "cigars").ab. or ("cigar" or "cigars").ti.) and (premium or large or "hand-made" or handmade or "hand-rolled" or handrolled or "hand rolled" or "roll- your-own" or "roll your own" or RYO or "R Y O ").ab.) or (premium or large or "hand-made" or handmade or "hand-rolled" or handrolled or "hand rolled" or "roll- your-own" or "roll your own" or RYO or "R Y O ").ti.	
5	3 and 4	278
6	limit 5 to (human and yr="1883 - 1995" and (article or "review") and journal)	7
Lim Lim Lim	it: Human it: < 1996 it: Article, Review it: Journal or Trade Journal u <b>lts: 20</b>	
ME	DLINE	
1	exp cigar smoking/	44
2	exp tobacco products/	8,378

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3 ((("cigar" or "cigars").ab. or ("cigar" or "cigars").ti.) and (premium or large or "hand-made" or handmade or "hand-rolled" or handrolled or "hand rolled" or "rollyour-own" or "roll your own" or RYO or "R Y O ").ab.) or (premium or large or "hand-made" or handmade or "hand-rolled" or handrolled or "hand rolled" or "rollyour-own" or "roll your own" or RYO or "R Y O ").ti.

4	2 and 3	119
5	exp tobacco/	31,786
6	3 and 5	150
7	limit 6 to (humans and yr="1860 - 1995" and (clinical trial,	10

7 limit 6 to (humans and yr="1860 - 1995" and (clinical trial, 10 all or journal article or randomized controlled trial or "systematic review"))

Limit: Humans Limit: > 1996 Limit: Clinical Trial, Journal Article, RCT, Systematic Review **Results: 10** 

*Updated Search Strategies for General Keyword and Database Index Terms for Premium Cigars in Human Populations Run in August 2021* 

## PubMed

(Cigar Smoking[MeSH Terms]) AND (premium[Text Word]) OR (Tobacco Products[MeSH Terms]) AND (Tobacco Products[MeSH Terms]) AND (("cigars"[Title/Abstract])) NOT ((cigarette\*[Title/Abstract]) OR (Tobacco Products[MeSH Terms]) AND ("premium cigar"[Title/Abstract]) OR ("premium cigars" [Title/Abstract]) OR (("hand-made" [Text Word] OR "handmade" [Text Word]) AND (("cigar" [Text Word] OR "cigars" [Text Word]) OR ("cigar"[Title/Abstract] OR "cigars"[Title/Abstract]))) OR (("hand-rolled" [Text Word] OR "handrolled" [Text Word]) AND (("cigar"[Text Word] OR "cigars"[Text Word]) OR ("cigar"[Title/Abstract] OR "cigars"[Title/Abstract]))) OR (("roll-your-own"[Text Word] OR "RYO" [Text Word] OR "R.Y.O." [Text Word]) AND (("cigar" [Text Word]) OR "cigars" [Text Word]) OR ("cigar" [Title/Abstract] OR "cigars" [Title/ Abstract]))) Limit: Humans Limit: March – August 2021 Limit: Journal Articles, Systematic reviews

Results: 1

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## Scopus

((INDEXTERMS ( cigar ) OR INDEXTERMS ( cigars ) OR AUTHKEY ( cigar ) OR AUTHKEY ( cigars ) OR INDEXTERMS ( "cigar smoking" ) OR AUTHKEY ( "cigar smoking" ) ) OR ( INDEXTERMS ( "tobacco products" ) OR AUTHKEY ( "tobacco products" ) AND TITLE-ABS-KEY-AUTH ( "cigar" ) OR TITLE-ABS-KEY ( "cigars" ) ) Limit: 2021 Limit: Articles, Reviews **Results: 31** 

## Embase

1 exp cigar/ or exp cigar smoking/ or (exp tobacco/ and 575 ("premium cigar" or "hand-made" or "hand-rolled" or "roll-your-own" or "RYO" or "handmade" or "handrolled" or "hand rolled" or "hand made").mp.)

2 Limit 1 to (human and yr="2021-Current") 53

Limit: Human Limit: 2021 **Results: 53** 

## MEDLINE

- 1 exp cigar smoking/ or (exp tobacco products/ and ("cigar" 658 or "cigars").mp.) or (exp tobacco/ and ("cigar" or "cigars"). mp.)
- 2 Limit 1 to (human and yr="2021-Current" and journal 14 article)

Limit: Human Limit: 2021 Limit: Journal article **Results: 14** 

# PsychINFO

su("cigar" OR "cigars") OR ti("cigar" OR "cigars") OR ft("cigar" OR "cigars") OR ab("cigar" OR "cigars") Limit: Humans Limit: April 2021 – present Limit: Journal Articles **Results: 5** 

Search Strategies on the Health Effects of Premium Cigars

## PubMed

(Tobacco Smoke Pollution[MeSH Terms] AND (("cigar"[Text Word] OR "cigars" [Text Word]) OR ("cigar" [Title/Abstract] OR "cigars" [Title/ Abstract]))) OR (("second-hand"[Text Word] OR "secondhand"[Text Word] OR "second-hand"[Title/Abstract] OR "secondhand"[Title/ Abstract]) OR (alcohol[Title/Abstract] OR alcohol[Text Word]) OR (nicotin\*[Title/Abstract] OR nicotin\*[Text Word]) OR (Polycyclic Aromatic Hydrocarbons[MeSH Terms]) OR (neoplasms[MeSH Terms] OR (cancer[Text Word] OR cancer[Title/Abstract])) OR (Nitrosamines[MeSH Terms]) OR (Volatile Organic Compounds[MeSH Terms]) OR (cutaneous[Title/Abstract] OR cutaneous[Text Word]) OR (derm\*[Title/ Abstract] OR derm\*[Text Word]) OR (Oropharyng\*[Title/Abstract] OR Oropharyng\*[Text Word]) OR (circulator\*[Title/Abstract] OR circulator\*[Text Word]) OR (respirator\*[Title/Abstract] OR respirator\*[Text Word]) OR (cardiov\*[Title/Abstract] OR cardiov\*[Text Word]) AND (("cigar"[Text Word] OR "cigars"[Text Word])) OR ("cigar"[Title/Abstract] OR "cigars" [Title/Abstract])) OR (("cigar" [Text Word] OR "cigars" [Text Word]) AND inhal\*[Text Word]) Limit: Humans Limit 1996 – present

Limit: Journal Article, Systematic Review

Results: 1,050

*Updated June* 2021 – 2 *additional results* 

## Scopus

( ( INDEXTERMS ( *cigar* ) OR INDEXTERMS ( *cigars* ) OR AUTHKEY ( cigar ) OR AUTHKEY ( cigars ) OR INDEXTERMS ( "cigar smoking" ) OR AUTHKEY ( "cigar smoking" ) ) OR ( INDEXTERMS ( "tobacco products" ) OR AUTHKEY ( "tobacco products" ) AND TITLE-ABS-KEY-AUTH ( "cigar" ) OR TITLE-ABS-KEY ( "cigars" ) ) AND ( INDEXTERMS ( addiction) OR INDEXTERMS (alcohol) OR INDEXTERMS (alcohol AND abuse ) OR INDEXTERMS ( alcohol AND consumption ) OR INDEXTERMS ( alcohol AND drinking) OR INDEXTERMS (alcohol AND intoxication) OR INDEXTERMS (alcoholic AND intoxication) OR INDEXTERMS (alcoholism ) OR INDEXTERMS ( cancer ) OR INDEXTERMS ( carcinogen ) OR INDEX-TERMS (cardiovascular AND system) OR INDEXTERMS (circulatory AND systems) OR INDEXTERMS (drinking AND behavior) OR INDEXTERMS ( drug AND abuse ) OR INDEXTERMS ( drug AND dependence ) OR INDEX-TERMS (drug AND use) OR INDEXTERMS (environmental AND exposure ) OR INDEXTERMS ( environmental AND tobacco AND smoke ) OR INDEX-TERMS (environmental AND tobacco AND smokes) OR INDEXTERMS (

inhalation ) OR INDEXTERMS ( inhalation AND exposure ) OR INDEX-TERMS (*intoxication*) OR INDEXTERMS (*neoplasm*) OR INDEXTERMS (neoplasms) OR INDEXTERMS (nicotiana AND tabacum) OR INDEX-TERMS ( nicotine ) OR INDEXTERMS ( nitrosamine ) OR INDEXTERMS ( respiratory AND distress ) OR INDEXTERMS (respiratory AND system) OR INDEXTERMS ( polycyclic AND aromatic AND hydrocarbon ) OR INDEX-TERMS (secondhand AND smoke) OR INDEXTERMS (secondhand AND smoke AND exposure ) OR INDEXTERMS ( smoke ) OR INDEXTERMS ( substance AND abuse ) OR INDEXTERMS (substance-related AND disorders ) OR INDEXTERMS ( substance AND use ) OR INDEXTERMS ( tobacco AND dependence ) OR INDEXTERMS (tobacco AND smoke) OR INDEX-TERMS ( tobacco AND smoke AND pollution ) OR INDEXTERMS ( tobacco AND use AND disorder ) OR INDEXTERMS (voc ) OR INDEXTERMS ( volatile AND organic AND compound ) OR INDEXTERMS (volatile AND *organic* AND *compounds* ) ) ) Limit: peer-reviewed journal articles, reviews

Limit: 1996 - present Results: 373

### Embase

7 2 or 4 or 6

- 8 exp addiction/ or exp "drug dependence"/ or exp 7,452,763 carcinogen/ or exp "cardiovascular system"/ or exp inhalation/ or exp "Malignant neoplasm"/ or exp Nicotine/ or exp "Malignant neoplasm"/ or exp Nicotine/ or exp "Nitrosamine/ or exp "passive smoking"/ or exp "Polycyclic Aromatic Hydrocarbon"/ or exp "respiratory system"/ or exp "respiratory tract disease"/ or exp smoke/ or exp "tobacco dependence"/ or exp "tobacco smoke"/ or exp "toxic inhalation"/ or exp "Volatile Organic Compound"/
- 9 limit 8 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))

10 7 and 9

Limit: Human Limit: < 1996 Limit: Article, Review Limit: Journal or Trade Journal **Results: 121** 

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352

121

# MEDLINE

7	2 or 4 or 6	473
11	exp "behavior, addictive"/ or exp carcinogens/ or exp "Cardiovascular System"/ or exp "Drinking Be- havior"/ or exp "Environmental Exposure"/ or exp Inhalation/ or exp "Inhalation Exposure"/ or exp neoplasms/ or exp nicotine/ or exp Nitrosamines/ or exp "Polycyclic Aromatic Hydrocarbons"/ or exp "Substance-Related Disorders"/ or exp "Tobacco Smoke Pollution"/ or exp "Volatile Organic Com- pounds"/	5,632,761
12	limit 11 to (humans and yr="1996 -Current" and (clinical trial, all or journal article or preprint or "review" or "systematic review"))	2,751,131
13	7 and 12	165
Limit: H	Humans	

Limit: 1996 – present

Limit: clinical trials, journal articles, preprints, reviews, systematic reviews **Results: 165** 

# PsychINFO

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND su("Substance Use Disorder" OR Neoplasms OR Carcinogens OR "cardiovascular system" OR "Mental disorders" OR "Mental health" OR "passive smoking" OR "respiratory system" OR "drug usage") OR (Nitrosamine\* OR "Polycyclic Aromatic Hydrocarbons") Limit: Humans Limit: 1996 – present Limit: Journal articles

Results: 264

# American Chemical Society

(nicotin\* OR nitrosamin\* OR "polycyclic aromatic hydrocarbon") AND ("cigar" OR "cigars") Limit: 1996 – present Limit: journal article Results: 63 Updated Results from June 2021 – 5 additional references

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*Search Strategies on Vulnerable Population Groups Concerning Use of Premium Cigars* 

## PubMed

(("cigar"[Text Word] OR "cigars"[Text Word]) AND youth[Title/ Abstract]) OR ((minority groups[MeSH Terms]) OR ((socioeconomic factors[MeSH Terms]) OR (socioeconmic status[MeSH Terms])) OR (pregnancy[MeSH Terms]) OR (reproduction[MeSh Terms]) OR ((Disabled Persons[MeSH Terms] OR Neurodevelopmental Disorders[MeSH Terms] OR Musculoskeletal Abnormalities[MeSH Terms] OR Nervous System Diseases[MeSH Terms])) OR (Mental Disorders[MeSH Terms]) OR ((Homosexuality[MeSH Terms] OR Bisexuality[MeSH Terms] OR Sexual and Gender Minorities[MeSH Terms])) AND (("cigar"[Text Word] OR "cigars"[Text Word]) OR ("cigar"[Title/Abstract] OR "cigars"[Title/ Abstract]))) Limit: Humans

Limit 1996 – present

Limit: Journal Article, Systematic Review

Results: 471

**Updated Result from June 2021 – 1 additional reference** 

## Scopus

( ( INDEXTERMS ( cigar ) OR INDEXTERMS ( cigars ) OR AUTHKEY (cigar) OR AUTHKEY (cigars) OR INDEXTERMS ("cigar smoking") OR ( "cigar smoking" ) ) OR ( INDEXTERMS ( "tobacco products" ) OR AUTHKEY ( "tobacco products" ) AND TITLE-ABS-KEY-AUTH ( "cigar" ) OR TITLE-ABS-KEY ( "cigars" ) ) AND ( INDEXTERMS ( adolescent ) OR INDEXTERMS ( adolescents ) OR INDEXTERMS ( african AND american ) OR INDEXTERMS ( african AND americans ) OR INDEXTERMS ( child ) OR INDEXTERMS ( demographic AND factors ) OR INDEXTERMS ( disability) OR INDEXTERMS (disabled AND person) OR INDEXTERMS ( disabled AND persons ) OR INDEXTERMS (educational AND status) OR INDEXTERMS ( ethnic AND group ) OR INDEXTERMS ( ethnic AND difference) OR INDEXTERMS ( ethnic AND minority ) OR INDEXTERMS ( hispanic AND americans ) OR INDEXTERMS ( hispanic ) OR INDEX-TERMS ( homosexuality ) OR INDEXTERMS ( intellectual AND disability ) OR INDEXTERMS ( intellectual AND impairment ) OR INDEXTERMS (juvenile) OR INDEXTERMS (mental AND disease) OR INDEXTERMS (mental AND disorders) OR INDEXTERMS (mental AND health) OR INDEXTERMS (minority AND group) OR INDEXTERMS (minority AND groups ) OR INDEXTERMS ( physical AND disability ) OR INDEXTERMS (sexual AND gender AND minority) OR INDEXTERMS (sexual AND minority) OR INDEXTERMS (social AND status) OR INDEXTERMS (

socioeconomic AND factors ) OR INDEXTERMS ( socioeconomic AND status ) OR INDEXTERMS ( transgender ) OR INDEXTERMS ( young AND adult ) OR INDEXTERMS ( youth ) ) ) Limit: peer-reviewed journal articles, reviews Limit: 1996 - present Results: 663

## Embase

7	2 or 4 or 6	352	
11	exp bisexuality/ or exp demography/ or exp dis- ability/ or exp "disabled person"/ or exp "edu- cational status"/ or exp "ethnic group"/ or exp "ethnic or racial aspects""/ or exp homosexuality/ or exp "mental disease"/ or exp "mental health"/ or exp "minority group"/ or exp "sexual and gender minority"/ or exp "social status"/ or exp "socioeconomics"/ or exp transgender/	3,335,742	
12	limit 11 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	1,833,453	
13	7 and 12	158	
31	limit 11 to (embryo <first trimester=""> or child <un- specified age&gt; or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or adolescent &lt;13 to 17 years&gt;)</un- </first>	576,464	
32	7 and 31	57	
33	exp pregnancy/	625,984	
34	limit 33 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	249,962	
35	7 and 34	3	
Limit: Human Limit: < 1996 Limit: Article, Review			

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Limit: Journal or Trade Journal **Results: 218** 

## MEDLINE

7	2 or 4 or 6	473
14	exp Adolescent/ or exp child/ or exp "ethnic groups"/ or exp Bisexuality/ or exp homosexual- ity/ or exp demography/ or exp "disabled per- sons"/ or exp "Socioeconomic Factors"/ or exp "Ex-Smokers"/ or exp "Minority Groups"/ or exp minors/ or exp "Psychological Distance"/ or exp "Sexual and Gender Minorities"/ or exp Smokers/ or exp "Social Class"/ or exp "Vulnerable Popula- tions"/	4,616,504
15	limit 14 to (humans and yr="1996" and (clinical trial, all or journal article or preprint or "review" or "systematic review"))	2,828,786
16	7 and 15	340
34	limit 14 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)" or "adolescent (13 to 18 years)")	3,156,650
35	7 and 34	272
Limit: H	Humans	

Limit: Humans Limit: 1996 – present Limit: clinical trials, journal articles, preprints, reviews, systematic reviews **Results: 612** 

## PsychINFO

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND su("racial and ethnic groups" OR "sexual minority groups" OR child OR demography OR "demographic characteristics" OR "disabled personnel" OR "minority groups" OR "racial and ethnic differences" OR "social status" OR "socioeconomic factors" OR "socioeconomic status") Limit: Humans Limit: 1996 – present

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Limit: Journal articles **Results: 104** 

Search Strategies on Behavioral Characteristics Regarding the Use of Premium Cigars

# PubMed

((addict\*[Text Word] OR addict\*[Title/Abstract] OR (abus\*[Text Word] OR abus\*[Title/Abstract]) OR (Tobacco Use Disorder[MeSH Terms]) OR (Smoking Cessation[MeSH Terms]) OR (Tobacco Use Cessation[MeSH Terms]) OR ("plasma nicotine"[Title/Abstract] AND "plasma nicotine"[Text Word]) OR ("ad libitum"[Title/Abstract] AND "ad libitum"[Text Word])) AND (("cigar"[Text Word] OR "cigars"[Text Word]) OR ("cigar"[Title/Abstract] OR "cigars"[Title/Abstract]])) Limit: Humans Limit 1996 – present Limit: Journal Article, Systematic Review **Results: 304** 

## Scopus

((INDEXTERMS ( cigar ) OR INDEXTERMS ( cigars ) OR AUTHKEY ( cigar ) OR AUTHKEY ( cigars ) OR INDEXTERMS ( "cigar smoking" ) OR ( "cigar smoking" ) ) OR ( INDEXTERMS ( "tobacco products" ) OR AUTHKEY ( "tobacco products" ) AND TITLE-ABS-KEY-AUTH ( "cigar" ) OR TITLE-ABS-KEY ( "cigars" ) ) AND ( INDEXTERMS ( addiction ) OR INDEXTERMS ( alcohol ) OR INDEXTERMS ( alcohol AND abuse ) OR INDEXTERMS ( alcohol ) OR INDEXTERMS ( alcohol AND abuse ) OR INDEXTERMS ( alcohol AND consumption ) OR INDEXTERMS ( alcohol AND drinking ) OR INDEXTERMS ( alcohol AND intoxication ) OR INDEX-TERMS ( alcoholic AND intoxication ) OR INDEXTERMS ( alcoholism ) OR INDEXTERMS ( drinking AND behavior ) OR INDEXTERMS ( drug AND abuse ) OR INDEXTERMS ( drug AND dependence ) OR INDEXTERMS ( drug AND use ) OR INDEXTERMS ( intoxication ) OR INDEXTERMS ( smoking AND cessation ) OR INDEXTERMS ( substance AND abuse ) OR INDEXTERMS ( substance-related AND disorders ) OR INDEXTERMS ( substance AND use ) ) )

Limit: peer-reviewed journal articles, reviews Limit: 1996 - present

Results: 547

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APPENDIX B			
Embas	e		
7	2 or 4 or 6	352	
14	exp addiction/ or exp "drug dependence"/ or exp "smoking cessation"/ or exp "substance abuse"/ or exp "substance use"/ or exp "tobacco depen- dence"/	802,188	
15	limit 14 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	427,004	:
16	7 and 15	305	
Limit: Limit: Limit: Result	Article, Review Journal or Trade Journal s: 305		
MEDL		470	
7	2 or 4 or 6	473	
17	exp "Tobacco Use Disorder"/ or exp "Tobacco Use Cessation"/ or exp "Tobacco Smoking"/ or exp "Smoking Reduction"/ or exp "Smoking Cessa- tion"/ or exp smokers/ or exp "ex-smokers"/ or exp "drinking behavior"/	117,511	
18	limit 17 to (humans and yr="1996 -Current" and (clinical trial, all or journal article or preprint or "review" or "systematic review"))	80,122	
19	7 and 18	200	
Limit: Humans Limit: 1996 – present Limit: clinical trials, journal articles, preprints, reviews, systematic reviews <b>Results: 200</b>			

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# PsychINFO

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND su("substance use disorder" OR "smoking cessation") Limit: Humans Limit: 1996 – present Limit: Journal articles **Results: 117** 

Search Strategies on Dual-Use of Premium Cigars and Cannabis Products PubMed

((blunt\*[Title/Abstract] OR blunt\*[Text Word] OR (hypin\*[Title/Abstract] OR hypin\*[Text Word]) OR (freakin\*[Title/Abstract] OR freakin\*[Text Word]) OR (champin\*[Title/Abstract] OR champin\*[Text Word])) AND (("cigar"[Text Word] OR "cigars"[Text Word]) OR ("cigar"[Title/Abstract] OR "cigars"[Title/Abstract]))) Limit: Humans

Limit 1996 – present Limit: Journal Article, Systematic Review **Results: 62** 

## Scopus

((INDEXTERMS ( *cigar* ) OR INDEXTERMS ( *cigars* ) OR AUTHKEY ( *cigar* ) OR AUTHKEY ( *cigars* ) OR INDEXTERMS ( "*cigar smoking*" ) OR ( "*cigar smoking*" ) ) OR ( INDEXTERMS ( "*tobacco products*" ) OR AUTH-KEY ( "*tobacco products*" ) AND TITLE-ABS-KEY-AUTH ( "*cigar*" ) OR TITLE-ABS-KEY ( "*cigars*" ) ) AND ( TITLE-ABS-KEY ( *blunt*\* ) OR TITLE-ABS-KEY ( *hypin*\* ) OR TITLE-ABS-KEY ( *freakin*\* ) OR TITLE-ABS-KEY ( *champin*\* ) ) ) Limit: peer-reviewed journal articles, reviews Limit: 1996 - present

Results: 57

# Embase

7	2 or 4 or 6	352
23	exp cannabis/	34,339
24	limit 23 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	17,509
25	blunt.mp.	48,552

APPEND	IX B	33
26	limit 25 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	25,652
27	(freakin* or hypin* or champin*).mp.	74
28	limit 27 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	21
29	24 or 26 or 28	43,126
30	7 and 29	38
	: 1996 Article, Review ournal or Trade Journal	
MEDLI	INE	
7	2 or 4 or 6	473
26	exp cannabis/	9,654
27	limit 26 to (humans and yr="1996 -Current" and (clin- ical trial, all or journal article or preprint or "review" or "systematic review"))	- 3,416
28	blunt.mp.	33,447
29	limit 28 to (humans and yr="1996 -Current" and (clin- ical trial, all or journal article or preprint or "review" or "systematic review"))	- 17,770
30	(freakin* or hypin* or champin*).mp.	69
31	limit 30 to (humans and yr="1996 -Current" and (clin- ical trial, all or journal article or preprint or "review" or "systematic review"))	- 22

350 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS
32 27 or 29 or 31 21,196
33 7 or 32 34
Limit: Humans
Limit: 1996 – present
Limit: clinical trials, journal articles, preprints, reviews, systematic reviews
Results:

## PsychINFO

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND su(Cannabis) OR (freakin\* OR hypin\* OR champin\*) Limit: Humans Limit: 1996 – present Limit: Journal articles **Results: 130** 

Search Strategies on Premium Cigars in the Context of the Tobacco Industry

### Scopus

((INDEXTERMS ( *cigar* ) OR INDEXTERMS ( *cigars* ) OR AUTHKEY ( *cigar* ) OR AUTHKEY ( *cigars* ) OR INDEXTERMS ( "*cigar smoking*" ) OR ( "*cigar smoking*" ) ) OR ( INDEXTERMS ( "*tobacco products*" ) OR AUTHKEY ( "*tobacco products*" ) AND TITLE-ABS-KEY-AUTH ( "*cigar*" ) OR TITLE-ABS-KEY ( "*cigars*" ) ) AND (INDEXTERMS ( *tobacco* AND *industry* ) ) ) Limit: peer-reviewed journal articles, reviews Limit: 1996 - present **Results: 56** 

*Updated results from June 2021 – 3 additional references* 

## Embase

7	2 or 4 or 6	352
17	exp "tobacco industry"/	5,845

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18 limit 17 to (human and yr="1996 -Current" and 2,991 (article or article in press or "review") and (journal or trade journal))

19 7 and 18

Limit: Human Limit: < 1996 Limit: Article, Review Limit: Journal or Trade Journal **Results: 21** 

## MEDLINE

7	2 or 4 or 6	473	
20	Exp "tobacco industry"/	4,658	
21	limit 20 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review"))	3,038	
22	7 and 21	32	
Limit: Humans Limit: 1996 – present			

Limit: clinical trials, journal articles, preprints, reviews, systematic reviews **Results: 32** 

## PsychINFO

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND "tobacco industry" Limit: Humans Limit: 1996 – present Limit: Journal articles **Results: 32** 

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LexisNexis				
Query	Results	Notes		
"cigar" or "cigars"	7,023	Search limited to "Tobacco Industry" and "Tobacco Mfg" Index Terms, 1996 – pres- ent, and the "Industry Trade Press" source group.		
("cigar" or "cigars") AND ("pre- mium" OR "large")	8,001	Same limits as last search.		
("cigar" or "cigars") AND ("pre- mium")	3,419	Same limits.		
("cigar" or "cigars") AND ("large")	5,872	Same lmits.		
(("cigar" or "cigars") w/5 ("pre- mium" OR "large"))	948	Proximity search; the terms appear within five words of each other		
• Previous search limited to Medicine and Health Industry subset	408			
• Previous search further limited to include the word "constituent"	17			

Search Strategies on the Marketing of Premium Cigars

## Scopus

((INDEXTERMS ( *cigar* ) OR INDEXTERMS ( *cigars* ) OR AUTHKEY ( *cigar* ) OR AUTHKEY ( *cigars* ) OR INDEXTERMS ( "*cigar smoking*" ) OR ( "*cigar smoking*" ) ) OR ( INDEXTERMS ( "*tobacco products*" ) OR AUTHKEY ( "*tobacco products*" ) AND TITLE-ABS-KEY-AUTH ( "*cigar*" ) OR TITLE-ABS-KEY ( "*cigars*" ) ) AND ( TITLE-ABS-KEY ( *market*\* ) OR TITLE-ABS-KEY ( *promot*\* ) ) ) AND PUBYEAR > 1995 AND ( LIMIT-TO ( SRCTYPE , "j" ) ) AND ( LIMIT-TO ( DOCTYPE , "ar" ) OR LIMIT-TO ( DOCTYPE , "re" ) )

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APPEI	NDIX B	353
Limi	t: peer-reviewed journal articles, reviews t: 1996 - present <b>lts: 236</b>	
Emba	ase	
7	2 or 4 or 6	352
20	exp "commercial phenomena"/	130,926
21	limit 20 to (human and yr="1996 -Current" and (article or article in press or "review") and (journal or trade journal))	42,090
22	7 and 21	63
Limit Limit Limit	t: Human t: < 1996 t: Article, Review t: Journal or Trade Journal <b>Its: 63</b>	
MED	DLINE	
7	2 or 4 or 6	473
23	Exp marketing/	35,562
24	limit 23 to (humans and yr="1996 -Current" and (clini- cal trial, all or journal article or preprint or "review" or "systematic review"))	16,997
25	7 and 24	70
Limit: Humans Limit: 1996 – present Limit: clinical trials, journal articles, preprints, reviews, systematic review <b>Results: 70</b>		
-	hINFO picotine) OR su("tobacco smoking")) AND ("cigar" OR	("cigars"))

((su(nicotine) OR su("tobacco smoking")) AND ("cigar" OR "cigars")) AND su(Advertising OR commerce OR "consumer behavior" OR Marketing OR retailing) Limit: Humans Limit: 1996 - present

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# Limit: Journal articles **Results: 76**

Search Strategies on Other Tobacco Products Cigarettes Search Strategies for Cigarette Keywords **PubMed** (Tobacco Products[MeSH Terms]) AND ((cigarette\*[Title/Abstract]) OR (cigarette\*[Text Word])) OR cigarette smoking[MeSH Terms] Limit: Humans Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 99** Updated Results from June 2021 – 2 additional references

## Embase

1	Exp cigarette/	2,893
2	limit 1 to (human and english language and "systematic review" and yr="2010 -Current")	67
Lin	nit: Human	
Lin	nit: 2010 - present	
Lin	nit: Systematic Review	
Re	sults: 67	
Up	dated Embase results from June 2021	
3	Exp cigarette/	3,013
4	Limit 3 to (human and yr="2021-Current")	423
5	Limit 3 to "review"	19
Lin	nit: Human	
Lin	nit: 2021 - current	
Lin	nit: Reviews	
Re	sults: 19	

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## MEDLINE

1	exp "tobacco products" / and cigarette*.mp.	4,560	
2	limit 1 to (english language and humans and yr="2010 -Current" and "systematic review")	49	
Limit: Humans Limit: 2010 - present Limit: systematic reviews <b>Results: 49</b> <i>Updated MEDLINE results from June 2021</i>			
3	exp "tobacco products"/ and cigarette*.mp.	4,917	
4	Limit 3 to (human and yr="2021-Current" and "system- atic review")	4	
Limit: Humans Limit: 2021 - current Limit: systematic reviews <b>Results: 4</b>			

Search Strategies of the Health Effects of Cigarettes **PubMed** 

(((Tobacco Products[MeSH Terms]) AND ((cigarette\*[Title/Abstract]) OR (cigarette\*[Text Word])) OR cigarette smoking[MeSH Terms])) AND (Cardiovascular System[MeSH Terms] OR Tobacco Smoke Pollution[MeSH Terms] OR neoplasms[MeSH Terms] OR nicotine[MeSH Terms] OR Polycyclic Aromatic Hydrocarbons[MeSH Terms] OR Nitrosamines[MeSH Terms] OR Volatile Organic Compounds[MeSH Terms] OR skin diseases[MeSH Terms] OR Respiratory System[MeSH Terms]) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 34** 

## Embase

1	Exp	cigarette,	/	
---	-----	------------	---	--

2 limit 1 to (human and english language and "systematic 67 review" and yr="2010 -Current")

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2,893

- exp carcinogen/ or exp "cardiovascular system"/ or 7 7,228,593 exp inhalation/ or exp "Malignant neoplasm"/ or exp Nicotine/ or exp Nitrosamine/ or exp "passive smoking"/ or exp "Polycyclic Aromatic Hydrocarbon"/ or exp "respiratory system" / or exp "respiratory tract disease"/ or exp smoke/ or exp "tobacco dependence"/ or exp "tobacco smoke" / or exp "toxic inhalation" / or exp "Volatile Organic Compound"/ or exp "Cigarette smoke" / or exp "Cigarette smoke condensate" /
- limit 7 to (human and english language and "systematic 69,075 8 review" and yr="2010 -Current")

33

9 2 and 8

Limit: Human Limit: 2010 - present Limit: Systematic Review **Results: 33** 

## **MEDLINE**

**Results: 20** 

1	exp "tobacco products"/ and cigarette*.mp.	4,560
2	limit 1 to (english language and humans and yr="2010 -Current" and "systematic review")	49
7	exp "behavior, addictive"/ or exp carcinogens/ or exp "Cardiovascular System"/ or exp "Drinking Behavior"/ or exp "Environmental Exposure"/ or exp Inhalation/ or exp "Inhalation Exposure"/ or exp neo- plasms/ or exp nicotine/ or exp Nitrosamines/ or exp "Polycyclic Aromatic Hydrocarbons"/ or exp "Sub- stance-Related Disorders"/ or exp "Tobacco Smoke Pollution"/ or exp "Volatile Organic Compounds"/	5,632,761
8	limit 7 to (english language and humans and yr="2010 -Current" and "systematic review")	24,368
9	2 and 8	20
Lin	nit: Humans nit: 2010 - present nit: systematic reviews	

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Search Strategies on Cigarettes and Vulnerable Populations

## PubMed

((Tobacco Products[MeSH Terms]) AND ((cigarette\*[Title/Abstract]) OR (cigarette\*[Text Word])) OR cigarette smoking[MeSH Terms]) AND ((adolescent[MeSH Terms]) OR (child[MeSH Terms]) OR (minority groups[MeSH Terms]) OR (socioeconomic factors[MeSH Terms]) OR (pregnancy[MeSH Terms]) OR (reproduction[MeSH Terms]) OR (Disabled Persons[MeSH Terms]) OR (Mental Disorders[MeSH Terms]) OR (Sexual and Gender Minorities[MeSH Terms]) OR (Homosexuality[MeSH Terms]) OR (Bisexuality[MeSH Terms])) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 28** 

## Embase

1	Exp cigarette/	2,893
2	limit 1 to (human and english language and "systematic review" and yr="2010 -Current")	67
16	exp bisexuality/ or exp demography/ or exp disabil- ity/ or exp "disabled person"/ or exp "educational status"/ or exp "ethnic group"/ or exp "ethnic or racial aspects'"/ or exp homosexuality/ or exp "mental disease"/ or exp "mental health"/ or exp "minority group"/ or exp "sexual and gender minority"/ or exp "social status"/ or exp "socioeconomics"/ or exp trans- gender/	3,341,522
17	limit 16 to (human and english language and "system- atic review" and yr="2010 -Current")	50,592
18	2 and 17	23
19	limit 17 to (embryo <first trimester=""> or infant <to one<br="">year&gt; or child <unspecified age=""> or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or adolescent &lt;13 to 17 years&gt;)</unspecified></to></first>	5,258
20	2 and 19	5

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358	PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND I	HEALTH EFFECTS			
21	exp child/ or exp adolescent/ or exp pregnancy/	3,789,956			
22	limit 21 to (human and english language and "system atic review" and yr="2010-current")	- 24,391			
23	2 and 22	11			
Lim Lim	it: Human it: 2010 - present it: Systematic Review <b>ults: 39</b>				
ME	DLINE				
1	exp "tobacco products" / and cigarette*.mp.	4,560			
2	limit 1 to (english language and humans and yr="2010 -Current" and "systematic review")	49			
12	exp Adolescent/ or exp child/ or exp "ethnic groups"/ or exp Bisexuality/ or exp homosexual- ity/ or exp demography/ or exp "disabled per- sons"/ or exp "Socioeconomic Factors"/ or exp "Ex-Smokers"/ or exp "Minority Groups"/ or exp minors/ or exp "Psychological Distance"/ or exp "Sexual and Gender Minorities"/ or exp Smokers/ or exp "Social Class"/ or exp "Vulnerable Popula- tions"/	4,616,504			
13	limit 12 to (english language and humans and yr="2010 -Current" and "systematic review")	35,195			
14	2 and 13	14			
Lim Lim	Limit: Humans Limit: 2010 - present Limit: systematic reviews <b>Results: 14</b>				
~					

Search Strategies on Behavioral Characteristics and Cigarette Use **PubMed** ((Tobacco Products[MeSH Terms]) AND ((cigarette\*[Title/Abstract])

((Iobacco Products[MeSH Ierms]) AND ((cigarette\*[Iitle/Abstract]) OR (cigarette\*[Text Word])) OR cigarette smoking[MeSH Terms]) AND

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((Tobacco Use Disorder[MeSH Terms]) OR (substance use disorder[MeSH Terms]) OR (Smoking Cessation[MeSH Terms]) OR (Tobacco Use Cessation[MeSH Terms])) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 34** 

## Embase

1	Exp cigarette/	2,893	
2	limit 1 to (human and english language and "system- atic review" and yr="2010 -Current")	67	
27	exp addiction/ or exp "drug dependence"/ or exp "smoking cessation"/ or exp "substance abuse"/ or exp "substance use"/ or exp "tobacco dependence"/ exp "smoking habit"/ or exp "cigarette smoking"/ or exp vaping/	804,557	
28	limit 27 to (human and english language and "system- atic review" and yr="2010 -Current")	10,395	
29	2 and 28	51	
Limit: Human Limit: 2010 - present Limit: Systematic Review <b>Results: 51</b>			
ME	DLINE		
1	exp "tobacco products"/ and cigarette*.mp.	4,560	
2	limit 1 to (english language and humans and yr="2010 -Current" and "systematic review")	49	
17	exp "Tobacco Use Disorder"/ or exp "Tobacco Use Ces- sation"/ or exp "Tobacco Smoking"/ or exp "Smoking Reduction"/ or exp "Smoking Cessation"/ or exp smol ers/ or exp "ex-smokers"/ or exp "drinking behavior", or exp vaping/	ζ-	

18 limit 17 to (english language and humans and yr="2010 1265 -Current" and "systematic review")

19 2 and 18

27

Limit: Humans Limit: 2010 - present Limit: systematic reviews **Results: 27** 

E-Cigarettes
Search Strategies for E-Cigarette Keywords
PubMed
Vaping[MeSH Terms] OR "Electronic Nicotine Delivery Systems"[MeSH
Terms]
Limit: Humans
Limit: English
Limit 2010 – present
Limit: Systematic Reviews
Results: 73
Updated Results from June 2021 – 4 additional references

## Embase

3	exp electronic cigarette/ or exp vaping/	9,144		
4	limit 3 to (human and english language and "systematic review" and yr="2010 -Current")	218		
Lim Lim Lim	Limit: Human Limit: English Limit: 2010 - present Limit: Systematic Review <b>Results: 218</b> <i>Updated results from June 2021</i>			
6	exp electronic cigarette/ or exp vaping/	9,548		
7	Limit 6 to (human and yr="2021-Current" and "Review")	92		
Lim Lim Lim	it: Human it: English it: 2021 - Current it: Reviews <b>ults: 92</b>			

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APPENDIX B		

361

## MEDLINE

3	exp "Electronic nicotine delivery systems"/	4,280
4	limit 3 to (english language and humans and yr="2010 -Current" and "systematic review")	68
Limi	it: Humans	
Limi	it: English	
Limi	it: 2010 - present	
Limi	it: Systematic Reviews	
Resi	1lts: 68	
Upd	ated Results from June 2021	
5	exp "Electronic nicotine delivery systems"/	4,747
6	Limit 5 to (human and yr="2021-Current" and "sys- tematic review")	12
Limi	it: Humans	
Limi	it: English	
Limi	it: 2021 - current	
Limi	it: Systematic Reviews	
Resi	ilts: 12	

Search Strategies for the Health Effects of E-Cigarettes **PubMed** 

((Vaping[MeSH Terms]) OR ("Electronic Nicotine Delivery Systems"[MeSH Terms])) AND (Cardiovascular System[MeSH Terms] OR Tobacco Smoke Pollution[MeSH Terms] OR neoplasms[MeSH Terms] OR nicotine[MeSH Terms] OR Polycyclic Aromatic Hydrocarbons[MeSH Terms] OR Nitrosamines[MeSH Terms] OR Volatile Organic Compounds[MeSH Terms] OR skin diseases[MeSH Terms] OR Respiratory System[MeSH Terms]) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 22** 

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## Embase

3	exp electronic cigarette/ or exp vaping/	9,144
4	limit 3 to (human and english language and "system- atic review" and yr="2010 -Current")	218
10	exp carcinogen/ or exp "cardiovascular system"/ or exp inhalation/ or exp "Malignant neoplasm"/ or exp Nicotine/ or exp Nitrosamine/ or exp "passive smok- ing"/ or exp "Polycyclic Aromatic Hydrocarbon"/ or exp "respiratory system"/ or exp "respiratory tract dis- ease"/ or exp smoke/ or exp "tobacco dependence"/ or exp "tobacco smoke"/ or exp "toxic inhalation"/ or exp "Volatile Organic Compound"/ or exp "Electronic cigarette vapor"/	7,225,692
11	limit 10 to (human and english language and "system- atic review" and yr="2010 -Current")	69,064
12	4 and 11	147
Lim Lim Lim	it: Human it: English it: 2010 - present it: Systematic Review <b>ults: 147</b>	
ME	DLINE	
3	exp "Electronic nicotine delivery systems"/	4,280
4	limit 3 to (english language and humans and yr="2010 -Current" and "systematic review")	68
7	exp "behavior, addictive" / or exp carcinogens / or exp "Cardiovascular System" / or exp "Drinking Behav- ior" / or exp "Environmental Exposure" / or exp Inhala- tion / or exp "Inhalation Exposure" / or exp neoplasms / or exp nicotine / or exp Nitrosamines / or exp "Polycy- clic Aromatic Hydrocarbons" / or exp "Substance-Relat- ed Disorders" / or exp "Tobacco Smoke Pollution" / or exp "Volatile Organic Compounds" /	5,632,761

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8 limit 7 to (english language and humans and yr="2010 24,368 -Current" and "systematic review")

10 4 and 8

Limit: Humans Limit: English Limit: 2010 - present Limit: Systematic Reviews **Results: 25** 

Search Strategies for Vulnerable Populations and E-Cigarette Use **PubMed** 

Vaping[MeSH Terms] OR "Electronic Nicotine Delivery Systems"[MeSH Terms] AND ((adolescent[MeSH Terms]) OR (child[MeSH Terms]) OR (minority groups[MeSH Terms]) OR (socioeconomic factors[MeSH Terms]) OR (pregnancy[MeSH Terms]) OR (reproduction[MeSH Terms]) OR (Disabled Persons[MeSH Terms]) OR (Mental Disorders[MeSH Terms]) OR (Sexual and Gender Minorities[MeSH Terms]) OR (Homosexuality[MeSH Terms]) OR (Bisexuality[MeSH Terms])) Limit: Humans Limit: English Limit: 2010 – present Limit: Systematic Reviews **Results: 25** 

### Embase

3	exp electronic cigarette/ or exp vaping/	9,144
4	limit 3 to (human and english language and "sys- tematic review" and yr="2010 -Current")	218
16	exp bisexuality/ or exp demography/ or exp dis- ability/ or exp "disabled person"/ or exp "edu- cational status"/ or exp "ethnic group"/ or exp "ethnic or racial aspects""/ or exp homosexuality/ or exp "mental disease"/ or exp "mental health"/ or exp "minority group"/ or exp "sexual and gender minority"/ or exp "social status"/ or exp "socioeco- nomics"/ or exp transgender/	3,341,522

25

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364	64 PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS		
17	limit 16 to (human and english language and "sys- tematic review" and yr="2010 -Current")	50,592	
19	limit 17 to (embryo <first trimester=""> or infant <to one year&gt; or child <unspecified age=""> or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or adolescent &lt;13 to 17 years&gt;)</unspecified></to </first>	5,258	
21	exp child/ or exp adolescent/ or exp pregnancy/	3,789,956	
22	limit 21 to (human and english language and "sys- tematic review" and yr="2010-current")	24,391	
24	17 and 22	68,303	
25	4 and 24	95	
Limit: Human Limit: English Limit: 2010 - present Limit: Systematic Review <b>Results: 95</b>			
ME	DLINE		
3	exp "Electronic nicotine delivery systems"/	4,280	
4	<ul> <li>limit 3 to (english language and humans and yr="2010 68</li> <li>-Current" and "systematic review")</li> </ul>		
12	12 exp Adolescent/ or exp child/ or exp "ethnic groups"/ 4,616,504 or exp Bisexuality/ or exp homosexuality/ or exp de- mography/ or exp "disabled persons"/ or exp "Socio- economic Factors"/ or exp "Ex-Smokers"/ or exp "Mi- nority Groups"/ or exp minors/ or exp "Psychological Distance"/ or exp "Sexual and Gender Minorities"/ or exp Smokers/ or exp "Social Class"/ or exp "Vulner- able Populations"/		

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13 limit 12 to (english language and humans and yr="2010 35,195 -Current" and "systematic review")

15 4 and 13

Limit: Humans Limit: English Limit: 2010 - present Limit: Systematic Reviews **Results: 23** 

Search Strategies for Behavioral Characteristics and E-Cigarette Use

### PubMed

Vaping[MeSH Terms] OR "Electronic Nicotine Delivery Systems"[MeSH Terms] AND ((Tobacco Use Disorder[MeSH Terms]) OR (substance use disorder[MeSH Terms]) OR (Smoking Cessation[MeSH Terms]) OR (Tobacco Use Cessation[MeSH Terms])) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 36** 

## Embase

3	exp electronic cigarette/ or exp vaping/	9,144
4	limit 3 to (human and english language and "systematic review" and yr="2010 -Current")	218
27	exp addiction/ or exp "drug dependence"/ or exp "smok- ing cessation"/ or exp "substance abuse"/ or exp "sub- stance use"/ or exp "tobacco dependence"/ exp "smoking habit"/ or exp "cigarette smoking"/ or exp vaping/	
28	limit 27 to (human and english language and "systematic review" and yr="2010 -Current")	10,395
30	4 and 28	187
	it: Human it: English	

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23

Limit: 2010 - present Limit: Systematic Review **Results: 187** 

# MEDLINE

3	exp "Electronic nicotine delivery systems"/	4,280
4	limit 3 to (english language and humans and yr="2010 -Current" and "systematic review")	68
17	exp "Tobacco Use Disorder"/ or exp "Tobacco Use Ces- sation"/ or exp "Tobacco Smoking"/ or exp "Smok- ing Reduction"/ or exp "Smoking Cessation"/ or exp smokers/ or exp "ex-smokers"/ or exp "drinking behavior"/ or exp vaping/	118,405
18	limit 17 to (english language and humans and yr="2010 -Current" and "systematic review")	1,265
20	4 and 18	43
Limit: Humans Limit: English Limit: 2010 - present Limit: Systematic Reviews <b>Results: 43</b>		
Smokeless Tobacco Search Strategies for Smokeless Tobacco Keywords <b>PubMed</b> (tobacco, smokeless[MeSH Terms]) OR ((tobacco use[MeSH Terms]) AND ((smokeless[Text Word]) OR (chewing[Text Word])) Limit: Humans Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews		
Res	ults: 38	
Eml		
5	exp smokeless tobacco/	5,433

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APP	ENDIX B		367
6	limit 5 to (human and english language and "systematic review" and yr="2010 -Current")	94	
Lim Lim Lim	uit: Human uit: English uit: 2010 - present uit: Systematic Review <b>ults: 94</b> dated results from June 2021		
8	exp smokeless tobacco/	5,484	1
9	Limit 8 to (human and yr="2021-Current" and "Review	r") 15	
Limit: Human Limit: English Limit: 2021 - current Limit: Reviews <b>Results: 15</b>			
ME	DLINE		
5	exp "smokeless tobacco"/	3,767	
6	limit 5 to (english language and humans and yr="2010 -Current" and "systematic review")	35	
Lim Lim Lim	uit: Humans uit: English uit: 2010 - present uit: Systematic Reviews ults: 35 Mated Results from June 2021		
7	exp smokeless tobacco/	3,810	
8	Limit 7 to (human and yr="2021-Current" and "sys- tematic review")	1	
Lim Lim Lim	iit: Humans iit: English iit: 2021 - current iit: Systematic Reviews <b>ults: 1</b>		

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Search Strategies for Health Effects of Smokeless Tobacco

## PubMed

(tobacco, smokeless[MeSH Terms]) OR ((tobacco use[MeSH Terms]) AND ((smokeless[Text Word]) OR (chewing[Text Word])) AND (Cardiovascular System[MeSH Terms] OR Tobacco Smoke Pollution[MeSH Terms] OR neoplasms[MeSH Terms] OR nicotine[MeSH Terms] OR Polycyclic Aromatic Hydrocarbons[MeSH Terms] OR Nitrosamines[MeSH Terms] OR Volatile Organic Compounds[MeSH Terms] OR skin diseases[MeSH Terms] OR Respiratory System[MeSH Terms]) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 17** 

## Embase

5	exp smokeless tobacco/	5,433
6	limit 5 to (human and english language and "system- atic review" and yr="2010 -Current")	94
13	exp carcinogen/ or exp "cardiovascular system"/ or exp inhalation/ or exp "Malignant neoplasm"/ or exp Nicotine/ or exp Nitrosamine/ or exp "passive smoking"/ or exp "Polycyclic Aromatic Hydrocar- bon"/ or exp "respiratory system"/ or exp "respira- tory tract disease"/ or exp smoke/ or exp "tobacco dependence"/ or exp "tobacco smoke"/ or exp "toxic inhalation"/ or exp "Volatile Organic Compound"/	7,225,669
14	limit 13 to (human and english language and "system- atic review" and yr="2010 -Current")	69,062
15	6 and 14	55
Limi	it: Human	
Limi	it: English	
Limi	it: 2010 - present	
	it: Systematic Review	
Resi	ults: 55	

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## MEDLINE

5	exp "smokeless tobacco"/	3,767
6	limit 5 to (english language and humans and yr="2010 -Current" and "systematic review")	35
7	exp "behavior, addictive" / or exp carcinogens / or exp "Cardiovascular System" / or exp "Drinking Behavior" / or exp "Environmental Expective" / or exp	5,632,761

- Behavior"/ or exp "Environmental Exposure"/ or exp Inhalation/ or exp "Inhalation Exposure"/ or exp neoplasms/ or exp nicotine/ or exp Nitrosamines/ or exp "Polycyclic Aromatic Hydrocarbons"/ or exp "Substance-Related Disorders"/ or exp "Tobacco Smoke Pollution"/ or exp "Volatile Organic Compounds"/
- 8 limit 7 to (english language and humans and yr="2010 24,368 -Current" and "systematic review")
- 11 6 and 8

Limit: Humans Limit: English Limit: 2010 - present Limit: Systematic Reviews **Results: 21** 

Search Strategies for Vulnerable Populations and Smokeless Tobacco Use **PubMed** 

(tobacco, smokeless[MeSH Terms]) OR ((tobacco use[MeSH Terms]) AND ((smokeless[Text Word]) OR (chewing[Text Word])) AND ((adolescent[MeSH Terms]) OR (child[MeSH Terms]) OR (minority groups[MeSH Terms]) OR (socioeconomic factors[MeSH Terms]) OR (pregnancy[MeSH Terms]) OR (reproduction[MeSH Terms]) OR (Disabled Persons[MeSH Terms]) OR (Mental Disorders[MeSH Terms]) OR (Disabled Persons[MeSH Terms]) OR (Mental Disorders[MeSH Terms]) OR (Sexual and Gender Minorities[MeSH Terms]) OR (Homosexuality[MeSH Terms]) OR (Bisexuality[MeSH Terms])) Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 14** 

21

# Embase

Results: 33

5	exp smokeless tobacco/	5,433
6	limit 5 to (human and english language and "system- atic review" and yr="2010 -Current")	94
16	exp bisexuality/ or exp demography/ or exp disabil- ity/ or exp "disabled person"/ or exp "educational status"/ or exp "ethnic group"/ or exp "ethnic or ra- cial aspects'"/ or exp homosexuality/ or exp "mental disease"/ or exp "mental health"/ or exp "minority group"/ or exp "sexual and gender minority"/ or exp "social status"/ or exp "socioeconomics"/ or exp transgender/	3,341,522
17	limit 16 to (human and english language and "sys- tematic review" and yr="2010 -Current")	50,592
19	limit 17 to (embryo <first trimester=""> or infant <to one<br="">year&gt; or child <unspecified age=""> or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or ado- lescent &lt;13 to 17 years&gt;)</unspecified></to></first>	5,258
21	exp child/ or exp adolescent/ or exp pregnancy/	3,789,956
22	limit 21 to (human and english language and "sys- tematic review" and yr="2010-current")	24,391
24	17 and 22	68,303
26	6 and 24	33
Limi Limi	it: Human it: English it: 2010 - present it: Systematic Review	

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	APPE	ENDIX B		371
	ME	DLINE		
	5	exp "smokeless tobacco"/	3,767	
	6	limit 5 to (english language and humans and yr="2010 -Current" and "systematic review")	35	
	12	exp Adolescent/ or exp child/ or exp "ethnic groups"/ or exp Bisexuality/ or exp homosexuality/ or exp demography/ or exp "disabled persons"/ or exp "Socioeconomic Factors"/ or exp "Ex-Smok- ers"/ or exp "Minority Groups"/ or exp minors/ or exp "Psychological Distance"/ or exp "Sexual and Gender Minorities"/ or exp Smokers/ or exp "Social Class"/ or exp "Vulnerable Populations"/	4,616,504	
	13	limit 12 to (english language and humans and yr="2010 -Current" and "systematic review")	35,195	
	16	6 and 13	13	
Limit: Humans Limit: English Limit: 2010 - present Limit: Systematic Reviews <b>Results: 13</b>				

Search Strategies for Behavioral Characteristics and Smokeless Tobacco Use

## PubMed

(tobacco, smokeless[MeSH Terms]) OR ((tobacco use[MeSH Terms]) AND ((smokeless[Text Word]) OR (chewing[Text Word])) AND ((Tobacco Use Disorder[MeSH Terms]) OR (substance use disorder[MeSH Terms]) OR (Smoking Cessation[MeSH Terms]) OR (Tobacco Use Cessation[MeSH Terms])) Limit: Humans Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 16** 

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372

Embase 5 exp smokeless tobacco/ 5,433 6 limit 5 to (human and english language and "systematic 94 review" and yr="2010 -Current") 27 exp addiction/ or exp "drug dependence"/ or exp 804,557 "smoking cessation" / or exp "substance abuse" / or exp "substance use" / or exp "tobacco dependence" / exp "smoking habit" / or exp "cigarette smoking" / or exp vaping/ 28 limit 27 to (human and english language and "system-10,395 atic review" and yr="2010 -Current") 31 6 and 28 68 Limit: Human Limit: English Limit: 2010 - present Limit: Systematic Review **Results: 68 MEDLINE** 5 exp "smokeless tobacco"/ 3,767 6 35 limit 5 to (english language and humans and yr="2010" -Current" and "systematic review") 17 exp "Tobacco Use Disorder"/ or exp "Tobacco Use Ces-118,405 sation" / or exp "Tobacco Smoking" / or exp "Smoking Reduction" / or exp "Smoking Cessation" / or exp smokers/ or exp "ex-smokers"/ or exp "drinking behavior"/ or exp vaping/ 18 limit 17 to (english language and humans and yr="2010" 1,265 -Current" and "systematic review") 21 6 and 18 15 Limit: Humans Limit: English Limit: 2010 - present

PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS

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APPENDIX B	3
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Limit: Systematic Reviews **Results: 15** 

Cigarillos and Other Small Cigars Search Strategies for Small Cigar Keywords **PubMed** (Tobacco Products[MeSH Terms]) AND ((cigarillo\*[Title/Abstract]) OR (cigarillo\*[Text Word])) Limit: Humans Limit: Humans Limit: English Limit 2010 – present Limit: Systematic Reviews **Results: 2** 

### Embase

1	Exp tobacco/	Many
2	Cigarillo.mp	133
3	1 and 2	60
4	Limit 3 to (human and "systematic review" and yr="2010 – 2021")	0
5	Limit 3 to (human and yr="2010-Current)	51
6	"small cigar*".mp.	33
7	Limit 6 to (human and "systematic review" and yr="2010 – 2021")	26
8	("filtered cigar*" NOT "cigarette.mp.	19
9	Limit 8 to (human and "systematic review" and yr="2010 – 2021")	7
Limit: Human Limit: English Limit: 2010 - present Limit: Systematic Review <b>Results: 84</b>		

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## MEDLINE

1	exp "tobacco products"/ and cigarillo*.mp.	37
2	limit 1 to (humans and yr="2010-current")	25
3	"small cigar*".mp.	32
4	limit 3 to (humans and yr="2010-current")	20
5	("filtered cigar*" NOT "cigarette").mp.	33
6	limit 5 to (humans and yr="2010-current")	9
Lim Lim Lim	uit: Humans uit: English uit: 2010 - present uit: Systematic Reviews <b>ults: 54</b>	
Agr	icola	

1 Cigarillo.mp.

3

# **Results: 3**

Select Searches of Specific Journals: Journal of Consumer Research; Food and Cosmetics Toxicology/Food and Chemical Toxicology; Contributions to Tobacco & Nicotine Research/Contributions to Tobacco Research; Consumer Reports

These journals were searched for additional content on the use of "premium" in consumer products, and for additional content on cigars/premium cigars.

# Scopus

Query	Results	Notes
SOURCE-ID ( 22899 ) AND TITLE- ABS-KEY ( premium )	8	Search in Scopus for relevant articles in the <i>Journal of Consumer</i> Research.

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APPENDIX B		375
SOURCE-ID ( 22899 ) AND ( TITLE- ABS-KEY ( premium ) OR TITLE- ABS-KEY ( status ) OR TITLE-ABS- KEY ( luxury ) )	40	Additional search in Scopus for relevant articles in the <i>Journal of</i> <i>Consumer</i> Research.
(TITLE-ABS-KEY(premium) OR TI- TLE-ABS-KEY("premium products")) AND TITLE-ABS-KEY(consumer behavior) AND PUBYEAR AFT 2010 AND DOCTYPE(ar) AND LANGUAGE(english)	636	
(TITLE-ABS-KEY ( premium ) AND TITLE-ABS-KEY ( "brand image" ) ) AND PUBYEAR > 2010 AND DOC- TYPE ( ar ) AND LANGUAGE ( eng- lish ) AND NOT SRCID ( 22899 )	40	
SOURCE-ID ( 25096 )	12,335	Search of Food and Chemical Toxicology
SOURCE-ID ( 25096 ) AND TITLE- ABS-KEY ( "cigar" OR "cigars" )	4	
SOURCE-ID ( 33369 ) AND TITLE- ABS-KEY ( "cigar" OR "cigars" )	1	
Limit: 2011 – present Limit: English language Limit: Articles		

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# PsychINFO

Query	Results
noft(premium) OR noft("premium products") AND noft("consumer behavior") OR noft("brand image")	1,325
<ul> <li>Applied subject filters to previous search:</li> <li>consumer behavior OR brand names OR marketing OR consumer attitudes OR brand preferences OR intention OR choice behavior OR preferences</li> </ul>	726
Removed "brand image" from the previous searches – results seem less germane	380
Limit: English language Limit: 2010 – present Limit: journal article; peer-reviewed	
LexisNexis	
Query	Results
premium OR premiumization	2,131
(premium OR premiumization) AND NOT insurance	1,309
(premium OR premiumization) AND NOT insurance AND NOT (gas OR gasoline)	1,006
Limit: English Limit: 2011 – present	
PubMed	
(0278-6915) AND (("cigar"[Title/Ab- stract]) OR ("cigars"[Title/Abstract]))4Search of Food Chemical Toxical	

No limits applied due to low number of results

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# Appendix C

# Cross-Sectional Patterns of Cigar Use by Type in the National Survey on Drug Use and Health

Authored by:<sup>1</sup> Michelle T. Bover Manderski,<sup>2</sup> Ollie Ganz,<sup>3</sup> Julia Chen-Sankey<sup>4</sup>

#### BACKGROUND

In 2021, FDA tasked the National Academy of Sciences, Engineering and Medicine (the National Academies) to evaluate the current evidence base related to the health effects from use of premium cigars and identify areas for further research (NASEM, 2021). The committee's scope of work included but was not limited to patterns of use for premium cigars, how those may differ among cigar types and other tobacco products, and data on both short- and long-term health effects of premium cigars. Given the paucity of published data on premium cigar use (Corey et al., 2014, 2018), the committee commissioned a paper to provide insight into U.S. premium and nonpremium cigar use with 10 years of data from the National Survey on Drug Use and Health (NSDUH; 2010–2019). Specifically, analyses were to focus on a) use patterns over time, b) demographic characteristics of premium versus nonpremium past-30-day cigar smokers, c) tobacco use patterns among premium versus nonpremium past-

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<sup>&</sup>lt;sup>1</sup>Committee member Cristine Delnevo oversaw this analysis, reviewed the results for accuracy, provided regular feedback to the authors, and edited the final paper.

<sup>&</sup>lt;sup>2</sup> Department of Biostatistics and Epidemiology, School of Public Health, Rutgers University

<sup>&</sup>lt;sup>3</sup> Department of Health Behavior, Society and Policy, School of Public Health, Rutgers University

<sup>&</sup>lt;sup>4</sup> Department of Health Behavior, Society and Policy, School of Public Health, Rutgers University

30-day cigar smokers, and d) health indicators among premium versus nonpremium past-30-day cigar smokers.

#### **METHODS**

#### **Data Source**

The NSDUH has collected data from residents of households, noninstitutional group quarters, and civilians living on military bases since 1971. Each year, approximately 56,500 individuals aged 12 and older are surveyed via a computer-assisted interview. The sample is equally distributed among three age groups: 12–17, 18–25, and 26+. The questionnaire contains many tobacco measures, including tobacco use patterns (except e-cigarettes), usual tobacco brand, age of initiation, frequency of tobacco product use, addiction indicators, alcohol and drug use/abuse, pregnancy status, mental health indicators, and some basic disease status measures (e.g., diagnoses with cancer, heart disease). For the present study, data from 2010 through 2019 were analyzed from the NSDUH Concatenated 2002–2019 Public Use File,<sup>5</sup> except for analyses related to health outcomes, which included 2015–2019.

#### **Coding of Cigar Type**

In NSDUH, all past-30-day cigar users were asked to report the brand that they used most often in the past 30 days. NSDUH does not distinguish between premium versus nonpremium cigar types or brands, so all brands were manually coded. Three expert coders (Ganz, Villanti, and Sterling)<sup>6</sup> independently coded each brand based on the following criteria for what defined a premium cigar from the National Academies committee: a) handmade, b) filler at least 50 percent natural long-leaf filler tobacco, c) wrapped in whole leaf (i.e., not reconstituted tobacco), d) weight of at least 6 lbs per 1,000, e) no filters/tips, and f) no characterizing flavor other than tobacco. Coders were able to look at brand and vendor websites to make their determinations. The three coders achieved 84 percent agreement (n = 110). Any disagreements (n = 21) were discussed among the three coders and an additional cigar expert (Delnevo).<sup>7</sup> The majority of disagreements were resolved after review of additional brand

<sup>&</sup>lt;sup>5</sup> See https://www.datafiles.samhsa.gov/dataset/nsduh-2002-2019-ds0001-nsduh-2002-2019-ds0001.

<sup>&</sup>lt;sup>6</sup> Ganz is an author of this paper; Villanti and Sterling are members of the NASEM committee.

 $<sup>^7\,\</sup>mathrm{Delnevo}$  oversaw the development of this paper and is a member of the NASEM committee.

and vendor websites indicated those that were (e.g., description of whole leaf wrapper) and were not (e.g., presence of a filter) consistent with the committee definition. Ultimately, the three coders and additional expert could not determine the category of four brands: Marsh Wheeling, Isla Del Sol, Java and Acid. These brands were consistent with premium cigars outside of their use of characterizing flavors. The group decided to treat these brands as nonpremium but conducted a sensitivity analysis treating them as premium.

Codes were cross-referenced with definitions employed by Corey et al. (2018); only two brands were coded differently. Specifically, Corey et al. categorized Acid and Optimo as premium, whereas these were coded as nonpremium for this project. Furthermore, Corey et al. coded Marsh Wheeling as premium, whereas it was coded as both for this project (i.e., included in the sensitivity analysis). The final categorizations were shared for use in the Jeon and Mok, Population Assessment of Tobacco and Health replication commissioned paper (see Appendix D).

#### Measures

#### Tobacco Use

Using the coding scheme described above, individuals who had smoked a cigar in the past 30 days were categorized as premium or nonpremium based on the reported brand used most often in the past month. Individuals who cited a known cigarette brand (e.g., Marlboro, Camel, Newport) were excluded. Individuals for whom cigar type could not be determined (e.g., did not know the brand of cigar they smoked) were categorized as "Unknown/Insufficient Information."

Current cigar use was defined as any cigar use in the past 30 days. Frequent cigar use was defined as at least 20 of the past 30 days. Daily cigar use was defined as 30 of the past 30 days.

Established cigarette smoking was defined as having smoked 100 or more cigarettes in one's lifetime. Current established cigarette smoking was defined as having ever smoked 100 or more cigarettes and smoked cigarettes in the past 30 days. Former established cigarette smoking was defined as having ever smoked 100 or more cigarettes but NOT having smoked in the past 30 days.

Current use of other tobacco products (i.e., smokeless tobacco, pipe) was defined as use on one or more of the past 30 days; former use for each product was defined as ever having used it but not in the past 30 days; and never use was defined as not having used it even once. NSDUH does not include questions about e-cigarettes, so that was not considered in this analysis.

## Demographics

**Age** The NSDUH Public Use File includes several age group variables but not a continuous age variable. For this study, age was categorized as 12–17, 18–25, 26–34, 35–49, 50–64, and 65+.

**Gender** According to NSDUH documentation, participant gender is recorded by the survey interviewer as either male or female. This classification was retained for this study.

**Race and ethnicity** A single race and ethnicity variable was used for this study, classifying respondents as non-Hispanic white, non-Hispanic Black, non-Hispanic American Indian or Alaskan Native (AI/AN), non-Hispanic Native Hawaiian or Pacific Islander (NH/PI), non-Hispanic Asian, non-Hispanic other or multiple races, or Hispanic (any race).

**Sexual identity** In 2015, the NSDUH began asking adults about sexual identity. The question was "Which one of the following do you consider yourself to be? Heterosexual, that is, straight; Lesbian [if female] or Gay [if male]; Bisexual." The classification was retained for this study; however, for adults during 2010–2014 and youth during any year, this information was not ascertained.

**Education** For persons over age 18, NSDUH collects highest educational attainment with a question, "What is the highest grade or year of school you have completed?" with 21 response options ranging from "no school completed" to "professional degree beyond a bachelor's degree" (for example, M.D., D.D.S., D.V.M., L.L.B., J.D.). For this study, this was classified as less than high school education, high school graduate or equivalent (e.g., GED), some college or technical school, or college graduate.

**Metropolitan status** The NSDUH classifies respondents as living in a large metro, small metro, or nonmetropolitan county; this classification was retained for this study.

**Poverty** Individuals were classified based on a ratio-to-poverty threshold as "living in poverty," "income up to two times the federal poverty threshold," or "income above two times the federal poverty threshold."

## Health Outcomes

In 2015, the NSDUH began including a check-all-that-apply question about a variety of health conditions: "The following is a list of health conditions. Please read the list, and type in the numbers of any of these

conditions that a doctor or other medical professional has ever told you that you had." For cancer, heart condition, chronic obstructive pulmonary disease (COPD), and asthma, respondents were classified as having a particular condition if they selected it and as not having it if they did not select it or selected "none of the above."

Past-month serious psychological distress (SPD), past-year major depressive episode (MDE), past-year alcohol dependence, past-year cannabis dependence, and past-year illicit drug dependence (other than cannabis) are binary (yes or no) derived variables provided in the NSDUH concatenated datasets. These were retained for the present study.

Current pregnancy status was only asked of female respondents aged 12–44, so respondents not meeting this criterion were classified as "Not Applicable."

#### **Statistical Analysis**

All analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA) survey procedures using complex sampling and weight variables, per NSDUH documentation (SAMHSA, 2021). Variance was estimated using Taylor Series Linearization with missing values assumed to be not completely random; 95 percent CIs were computed and reported for all point estimates, which were considered significantly different if the CIs did not overlap.

Demographic characteristics of premium and nonpremium cigar smokers (Table C-1), prevalence of premium and nonpremium cigar smoking (Table C-2), and tobacco and substance use characteristics among premium and nonpremium cigar smokers (Table C-3) were calculated from pooled 2010–2019 data. Prevalence of medical conditions, mental health conditions, substance dependence, and pregnancy were calculated from pooled 2015–2019 data, because NSDUH did not begin assessing medical conditions until 2015. Estimates for which the coefficient of variation (CV) exceeded 0.3 were deemed statistically unreliable and not reported.

To demonstrate temporal trends, figures were created to show prevalence of current, frequent, and daily premium and nonpremium current cigar use among adults and premium cigar use by age group over time (2010–2019). Ultimately, only the figures showing the prevalence of current premium and nonpremium cigar use among adults (Figure C-1) and use by age over time (Figure C-2) were reported, since sample size limitations provided unreliable estimates for the other two figures, with some cells containing as few as four respondents.

Binary logistic regression modeling was used to assess the association between premium cigar smoking and each health characteristic, adjusted for age group and gender, given that both cigar type and risk vary by these factors. Age was included as a six-level (<18, 18–25, 25–34, 35–49,

50–64, 65+) ordinal variable. Ordinal age group (one parameter, no reference group), as opposed to nominal (five parameters, compared to a common reference group) was selected because it provided better model fit without substantively impacting the estimates of interest. Continuous age is not available in the NSDUH Public Use File, thus we could not model age as a continuous variable. Gender was included as a binary nominal variable (male or female). Four comparisons were modeled for adults: 1) premium versus nonpremium cigar smoking among those who smoked cigars in the past 30 days; 2) premium versus nonpremium cigar smoking adjusted for established cigarette smoking status (nominal variable: current, former, never); 3) past-30-day premium cigar smoking versus never-tobacco use; and 4) past-30-day premium cigar smoking versus current or former established cigarette smoking. The statistical significance of regression parameters was determined by a p value >.05.

### RESULTS

Among civilian noninstitutionalized individuals ages 12+ living in the United States, 2010–2019, an estimated 4.7 percent (95 percent CI: 4.6–4.8) currently smoked cigars. Nonpremium cigar smoking (3.0 percent; 95 percent CI: 2.9–3.1) was significantly more prevalent than premium cigar smoking (0.9 percent; 95 percent CI: 0.8–0.9) and smoking of an unknown cigar type (0.8 percent; 95 percent CI: 0.7–0.8).

## Distribution of Demographic Characteristics by Cigar Type

Table C-1 presents the distribution of demographic characteristics of people who currently smoke cigars, overall and by cigar type.

**Age** The age distribution of premium cigar smokers trended older relative to nonpremium cigar smokers; an estimated 14.1 percent of premium cigar smokers were under age 25 compared to about 38.5 percent of nonpremium cigar smokers. Additionally, more than one-third (34.5 percent) of premium cigar smokers were 50+, compared to less than 20 percent (19.1 percent) of nonpremium cigar smokers.

**Gender** Although female smokers are the minority among all cigar types, premium cigar smokers were substantially less likely than nonpremium smokers to be female (6.3 versus 25.8 percent).

Race and ethnicity An overwhelming majority of premium cigar smokers were non-Hispanic white (78.0 percent), followed by Hispanic (12.1

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percent) and non-Hispanic Black (5.5 percent). In contrast, nonpremium cigar smokers were more racially diverse, with 57.7 percent identified as non-Hispanic white, 11.5 percent Hispanic, and 25.7 percent non-Hispanic Black.

**Sexual identity** A greater proportion of premium than nonpremium cigar smokers identified as heterosexual or straight (97.5 versus 89.6 percent); 3.1 percent and 6.6 percent of nonpremium cigar smokers identified as lesbian/gay or bisexual, respectively, compared to just 0.9 percent and 1.6 percent of premium cigar smokers, respectively.

**Education** Premium cigar smokers tended to be more highly educated, with 47.5 percent having a college degree compared to 12.1 percent of nonpremium cigar smokers. Concurrently, 18.9 percent of nonpremium cigar smokers did not complete high school, compared to only 3.7 percent of premium cigar smokers.

**Metropolitan status** Premium cigar smokers were more likely to live in a large metro area than nonpremium cigar smokers (65.0 versus 50.5 percent), while nonpremium cigar smokers were more likely to live in a nonmetropolitan area (16.5 versus 6.5 percent).

**Poverty level** Income distribution trended higher for premium cigar smokers; they were significantly more likely to have an income above 200 percent of the poverty threshold (84.7 versus 49.8 percent) and significantly less likely to be living in poverty (5.8 versus 24.9 percent).

## Prevalence of Premium and Nonpremium Cigar Smoking Among Demographic Groups

**Table C-2** presents the prevalence of premium and nonpremium cigar smoking among civilian noninstitutionalized people aged 12+ living in the United States from 2010 to 2019, stratified by demographic characteristics.

**Age** The prevalence of current any cigar smoking was highest among those aged 18–25 years (9.5 percent), followed by 26–34 (7.0 percent), 35–49 (4.6 percent), 50–64 (3.7 percent), 12–17 (2.3 percent), and 65+ (1.7 percent). The prevalence of current nonpremium cigar smoking followed a similar pattern, being highest among those aged 18–25 (7.5 percent) and lowest among those 65+ (0.8 percent). In contrast, prevalence of current premium cigar smoking was highest among those aged 26–34 (1.4 percent), followed by 35–49 (1.1 percent), 50–64 (1.0 percent), 18–25 (0.9 percent), 65+ (0.4 percent), and 12–17 (0.1 percent).

**Gender** Male individuals were more likely to smoke cigars, regardless of type. Prevalence of any cigar smoking was 7.6 percent for male and 1.9 percent for female smokers. Current premium cigar smoking was reported by 1.7 percent of male and 0.1 percent of female smokers. Current nonpremium cigar smoking was reported by 4.6 percent of male and 1.5 percent of female smokers.

**Race and ethnicity** The prevalence of current any cigar smoking was highest among people who are non-Hispanic Black (7.4 percent), followed by non-Hispanic multiracial (6.6 percent), non-Hispanic AI/AN (5.4 percent), non-Hispanic white (4.7 percent), non-Hispanic NH/PI (3.6 percent), Hispanic (3.3 percent), and non-Hispanic Asian (1.4 percent). The prevalence of current nonpremium cigar smoking followed a similar pattern, being highest among non-Hispanic Black people (6.5 percent) and lowest among non-Hispanic Asian people (0.6 percent). In contrast, non-Hispanic white people were more likely to be premium cigar smoking was highest among those who reported being non-Hispanic white (1.1 percent), followed by Hispanic (0.7 percent), non-Hispanic multiracial (0.7 percent), non-Hispanic AI/AN (0.5 percent), non-Hispanic NH/PI (0.5 percent), non-Hispanic Black (0.4 percent), and non-Hispanic Asian (0.4 percent).

**Sexual identity** Among those aged 18+ during 2015 to 2019, the prevalence of current any cigar smoking was higher among adults who reported being bisexual (7.9 percent) or lesbian or gay (6.3 percent) than heterosexual or straight (4.6 percent). Similarly, prevalence of current nonpremium cigar smoking was higher among adults who reported being bisexual (6.3 percent) or lesbian or gay (4.8 percent) than heterosexual or straight (2.9 percent). In contrast, heterosexual or straight individuals were more likely to smoke premium cigars. Prevalence of current premium cigar smoking was higher among adults who reported being heterosexual or straight (1.0 percent) than bisexual (0.5 percent) or lesbian or gay (0.5 percent).

**Education** Among those aged 18+, the prevalence of current any cigar smoking was highest among those with less than a high school education (5.6 percent), followed by those with some college or technical school education (5.5 percent), high school graduates (5.2 percent), and college graduates (3.8 percent). Prevalence of current nonpremium cigar smoking was also highest among people without a high school education (4.7 percent) and lowest among college graduates (1.3 percent). In contrast, the prevalence of current premium cigar smoking was higher among college graduates (1.5 percent) and those with some college or technical school

**Metropolitan status** The prevalence of current any cigar smoking did not vary significantly by metropolitan status but was highest among people living in a small metropolitan area (5.0 percent), followed by those in a large metropolitan area (4.6 percent) and nonmetropolitan area (4.3 percent). The prevalence of current nonpremium cigar smoking was significantly lower among people living in a large metropolitan area (2.8 percent) than for those in a small metropolitan area (3.3 percent) or nonmetropolitan area (3.3 percent). The opposite was observed for premium cigar smoking—the prevalence of current premium cigar smoking was significantly higher among people living in a large metropolitan area (1.1 percent, than among those in a small metropolitan area (0.8 percent) or nonmetropolitan area (0.4 percent).

**Poverty level** The prevalence of current any cigar smoking was higher among people living in poverty (6.1 percent) than those with income up to twice the poverty threshold (4.8 percent) or higher (4.3 percent). Similarly, the prevalence of current nonpremium cigar smoking was inversely associated with income: 5.0 percent for people with income below the poverty threshold, followed by those with income up to twice the threshold (3.8 percent) and higher (2.3 percent). In contrast, the prevalence of current premium cigar smoking was approximately threefold higher among people in the highest income group (1.2 percent) than those with income up to twice the poverty threshold (0.4 percent) or living in poverty (0.3 percent).

**Table C-2a** presents prevalence of any, nonpremium, premium, and unknown-type cigar smoking among civilian noninstitutionalized U.S. youth aged 12–17. Although prevalence of each type is lower, demographic patterns are similar to those observed for the full population. Race/ethnicity- and poverty-level-specific premium cigar prevalence estimates could not be reported due to imprecision of estimates (CV >0.3).

**Gender** Current cigar smoking of any type was more prevalent among male (2.9 percent) than female (1.5 percent) smokers. Current premium cigar smoking was reported by 0.1 percent of male and 0.0 percent of female smokers. Current nonpremium cigar smoking was reported by 2.6 percent of male and 1.2 percent of female smokers.

**Race and ethnicity** The prevalence of current any cigar smoking was higher among youth who reported being non-Hispanic white (2.7 percent), non-Hispanic multiracial (2.6 percent), non-Hispanic AI/AN (2.4

percent), non-Hispanic Black (2.1 percent), or Hispanic (1.6 percent) than non-Hispanic Asian (0.6 percent; see Table C-2a). The prevalence of current nonpremium cigar smoking was higher among youth identifying as non-Hispanic white (2.3 percent), non-Hispanic multiracial (2.3 percent), non-Hispanic AI/AN (2.1 percent), non-Hispanic Black (2.0 percent), Hispanic (1.3 percent), or non-Hispanic NH/PI (1.1 percent) than non-Hispanic Asian (0.4 percent).

**Metropolitan status** The prevalence of current any cigar smoking was higher among youth living in a nonmetropolitan area (2.8 percent) or small metropolitan area (2.6 percent) than large metropolitan area (1.9 percent; Table C-2a). The prevalence of current premium cigar smoking was equivalent among youth in various metropolitan areas (0.1 percent). The prevalence of current nonpremium cigar smoking was higher among youth living in a nonmetropolitan area (2.5 percent) or small metropolitan area (2.2 percent) than large metropolitan area (1.6 percent).

**Poverty level** The prevalence of current any cigar smoking was higher among youth living in poverty (2.4 percent) or up to twice the poverty threshold (2.3 percent) than those at higher than twice the threshold (2.2 percent; see Table C-2a). The prevalence of current nonpremium cigar smoking was higher among youth living in poverty (2.1 percent) or up to twice the poverty threshold (2.0 percent) than those at higher than twice the threshold (1.8 percent).

**Table C-2b** presents prevalence of any, nonpremium, premium, and unknown-type cigar smoking among civilian noninstitutionalized U.S. adults ages 18+. Demographic patterns are similar to those observed among the full population.

Age See Table C-2.

**Gender** Prevalence of any cigar smoking was 8.1 percent among male and 2.0 percent among female smokers. Current premium cigar smoking was reported by 1.9 percent of male and 0.1 percent of female smokers. Current nonpremium cigar smoking was reported by 4.8 percent of male and 1.5 percent of female smokers.

**Race and ethnicity** The prevalence of current any cigar smoking was higher among adults identifying as non-Hispanic Black (8.1 percent), non-Hispanic multiracial (7.4 percent), non-Hispanic AI/AN (5.7 percent), non-Hispanic white (4.9 percent), non-Hispanic NH/PI (3.9 percent), or Hispanic (3.6 percent) than non-Hispanic Asian (1.5 percent).

The prevalence of current premium cigar smoking was higher among those identifying as non-Hispanic white (1.2 percent), Hispanic (0.8 percent), non-Hispanic multiracial (0.8 percent), or non-Hispanic NH/PI (0.6 percent) than non-Hispanic AI/AN (0.5 percent), non-Hispanic Black (0.5 percent), non-Hispanic Asian (0.5 percent). The prevalence of current nonpremium cigar smoking was higher among adults who reported being non-Hispanic Black (7.0 percent), non-Hispanic multiracial (5.8 percent), non-Hispanic AI/AN (4.5 percent), non-Hispanic NH/PI (3.2 percent), non-Hispanic white (2.7 percent), or Hispanic (2.3 percent) than non-Hispanic Asian (0.6 percent).

Sexual identity See Table C-2 (sexual identity was only asked of adults).

**Education**. See Table C-2 (educational attainment was only determined for adults).

**Metropolitan status** The prevalence of current any cigar smoking was higher among adults living in a small metropolitan area (5.2 percent) or large metropolitan area (4.9 percent) than nonmetropolitan area (4.5 percent). The prevalence of current premium cigar smoking was higher among adults living in a large metropolitan area (1.2 percent) or small metropolitan area (0.9 percent) than a nonmetropolitan area (0.4 percent). The prevalence of current nonpremium cigar smoking was higher among adults living in a small metropolitan area (3.4 percent) or nonmetropolitan area (3.4 percent) than a large metropolitan area (2.9 percent).

**Poverty level** The prevalence of current any cigar smoking was higher among adults living in poverty (6.6 percent) or with income up to twice the poverty threshold (5.1 percent) than those with higher income (4.5 percent; see Table C-2). The prevalence of current premium cigar smoking was higher among adults at higher than (1.3 percent) or up to twice (0.5 percent) the poverty threshold than those in poverty (0.4 percent). The prevalence of current nonpremium cigar smoking was higher among adults living in poverty (5.4 percent) or with income up to twice the poverty threshold (4.0 percent) than those with higher income (2.3 percent).

## Tobacco and Substance Use Characteristics of Premium and Nonpremium Cigar Smokers

**Table C-3** presents tobacco use characteristics and alcohol and cannabis use history among civilian noninstitutionalized people aged 12+ living in the United States from 2010 to 2019 who currently smoke cigars. Relative to nonpremium cigar smokers, premium cigar smokers were less

likely to initiate cigar smoking before age 18, smoke cigars frequently or daily, smoke cigarettes, or use cannabis but were more likely to consume alcohol.

**Age first cigar smoked** Most current cigar smokers smoked their first cigar aged 18–29 (45.2 percent), followed by before 18 (38.0 percent), 30–49 (13.3 percent), and 50+ (3.5 percent). Among premium cigar smokers, a similar pattern was observed, with more than half (54.4 percent) initiating at 18–29 years and about one-fourth before 18 (24.5 percent). In contrast, nearly 45 percent of nonpremium cigar smokers initiated before 18.

**Number of days cigars smoked in the past 30 days** Premium cigar smokers were more likely than nonpremium cigar smokers to smoke cigars on 1 or 2 days in the previous month (60.3 percent versus 38.1 percent) and less likely to do so daily (3.5 percent versus 13.1 percent).

**Recency of established cigarette smoking** Cigarette smoking was much more common among nonpremium cigar smokers. Premium cigar smokers were about half as likely to be current established cigarette smokers (23.3 percent versus 50.7 percent). Most premium cigar smokers had quit cigarette smoking more than 3 years ago (21.8 percent) or never established it (47.5 percent), as compared to 8.0 and 35.1 percent of nonpremium cigar smokers, respectively.

**Recency of smokeless tobacco use** Smokeless tobacco use history differed minimally between premium and nonpremium cigar smokers. For both groups, about 13 percent were current smokeless tobacco users and a majority (49.1 percent of premium and 55.2 percent of nonpremium) had never used smokeless tobacco.

**Recency of pipe smoking** Tobacco pipe smoking history varied somewhat by cigar type, although for both groups, the majority had never used a pipe (61.7 percent of premium, 70.5 percent of nonpremium). Nonpremium cigar smokers were more likely than premium cigar smokers to also use a pipe (6.8 versus 4.8 percent).

**Recency of alcohol use** For both cigar types, alcohol consumption was common. However, premium cigar smokers were more likely than non-premium cigar smokers to currently consume alcohol (89.0 versus 74.9 percent) and less likely to have never done so (1.1 versus 4.1 percent).

**Recency of cannabis use** Cannabis use history differed notably by cigar type; nonpremium cigar smokers were more than twice as likely to have

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used it in the past month (40.7 versus 16.8 percent). Significantly more premium cigar smokers had never used it (24.7 versus 18.7 percent).

**Table C-3a** presents tobacco use characteristics and alcohol and cannabis use history among civilian noninstitutionalized people aged 18+ living in the United States from 2010 to 2019 who currently smoke cigars. The patterns are virtually identical to what was observed for the entire 12+ population.

### Trends in the Prevalence of Premium Versus Nonpremium Cigar Smoking (2010–2019)

Current nonpremium cigar smoking prevalence steadily declined 2010–2019 (from 3.4 to 2.7 percent). The prevalence of premium cigar smoking stayed almost unchanged (from 1.1 to 0.9 percent). By age group, the prevalence of premium cigar smoking slightly increased for individuals aged 50–64 (from 0.87 to 1.46 percent) and 65+ (from 0.25 to 0.48 percent) and slightly decreased for 12–17 (from 0.09 to 0.03 percent), 18–25 (from 1.12 to 0.84 percent), 26–34 (from 1.45 to 1.12 percent), and 35–49 (from 1.68 to 0.94 percent).

## Health Characteristics of Adult Premium and Nonpremium Cigar Smokers, Cigarette Smokers, and Nontobacco Users

**Table C-4** presents prevalence of medical, mental health, and substance dependence conditions among premium and nonpremium cigar smokers, current and former established cigarette smokers, and nontobacco users. These results are representative of civilian noninstitutionalized U.S. adults from 2015 to 2019. Relative to nonpremium cigar smokers, premium cigar smokers were more likely to have cancer but less likely to report COPD, SPD, a MDE, cannabis dependence, and illicit drug dependence. Premium cigar smokers and never-tobacco users had similar prevalence of cancer, heart condition, COPD, and asthma.

**Cancer** Former established cigarette smokers had the highest prevalence of cancer (10.5 percent) followed by adults who had not used tobacco in the past 30 days (7.1 percent) and never-tobacco users (5.2 percent). Cancer prevalence among premium cigar smokers (5.1 percent) was comparable to that of never-tobacco users. Nonpremium cigar smokers had the lowest prevalence (2.2 percent), likely reflecting the younger age distribution of this group.

**Heart condition**. Similar to cancer, prevalence of a heart condition was highest among former established cigarette smokers (17.8 percent), with both premium (8.0 percent) and nonpremium (7.4 percent) cigar smokers having marginally lower prevalence than current established cigarette smokers (8.8 percent) and never-tobacco users (8.4 percent).

**COPD** Prevalence of COPD was lowest among premium cigar smokers (1.7 percent) and never-tobacco users (2.3 percent) and highest among current (8.0 percent) and former (7.5 percent) established cigarette smokers. It was moderate for nonpremium cigar smokers (4.6 percent).

**Asthma** Asthma prevalence ranged from 8.8 percent among never-tobacco users to 10.4 percent among current nonpremium cigar smokers, with minimal variation across other groups.

**SPD** Past-month SPD was significantly more prevalent among current nonpremium cigar smokers (14.5 percent) than among any other group, including current cigarette smokers (11.3 percent); in contrast, premium cigar smokers had the lowest prevalence (2.7 percent).

**Major Depressive Disorder (MDE)** A similar pattern was observed for past-year MDE, with prevalence being highest among nonpremium cigar smokers (12.8 percent), followed by current cigarette smokers (11.1 percent). It was lowest among nonpremium cigar smokers (5.0 percent), who were similar to never-tobacco users (5.3 percent).

**Alcohol dependence** Prevalence of past-year alcohol dependence was marginally higher among nonpremium (9.6 percent) and premium (7.3 percent) cigar smokers and current cigarette smokers (7.3 percent). It was lowest among never-tobacco users (0.8 percent).

**Cannabis dependence** Past-year cannabis dependence was significantly more prevalent among nonpremium cigar smokers (7.4 percent) than any other group, being nearly threefold higher relative to current cigarette smokers (2.5 percent) and more than five times higher than premium cigar smokers (1.3 percent). It was lowest for never-tobacco users (0.2 percent).

**Illicit drug dependence** Past-year illicit (other than cannabis) drug dependence was significantly higher among nonpremium cigar smokers (5.8 percent) than any other group, including current and former cigarette smokers (4.8 percent), and lowest among never-tobacco users (0.2 percent). Prevalence among premium cigar smokers was 1.9 percent.

**Pregnancy** Pregnancy was uncommon for all groups, ranging from approximately 0 percent among premium cigar smokers to 1.1 percent among never-tobacco users.

### Multivariable Associations Between Premium Cigar Smoking and Health Conditions

**Table C-5** presents age- and sex-adjusted associations between premium cigar smoking and odds of medical, mental health, and substance dependence conditions. These results are representative of civilian noninstitutionalized U.S. adults from 2015 to 2019.

**Premium versus nonpremium cigar smoking** Relative to nonpremium cigar smoking, premium cigar smoking was significantly associated with 83 percent increased odds of having cancer, but this was the only positive association. Premium cigar smokers had significantly lower odds of COPD (OR: 0.32), past-month SPD (OR: 0.23), past-year MDE (OR: 0.50), alcohol dependence (OR: 0.75), cannabis dependence (OR: 0.26), and illicit drug dependence (OR: 0.34) compared to nonpremium cigar smokers. No significant association was observed for heart condition, asthma, or pregnancy.

**Premium versus nonpremium cigar smoking, additionally adjusted for smoking status** Upon adjusting for established cigarette smoking status, the observed association between premium cigar type and cancer or alcohol dependence attenuated and became no longer significant (ORs: 1.67 and 1.94, respectively). However, the negative associations with COPD, SPD, MDE, cannabis dependence, and illicit drug dependence persisted.

**Premium cigar smoking versus never-tobacco use** Compared to never-tobacco users, premium cigar smokers had increased odds of cancer (OR: 1.47), alcohol dependence (OR: 7.99), cannabis dependence (OR: 8.30) and illicit drug dependence (OR: 7.22) and decreased odds of past-month SPD (OR: 0.67) and pregnancy (OR: 0.15). No significant associations were observed for heart condition, asthma, or past-year MDE.

**Premium cigar smoking versus current/former established cigarette smoking** Compared to current or former established tobacco users, premium cigar smoking was not significantly associated with having cancer (OR: 1.09), a heart condition (OR: 0.69), asthma (OR: 1.16), or alcohol dependence (OR: 0.93). However, premium cigar smokers had significantly lower odds of COPD (OR: 0.19), past-month SPD (OR: 0.29), past-

year MDE (OR: 0.63), cannabis dependence (OR: 0.35), illicit drug dependence (OR: 0.08), and pregnancy (OR: 0.12).

#### SUMMARY AND LIMITATIONS

Overall, premium cigar smoking is less prevalent than nonpremium cigar smoking, especially among priority populations, including youth, racial and ethnic populations, those without a high school education, and those living in poverty. People who smoke premium cigars tend to do so infrequently and initiate later in life, relative to people who smoke nonpremium cigars. Premium cigar smokers are also less likely to also be established cigarette smokers or cannabis users. Finally, premium cigar smoking is negatively associated with poor mental health outcomes, COPD, and substance use relative to nonpremium cigar and established cigarette smoking.

These results should be reviewed in light of several limitations. First, cigar type is subject to misclassification for several reasons. Cigar brand was only assessed among past-30-day cigar smokers; thus, we were unable to classify cigar type among former cigar smokers. Additionally, information was insufficient to determine cigar type for a small proportion of past-30-day cigar smokers, and some respondents cited a cigarette brand when asked about their usual cigar brand, suggesting potential confusion about the cigar question. These respondents were excluded from analysis, but additional research into this observation is warranted.

A second set of limitations is related to the design and data source. The NSDUH sampling design excludes noncivilian and institutionalized populations who may have different tobacco use patterns than the general U.S. population. These results may not apply to these excluded populations. Additionally, the cross-sectional nature of this study prohibits inference about temporal associations, and data are based on self-report and subject to response bias. Moreover, prevalence estimates for health effects are not age adjusted and thus should be interpreted with caution, given that several of the reported health outcomes and premium cigar smoking are both positively associated with age. Although the reported ORs are adjusted for age and sex, they do not control for other potentially important confounders.

Finally, due to small numbers, particularly for subgroups of premium cigar smokers, some point estimates lacked adequate precision and could not be reported.

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Age Group										
12 to 17 years	4.5	(4.3 , 4.7)	6.0	(5.7 , 6.2)	0.6	(0.5, 0.8)	, 0.8)	3.4	(3.0	(3.0, 3.8)
18 to 25 years	26.4	(25.7 , 27.1)	32.5	(31.6 , 33.4)	13.5	(12.4 , 14.7)	, 14.7)	17.5	(16.2	(16.2 , 19.0)
26 to 34 years	21.5	(20.8, 22.3)	21.5	(20.6 , 22.3)	23.1	(21.4 , 25.0)	, 25.0)	19.8	(18.0 , 21.8)	, 21.8)
35 to 49 years	22.8	(22.0 , 23.5)	21.0	(20.0 , 21.9)	28.2	(26.3 , 30.3)	, 30.3)	23.4	(21.4 , 25.6)	, 25.6)
50 to 64 years	18.4	(17.3 , 19.5)	14.2	(13.2 , 15.3)	26.6	(23.9 , 29.4)	, 29.4)	25.1	(22.3	(22.3 , 28.0)
65 years or older	6.4	(5.9 , 7.0)	4.9	(4.3 , 5.5)	7.9	(6.5 , 9.6)	, 9.6)	10.8	(9.1	(9.1 , 12.6)
Gender										
Male	78.7	(78.0 , 79.3)	74.2	(73.4 , 75.1)	93.7	93.7 (92.7 , 94.7)	, 94.7)	78.5	(76.4, 80.4)	, 80.4)
Female	21.3	(20.7 , 22.0)	25.8	(24.9 , 26.6)	6.3	(5.3,7.3)	, 7.3)	21.5	(19.6 , 23.6)	, 23.6)
Race/Ethnicity										
Non-Hispanic White	64.7	64.7 (63.8 , 65.6)	57.7	(56.5 , 58.8)	78.0	78.0 (76.0 , 79.9)	, 79.9)	76.7	76.7 (75.1,78.3)	, 78.3)
Non-Hispanic Black	18.9	(18.2 , 19.7)	25.7	(24.7 , 26.8)	5.5	(4.5, 6.7)	, 6.7)	8.1	(7.0	(7.0, 9.3)
Non-Hispanic American Indian/Alaskan Native	0.6	(0.5 , 0.7)	0.8	(0.7 , 0.9)	0.3	(0.2 , 0.5)	, 0.5)	0.5	(0.3	(0.3, 0.8)
Non-Hispanic Native Hawaiian/Pacific Islander	0.3	(0.2, 0.4)	0.4	(0.3 , 0.5)	0.2	(0.1, 0.7)	, 0.7)	0.1	(0.0)	(0.0, 0.1)
Non-Hispanic Asian	1.6	(1.4 , 1.9)	1.1	(0.9, 1.4)	2.6	(1.9, 3.5)	, 3.5)	2.7	(2.0	(2.0 , 3.6)
Non-Hispanic Other/Multiple Race(s)	2.4	(2.2 , 2.6)	2.9	(2.6 , 3.3)	1.3	(0.9, 1.8)	, 1.8)	1.6	(1.2	(1.2 , 2.0)
Hispanic	11.4	(10.9 , 12.0)	11.5	(10.8 , 12.1)	12.1	(10.5, 14.0)	, 14.0)	10.5	(9.1	(9.1 , 12.0)

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Sexual Identity <sup>a</sup>										
Heterosexual or straight	92.3	92.3 (91.7 , 92.9)	89.6	(91.1 , 0.0)	97.5	97.5 (96.3 , 98.3)	, 98.3)	93.3	93.3 (91.9 , 94.5)	94.5)
Lesbian or gay	2.5	(2.2 , 2.9)	3.1	(2.6 , 3.6)	0.9		(0.5, 1.6)	2.4	(1.7, 3.5)	3.5)
Bisexual	5.2	(4.7 , 5.6)	6.6	(6.0 , 7.2)	1.6	(1.0 , 2.5)	, 2.5)	4.3	(3.3 , 5.5)	5.5)
Education										
Did not complete high school	14.6	14.6 (14.0 , 15.3)	18.9	(18.0 , 19.9)	3.7	3.7 (2.9 , 4.8)	, 4.8)	10.4	(9.0 , 12.2)	12.2)
High school diploma or GED	27.5	(26.8 , 28.2)	32.9	(32.0,33.9)	15.8	15.8 (14.3 , 17.4)	, 17.4)	20.2	(18.3, 22.3)	22.3)
Some college/technical school	30.5	(29.7, 31.4)	30.1	(29.0 , 31.2)	32.3	(30.5	(30.5, 34.3)	30.2	(28.0, 32.4)	32.4)
College graduate	22.8	22.8 (22.0 , 23.6)	12.1	(11.3 , 12.8)	47.5	47.5 (45.5 , 49.6)	, 49.6)	35.7	(33.3 , 38.3)	38.3)
Under 18	4.5	(4.3,4.7)	6.0	(5.7 , 6.2)	0.6	(0.5, 0.8)	, 0.8)	3.4	(3.0 , 3.8)	3.8)
Metro Status										
Large metro	54.3	(53.3 , 55.2)	50.5	(49.3,51.8)	65.0	65.0 (62.8 , 67.1)	, 67.1)	56.4	(53.7 , 59.0)	59.0)
Small metro	31.9	(31.0, 32.9)	33.0	(32.0,34.0)	28.5	(26.5, 30.6)	, 30.6)	31.7	(29.1, 34.4)	34.4)
Nonmetro	13.8	(13.2, 14.5)	16.5	(15.7 , 17.4)	6.5	(5.6 , 7.6)	, 7.6)	11.9	(10.5, 13.5)	13.5)
Poverty level										
Living in poverty	19.5	(18.8, 20.2)	24.9	(24.0 , 25.8)	5.8	5.8 (4.9 , 6.7)	, 6.7)	14.4	(13.0 , 16.0)	16.0)
Up to 2x threshold	20.9	(20.2, 21.5)	25.3	(24.4 , 26.3)	9.6		(8.3, 10.9)	16.8	(15.1 , 18.6)	18.6)
Greater than 2x threshold	59.6	(58.7, 60.5)	49.8	(48.6 , 50.9)	84.7	84.7 (83.1, 86.2)	, 86.2)	68.7	68.7 (66.4 , 71.0)	71.0)
<sup><i>a</i></sup> Estimates for sexual identity categories were calculated using data from adult (ages 18+) respondents in years 2015 through 2019, because questions about sexual identity were added to NSDUH in 2015 and asked of adult respondents only.	ed usi 2015 (	ng data from a and asked of a	adult (a dult res	ges 18+) respor pondents only.	i dents i	n years	\$ 2015 th	nrough	2019, 1	ecause

questions about sexual identity were added to NSDUH in 2015 and asked of adult respondents only. NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval.

Premium Cigars: Patterns of Use, Marketing, and Health Effects

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Cte	ABLE C-2 Prevalence of past 30-day premium and n haracteristics, 2010–2019 NSDUH
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TABLE C-2 Prevalence of past 30-day premium and nonpremium cigar smoking by demographic characteristics, 2010–2019 NSDUH	remiu	m and non	premiu	ım cigar smo	king l	yy demogra	ıphic	
	Any	Any Cigar Type	IduoN	Nonpremium Cigars	Pren	Premium Cigars	Unk	Unknown Type
	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)
Overall	4.7	(4.6 , 4.8)	3.0	(2.9, 3.1)	0.9	(0.8, 0.9)	0.8	(0.7 , 0.8)
Age Group								
12 to 17 years	2.3	(2.2 , 2.3)	1.9	(1.8 , 2.0)	0.1	(0.0, 0.1)	0.3	(0.3, 0.3)
18 to 25 years	9.5	(9.3, 9.7)	7.5	(7.4 , 7.7)	0.9	(0.9, 1.0)	1.1	(1.0, 1.1)
26 to 34 years	7.0	(6.7, 7.3)	4.5	(4.3,4.7)	1.4	(1.3, 1.6)	1.1	(1.0 , 1.2)
35 to 49 years	4.6	(4.5, 4.8)	2.7	(2.6 , 2.9)	1.1	(1.0, 1.2)	0.8	(0.7 , 0.9)
50 to 64 years	3.7	(3.5, 4.0)	1.8	(1.7 , 2.0)	1.0	(0.9 , 1.2)	0.8	(0.7, 1.0)
65 years or older	1.7	(1.6 , 1.9)	0.8	(0.7 , $1.0)$	0.4	(0.3, 0.5)	0.5	(0.4 , 0.6)
Gender								
Male	7.6	(7.4,7.8)	4.6	(4.5 , 4.7)	1.7	(1.6, 1.8)	1.3	(1.2 , 1.3)
Female	1.9	(1.9 , 2.0)	1.5	(1.4, 1.6)	0.1	(0.1, 0.1)	0.3	(0.3, 0.4)
Race/Ethnicity								
Non-Hispanic White	4.7	(4.6, 4.8)	2.7	(2.6 , 2.8)	1.1	(1.0 , 1.2)	0.9	(0.9, 1.0)
Non-Hispanic Black	7.4	(7.1 , 7.7)	6.5	(6.2 , 6.8)	0.4	(0.3, 0.5)	0.5	(0.5 , 0.6)
Non-Hispanic American Indian/Alaskan Native	5.4	(4.7, 6.1)	4.2	(3.7,4.9)	0.5	(0.3, 0.9)	0.7	(0.4, 1.1)
Non-Hispanic Native Hawaiian/Pacific Islander	3.6	(2.8 , 4.8)	3.0	(2.2,4.1)	0.5	(0.2, 1.6)	0.1	(0.0 , 0.3)
Non-Hispanic Asian	1.4	(1.2 , 1.7)	0.6	(0.5 , 0.8)	0.4	(0.3, 0.6)	0.4	(0.3, 0.5)
Non-Hispanic Other/Multiple Race(s)	6.6	(5.9 , 7.3)	5.2	(4.6 , 5.8)	0.7	(0.5, 0.9)	0.7	(0.0 , 0.0)
Hispanic	3.3	(3.2, 3.5)	2.1	(2.0 , 2.3)	0.7	(0.6 , 0.8)	0.5	(0.4, 0.6)

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Sexual Identity <sup>a</sup>								
Heterosexual or straight	4.6	(4.5,4.8)	2.9	(2.7,3.0)	1.0	(0.9, 1.1)	0.8	(0.7 , 0.8)
Lesbian or gay	6.3	(5.5 , 7.2)	4.8	(4.1 , 5.6)	0.5	(0.3, 0.8)	1.0	(0.7, 1.5)
Bisexual	7.9	(7.2, 8.6)	6.3	(5.7,7.0)	0.5	(0.3, 0.8)	1.1	(0.8, 1.4)
Education								
Did not complete high school	5.6	(5.4, 5.9)	4.7	(4.4 , 5.0)	0.3	(0.2, 0.4)	0.7	(0.6 , 0.8)
High school diploma or GED	5.2	(5.1, 5.4)	4.0	(3.9 , 4.1)	0.6	(0.5, 0.6)	0.6	(0.6 , 0.7)
Some college/technical school	5.5	(5.3, 5.7)	3.5	(3.3, 3.6)	1.1	(1.0 , 1.2)	0.9	(0.8, 1.0)
College graduate	3.8	(3.7,4.0)	1.3	(1.2, 1.4)	1.5	(1.4, 1.6)	1.0	(0.9, 1.1)
Under 18	2.3	(2.2 , 2.3)	1.9	(1.8 , 2.0)	0.1	(0.0, 0.1)	0.3	(0.3, 0.3)
Metro Status								
Large metro	4.6	(4.5,4.7)	2.8	(2.7 , 2.9)	1.1	(1.0, 1.1)	0.8	(0.8 , 0.9)
Small metro	5.0	(4.8, 5.1)	3.3	(3.2, 3.4)	0.8	(0.8 , 0.9)	0.8	(0.7 , 0.9)
Nonmetro	4.3	(4.1,4.5)	3.3	(3.1,3.5)	0.4	(0.3, 0.5)	0.6	(0.5 , 0.7)
Poverty level								
Living in poverty	6.1	(5.9, 6.3)	5.0	(4.8 , 5.2)	0.3	(0.3, 0.4)	0.7	(0.7 , 0.8)
Up to 2x threshold	4.8	(4.7, 5.0)	3.8	(3.6,3.9)	0.4	(0.4, 0.5)	0.7	(0.6 , 0.7)
Greater than 2x threshold	4.3	(4.2, 4.4)	2.3	(2.2 , 2.4)	1.2	(1.1 , 1.2)	0.8	(0.8 , 0.9)
<sup><i>a</i></sup> Estimates for sexual identity categories were calculated using data from adult (ages 18+) respondents in years 2015 through 2019, because questions about sexual identity were added to NSDUH in 2015 and asked of adult respondents only.	in 201	ing data from 5 and asked of	adult (ag f adult ree	es 18+) responde spondents only.	ents in y	ears 2015 throu	ıgh 2019	9, because

NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval.

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IABLE C-2a Prevalence of past 30-day premium and nonpremium cigar smoking among youth ages 12 to	npremium cigar	smoking among y	outh ages 12 to
17 by demographic characteristics, 2010–2019 NSDUH			
Any Cigar Tyme	Nonpremium Cigar	Monvremium Cioars Premium Cioars Hhknown Tyne	Huknown Twee

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<b>TABLE C-2a</b> Prevalence of past 30-day premium and nonpremium cigar smoking among youth ages 12 to 17 by demographic characteristics, 2010–2019 NSDUH	oremi -2019	um and nc NSDUH	nprem	ıium cigar sı	nokir	ıg among y	outh	ages 12 to
	Any	Any Cigar Type	Nonpr	Nonpremium Cigars	Pren	Premium Cigars	Unk	Unknown Type
	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)
Overall	2.3	(2.2, 2.3)	1.9	(1.8 , 2.0)	0.1	(0.0, 0.1)	0.3	(0.3, 0.3)
Gender								
Male	2.9	(2.8, 3.1)	2.6	(2.4 , 2.7)	0.1	(0.1, 0.1)	0.3	(0.2, 0.3)
Female	1.5	(1.4, 1.7)	1.2	(1.1, 1.3)	0.0	(0.0 , 0.0)	0.3	(0.2, 0.3)
Race/Ethnicity								
Non-Hispanic White	2.7	(2.6 , 2.9)	2.3	(2.2 , 2.4)	0.1	(0.1, 0.1)	0.4	(0.3, 0.4)
Non-Hispanic Black	2.1	(1.9, 2.4)	2.0	(1.7 , 2.2)	ł	:	0.1	(0.1 , 0.2)
Non-Hispanic American Indian/Alaskan Native	2.4	(1.6, 3.7)	2.1	(1.4 , 3.2)		:	I	1
Non-Hispanic Native Hawaiian/Pacific Islander	I	:	-			:	I	1
Non-Hispanic Asian	0.6	(0.4, 0.9)	0.4	(0.3 , 0.7)	I	:	I	1
Non-Hispanic Other/Multiple Race(s)	2.6	(2.2, 3.0)	2.3	(1.9 , 2.7)	ł	:	0.2	(0.2, 0.4)
Hispanic	1.6	(1.4, 1.8)	1.3	(1.2 , 1.5)	I	1	0.2	(0.2, 0.3)
Metro Status								
Large metro	1.9	(1.8 , 2.1)	1.6	(1.5 , 1.7)	0.1	(0.0, 0.1)	0.3	(0.2, 0.3)
Small metro	2.6	(2.4 , 2.8)	2.2	(2.1 , 2.4)	0.1	(0.0, 0.1)	0.3	(0.2, 0.3)
Nonmetro	2.8	(2.6, 3.1)	2.5	(2.3 , 2.7)	0.1	(0.0, 0.1)	0.3	(0.2, 0.4)

level	
overty	
Ă	

2.4 (2.2 , 2.6) 2.1 (1.9 , 2.3) 0.3 (0.2 , 0.4)	2.3 (2.1, 2.5) 2.0 (1.9, 2.2) 0.2 (0.2, 0.3)	2.2 (2.1, 2.3) 1.8 (1.7, 1.9) 0.1 (0.1, 0.1) 0.3 (0.3, 0.4)
Living in poverty	Up to 2x threshold	Greater than 2x threshold

age 18, because questions about sexual identity were added to NSDUH in 2015 and asked of adult respondents only. Prevalence by educational attainment is not reported, because it is not relevant for school-aged youth under age 18. Estimates for which the coefficient of variation (CV) NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval. Data on sexual identity is not available for youth under exceeded 0.3 were deemed statistically unreliable and not reported and are denoted with ---

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ABLE C-2b Prevalence	ance of past 30-day premium and nonpremium cigar smoking among adults ages 18+ by
UNDER PLANTIC CITATION	

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	Any	Any Cigar Type	Nonpr	Nonpremium Cigars	Pren	Premium Cigars	Unk	Unknown Type
	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)
Overall	4.9	(4.8, 5.0)	3.1	(3.0 , 3.2)	1.0	(0.9 , 1.0)	0.8	(0.8, 0.9)
Age Group								
18 to 25 years	9.5	(9.3, 9.7)	7.5	(7.4 , 7.7)	0.9	(0.9, 1.0)	1.1	(1.0, 1.1)
26 to 34 years	7.0	(6.7, 7.3)	4.5	(4.3,4.7)	1.4	(1.3 , 1.6)	1.1	(1.0 , 1.2)
35 to 49 years	4.6	(4.5, 4.8)	2.7	(2.6 , 2.9)	1.1	(1.0 , 1.2)	0.8	(0.7 , 0.9)
50 to 64 years	3.7	(3.5, 4.0)	1.8	(1.7 , 2.0)	1.0	(0.9 , 1.2)	0.8	(0.7, 1.0)
65+ years	1.7	(1.6, 1.9)	0.8	(0.7, 1.0)	0.4	(0.3, 0.5)	0.5	(0.4, 0.6)
Gender								
Male	8.1	(7.9, 8.3)	4.8	(4.7 , 5.0)	1.9	(1.8 , 2.0)	1.4	(1.3 , 1.5)
Female	2.0	(1.9 , 2.0)	1.5	(1.5 , 1.6)	0.1	(0.1, 0.1)	0.3	(0.3, 0.4)
Race/Ethnicity								
Non-Hispanic White	4.9	(4.8, 5.0)	2.7	(2.7 , 2.8)	1.2	(1.1, 1.3)	1.0	(0.9, 1.0)
Non-Hispanic Black	8.1	(7.7, 8.4)	7.0	(6.7 , 7.3)	0.5	(0.4, 0.6)	0.6	(0.5, 0.7)
Non-Hispanic American Indian/Alaskan Native	5.7	(4.9, 6.6)	4.5	(3.9 , 5.2)	0.5	(0.3, 1.0)	0.7	(0.4 , 1.2)
Non-Hispanic Native Hawaiian/Pacific Islander	3.9	(3.0 , 5.2)	3.2	(2.3 , 4.5)	0.6	(0.2, 1.8)	0.1	(0.0 , 0.3)
Non-Hispanic Asian	1.5	(1.3, 1.8)	0.6	(0.5 , 0.8)	0.5	(0.4, 0.6)	0.4	(0.3, 0.6)
Non-Hispanic Other/Multiple Race(s)	7.4	(6.6 , 8.2)	5.8	(5.1, 6.5)	0.8	(0.6, 1.1)	0.8	(0.6, 1.1)
Hispanic	3.6	(3.4 , 3.8)	2.3	(2.1 , 2.4)	0.8	(0.7 , 0.9)	0.6	(0.5 , 0.6)

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Sexual Identity <sup>a</sup>									
Heterosexual or straight	4.6	(4.5, 4.8)	2.9	(2.7 , 3.0)	3.0)	1.0	(0.9, 1.1)	0.8	(0.7, 0.8)
Lesbian or gay	6.3	(5.5 , 7.2)	4.8	(4.1 , 5.6)	5.6)	0.5	(0.3, 0.8)	1.0	(0.7 , 1.5)
Bisexual	7.9	(7.2, 8.6)	6.3	(5.7 , 7.0)	7.0)	0.5	(0.3, 0.8)	1.1	(0.8 , 1.4)
Education									
Did not complete high school	5.6	(5.4,5.9)	4.7	(4.4 , 5.0)	5.0)	0.3	(0.2, 0.4)	0.7	(0.6 , 0.8)
High school diploma or GED	5.2	(5.1,5.4)	4.0	(3.9 , 4.1)	4.1)	0.6	(0.5, 0.6)	0.6	(0.6 , 0.7)
Some college/technical school	5.5	(5.3, 5.7)	3.5	(3.3 , 3.6)	3.6)	1.1	(1.0 , 1.2)	0.9	(0.8, 1.0)
College graduate	3.8	(3.7,4.0)	1.3	(1.2, 1.4)	1.4)	1.5	(1.4, 1.6)	1.0	(0.9, 1.1)
Under 18		:		•			:		•
Metro Status									
Large metro	4.9	(4.8, 5.0)	2.9	(2.8, 3.0)	3.0)	1.2	(1.1 , 1.2)	0.9	(0.8, 0.9)
Small metro	5.2	(5.0,5.4)	3.4	(3.3 , 3.5)	3.5)	0.9	(0.8, 1.0)	0.9	(0.8, 1.0)
Nonmetro	4.5	(4.3,4.7)	3.4	(3.2 , 3.6)	3.6)	0.4	(0.4, 0.5)	0.7	(0.6 , 0.8)
Poverty level									
Living in poverty	6.6	(6.4, 6.9)	5.4	(5.2 , 5.6)	5.6)	0.4	(0.3, 0.5)	0.8	(0.7, 0.9)
Up to 2x threshold	5.1	(4.9, 5.3)	4.0	(3.8,4.1)	4.1)	0.5	(0.4, 0.5)	0.7	(0.6 , 0.8)
Greater than 2x threshold	4.5	(4.4 , 4.6)	2.3	(2.3 , 2.4)	2.4)	1.3	(1.2, 1.3)	0.9	(0.8 , 0.9)
<sup><i>a</i></sup> Estimates for sexual identity categories were calculated using data from years 2015 through 2019, because questions about sexual identity were added to NSDUH in 2015.	ed usir	ıg data from ye	ears 2015	throug	gh 2019, be	cause o	questions abo	ut sexua	l identity

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NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval.

ABLE C-3	ABLE C-3 Tobacco and substance use characteristics of individuals who currently (past	the use characteristics	s of individuals who	io currently (	(past-30-days)	smok
remium a	remium and nonpremium cigars, 2010-2019 INSDUH	HUULENI VIULAUUU				

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		I	Nor	Nonpremium	1	i		I	
	Any Cig	Any Cigar Type	-	Cigars	Prem	Premium Cigars	Unl	Unknown Type	ype
	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	CI)
Age first smoked cigar									
Less than 18 years	38.0	(37.1, 38.8)	44.9	(43.8,45.9)	24.5	(22.5 , 26.6)	27.1	(25.3 , 29.0)	29.0)
18 to 29 years	45.2	(44.3, 46.1)	41.2	(40.1,42.2)	54.1	(52.0,56.3)	50.6	(48.2 , 53.0)	53.0)
30 to 49 years	13.3	(12.5 , 14.1)	11.3	(10.4, 12.3)	17.2	(15.2, 19.4)	16.3	(14.3 , 18.6)	18.6)
50 years or older	3.5	(3.1 , 4.0)	2.7	(2.2, 3.2)	4.2	(3.1 , 5.7)	6.0	(4.6 , 7.8)	7.8)
Past 30 days, number of days									
1 or 2 days	46.0	(45.1,46.9)	38.1	(37.0, 39.3)	60.3	(57.9 , 62.7)	59.8	(57.6 , 62.0)	62.0)
3 to 5 days	20.4	(19.8, 21.2)	21.8	(21.0 , 22.7)	21.5	(19.2,24.0)	13.8	(12.2 , 15.6)	15.6)
6 to 9 days	5.0	(4.6, 5.4)	5.5	(5.1, 6.0)	4.5	(3.5 , 5.6)	3.8	(2.9 , 4.9)	4.9)
10 to 19 days	11.2	(10.6 , 11.7)	13.7	(13.0, 14.4)	6.1	(5.1,7.3)	7.3	(6.0 , 8.9)	8.9)
20 to 29 days	6.5	(6.0 , 6.9)	7.7	(7.1, 8.3)	4.1	(3.1,5.5)	4.6	(3.6 , 5.9)	5.9)
30 days	10.9	(10.2 , 11.5)	13.1	(12.4 , 13.9)	3.5	(2.5 , 4.7)	10.7	(9.0 , 12.6)	12.6)
Recency of established cigarette smoking <sup>a</sup>									
Past 30 days	42.9	(41.9 , 43.8)	50.7	(49.6,51.9)	23.3	(21.5 , 25.2)	35.0	(32.4 , 37.7)	37.7)
30 days to 1 year ago	3.7	(3.3 , 4.0)	3.5	(3.2, 3.9)	4.1	(3.2 , 5.1)	3.7	(2.9 , 4.8)	4.8)
1 to 3 years ago	2.7	(2.5 , 3.0)	2.6	(2.3 , 2.9)	3.3	(2.6, 4.1)	2.6	(1.9, 3.6)	3.6)
More than 3 years ago	12.0	(11.1 , 12.8)	8.0	(7.3, 8.9)	21.8	(19.8 , 24.0)	15.7	(13.8, 17.9)	17.9)
Never established	38.8	(37.9 , 39.7)	35.1	(34.2 , 36.0)	47.5	(45.0, 50.0)	42.9	(40.2,45.8)	45.8)

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Recency of SLT use									
Past 30 days	12.1	(11.3, 13.0)	12.5	(11.6 , 13.4)	12.9	(10.7, 15.4)	10.0	(8.2 , 12.2)	
30 days to 1 year ago	5.3	(4.9 , 5.7)	6.1	(5.6 , 6.6)	3.6	(2.7, 4.6)	4.0	(3.1,5.3)	
1 to 3 years ago	6.1	(5.6 , 6.6)	6.8	(6.2, 7.4)	5.8	(4.5 , 7.4)	3.9	(3.0, 5.1)	
More than 3 years ago	22.1	(20.8, 23.3)	19.4	(18.1, 20.8)	28.7	(25.2, 32.4)	25.0	(21.9 , 28.3)	
Never used	54.4	(53.0 , 55.8)	55.2	(53.6 , 56.9)	49.1	(45.5 , 52.7)	57.0	(53.8, 60.1)	
Recency of pipe smoking									
Past 30 days	6.2	(5.8 , 6.7)	6.8	(6.2,7.4)	4.8	(4.1 , 5.7)	5.7	(4.7, 6.9)	
More than 30 days ago	26.2	(25.3 , 27.1)	22.7	(21.8 , 23.7)	33.5	(31.2 , 35.8)	31.2	(28.9 , 33.7)	
Never used	67.6	(66.6 , 68.5)	70.5	(69.5 , 71.4)	61.7	(59.2,64.1)	63.0	(60.3 , 65.6)	
Recency of alcohol consumption									
Past 30 days	78.7	(77.9 , 79.5)	74.9	(74.1 , 75.8)	89.0	(87.2 , 90.6)	81.4	(79.3 , 83.2)	
30 days to 1 year ago	10.3	(9.8 , 10.9)	12.8	(12.2, 13.4)	4.8	(3.7, 6.3)	7.2	(6.1, 8.5)	
More than 1 year ago	7.6	(7.2 , 8.1)	8.2	(7.6 , 8.9)	5.1	(4.0, 6.4)	8.3	(6.9, 10.0)	
Never used	3.3	(3.0,3.7)	4.1	(3.6 , 4.6)	1.1	(0.7, 1.6)	3.1	(2.5, 3.9)	
Recency of cannabis use									
Past 30 days	32.9	(32.1, 33.8)	40.7	40.7 (39.7, 41.8)	16.8	16.8 (15.2 , 18.6)	21.4	(19.9 , 23.1)	
30 days to 1 year ago	11.0	(10.4, 11.5)	11.5	(10.9 , 12.2)	9.7	(8.5 , 11.1)	10.4	(9.1 , 11.7)	
More than 1 year ago	34.8	(33.8 , 35.7)	29.1	(28.0 , 30.2)	48.8	(46.4 , 51.2)	40.6	(38.4 , 42.8)	
Never used	21.3	(20.5 , 22.2)	18.7	(17.8 , 19.7)	24.7	(22.8 , 26.6)	27.6	(25.4,30.0)	
$^{a}$ Established cigarette smoking defined as having smoked at least 100 cigarettes.	d as having smok	ed at least 100 cigar	tettes.						

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NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval.

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<b>TABLE C-3a</b> Tobacco and substance use characteristics of adults ages 18+ who currently (past-30-days) smoke premium and nonpremium cigars, 2010–2019 NSDUH	acco and substance use characteristics of ad and nonpremium cigars, 2010–2019 NSDUH	haraci 2010–	teristic 2019 N	s of ad ISDUH	ults ag	ges 18+	- who	currer	ıtly (pa	st-30-c	lays)	
	Any Cigar Type	ır Type		Nonpre	Nonpremium Cigars	Cigars	Prem	Premium Cigars	gars	Unkn	Unknown Type	pe
	%	(95% CI)	CI)	%	(95% CI)	CI)	%	(95% CI)	CI)	%	(95% CI)	CI)
Age first smoked cigar												
Less than 18 years	35.1	(34.2	(34.2 , 35.9)	41.3	(40.3)	(40.3,42.4)	24.0	(22.1	(22.1 , 26.2)	24.5	(22.7 , 26.4)	, 26.4)
18 to 29 years	47.4	(46.4	(46.4 , 48.3)	43.8	(42.7	(42.7 , 44.9)	54.4	(52.3	(52.3 , 56.6)	52.4	(49.9 , 54.9)	, 54.9)
30 to 49 years	13.9	(13.1	(13.1 , 14.8)	12.1	(11.1)	(11.1 , 13.1)	17.3	(15.3)	(15.3, 19.5)	16.9	(14.8, 19.3)	, 19.3)
50 years or older	3.7	(3.2	(3.2, 4.2)	2.8	(2.4	(2.4,3.4)	4.2	(3.1	(3.1,5.7)	6.2	(4.8, 8.1)	, 8.1)
Past 30 days, number of days												
1 or 2 days	45.8	(44.8	(44.8, 46.7)	37.6	(36.4	(36.4 , 38.8)	60.3	(57.9	(57.9 , 62.7)	59.3	(56.9 , 61.5)	, 61.5)
3 to 5 days	20.3	(19.6	(19.6 , 21.0)	21.6	(20.7	(20.7 , 22.5)	21.5	(19.2	(19.2 , 24.0)	13.8	(12.1 , 15.7)	, 15.7)
6 to 9 days	5.0	(4.6	(4.6 , 5.4)	5.5	(5.0)	(5.0, 6.0)	4.4	(3.5	(3.5,5.6)	3.8	(2.9 , 5.0)	, 5.0)
10 to 19 days	11.1	(10.6)	(10.6 , 11.7)	13.7	(13.0)	(13.0 , 14.4)	6.1	(5.1	(5.1,7.3)	7.4	(6.0, 9.1)	, 9.1)
20 to 29 days	6.6	(6.1)	(6.1,7.1)	7.8	(7.3	(7.3, 8.5)	4.1	(3.1	(3.1 , 5.5)	4.7	(3.7 , 6.0)	, 6.0)
30 days	11.3	(10.6)	(10.6 , 12.0)	13.8	(13.0)	(13.0 , 14.7)	3.5	(2.5	(2.5 , 4.7)	11.0	(9.3	(9.3, 13.0)
Recency of established cigarette smoking <sup>a</sup>												
Past 30 days	43.4	(42.4	(42.4 , 44.4)	51.8	(50.7	(50.7 , 53.0)	23.4	(21.5	(21.5 , 25.3)	35.5	(32.8 , 38.3)	, 38.3)
30 days to 1 year ago	3.8	(3.4	(3.4, 4.1)	3.6	(3.3	(3.3,4.0)	4.1	(3.2	(3.2 , 5.2)	3.8	(3.0 , 5.0)	, 5.0)
1 to 3 years ago	2.8	(2.6	(2.6 , 3.1)	2.7	(2.4	(2.4 , 3.1)	3.3	(2.6	(2.6, 4.1)	2.7	(2.0, 3.7)	, 3.7)
More than 3 years ago	12.5	(11.7)	(11.7 , 13.4)	8.5	(7.7	(7.7, 9.4)	22.0	(19.9	(19.9 , 24.2)	16.3	(14.3 , 18.5)	, 18.5)
Never established	37.5	(36.6	(36.6 , 38.4)	33.3	(32.3	(32.3 , 34.2)	47.3	(44.8	(44.8, 49.8)	41.7	(38.9 , 44.6)	, 44.6)

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Recency of SLT use								
Past 30 days	11.6	(10.8 , 12.5)	11.8	(10.8 , 12.8)	12.7	(10.5, 15.3)	9.6	(8.0 , 12.2)
30 days to 1 year ago	4.9	(4.4 , 5.3)	5.5	(5.0, 6.1)	3.5	(2.7 , 4.6)	3.9	(2.9 , 5.2)
1 to 3 years ago	6.0	(5.5 , 6.6)	6.6	(6.0 , 7.3)	5.8	(4.5 , 7.4)	3.9	(2.9 , 5.1)
More than 3 years ago	23.1	(21.8 , 24.5)	20.6	(19.2 , 22.1)	28.9	(25.4 , 32.7)	26.0	(22.8 , 29.5)
Never used	54.4	(52.9,55.9)	55.5	(53.7 , 57.2)	49.1	(45.5 , 52.7)	56.4	(53.0 , 59.6)
Recency of pipe smoking								
Past 30 days	6.1	(5.7 , 6.6)	6.7	(6.1 , 7.3)	4.8	(4.1 , 5.6)	5.7	(4.7 , 6.9)
More than 30 days ago	26.8	(25.9 , 27.8)	23.3	(22.3 , 24.3)	33.6	(31.3, 35.9)	32.0	(29.5, 34.5)
Never used	67.0	(66.0 , 68.0)	70.0	(69.0 , 71.0)	61.6	(59.1,64.0)	62.3	(59.6 , 65.0)
Recency of alcohol consumption								
Past 30 days	79.4	(78.6 , 80.2)	75.6	(74.8 , 76.5)	89.1	(87.3 , 90.7)	82.2	(80.2, 84.1)
30 days to 1 year ago	9.8	(9.2, 10.3)	12.2	(11.6 , 12.9)	4.8	(3.7 , 6.2)	6.6	(5.5,7.9)
More than 1 year ago	7.7	(7.2, 8.3)	8.4	(7.7 , 9.1)	5.1	(4.0, 6.5)	8.5	(7.0 , 10.2)
Never used	3.1	(2.7,3.5)	3.8	(3.3,4.3)	1.0	(0.7 , 1.6)	2.8	(2.1, 3.6)
Recency of cannabis use								
Past 30 days	31.6	(30.7 , 32.4)	39.3	(38.2 , 40.4)	16.6	(14.9 , 18.4)	20.4	(18.9 , 22.0)
30 days to 1 year ago	10.8	(10.2, 11.4)	11.3	(10.6 , 12.0)	9.7	(8.5 , 11.1)	10.1	(8.9 , 11.4)
More than 1 year ago	36.1	(35.1,37.1)	30.5	(29.4 , 31.7)	49.0	(46.6 , 51.5)	41.8	(39.5, 44.1)
Never used	21.5	(20.7 , 22.4)	18.9	(17.9 , 20.0)	24.7	(22.8 , 26.6)	27.7	(25.4, 30.1)
<sup>a</sup> Established cigarette smoking defined as having smoked at least 100 cigarettes. NOTE: NSDUH: National Survey on Drug Use and Health, CI: confidence interval.	aving smo and Heal	oked at least 100 th; CI: confidenc	cigarette: se interva	i ii				

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TABLE C-4 Health characteristics of U.S. adults by tobacco use type, 2015-2019 NSDUH	naract	eris	tics (	of U	S.	dult	s by	r tok	acco	) use	e typ	ю, 20	15-1	2019	NSI	HUC					
	Curr lishe	rrent Esta led Cigare Smoking	Current Estab- lished Cigarette Smoking	For lishe	Former Estab- ished Cigarette Smoking	Former Estab- lished Cigarette Smoking	Cig	Any Current igar Smoking	Any Current Cigar Smoking	bic C	Current Non- sremium Ciga Smoking	Current Non- premium Cigar Smoking	0 E ~	Current Pre- mium Cigar Smoking	Pre- igar 1g	No I tol	o Past-30-d <i>e</i> tobacco use	No Past-30-day tobacco use	Nev	Never Tobacco Use	acco
	%	(959	(95% CI)	%	(95	(95% CI)	%		(95% CI)	%		(95% CI)	%	(95%	(95% CI)	%	(95%	(95% CI)	%	(95%	(95% CI)
Ever told had cancer	4.0	(3.7	, 4.3)	10.5	(10.0	(10.0 , 11.1)	3.0		(2.5 , 3.7)	2.2		(1.7, 2.8)	5.1	(3.6	(3.6 , 7.4)	7.1	(6.9	(6.9 , 7.3)	5.2	(4.9	(4.9 , 5.5)
Ever told had heart condition	8.8	(8.4	, 9.3)	17.8		(17.2, 18.5)	7.8		(7.0 , 8.6)	7.4		(6.5, 8.4)	8.0	(6.1)	(6.1, 10.4)	11.2	(10.9	(10.9 , 11.5)	8.4	(8.0	(8.0 , 8.8)
Ever told had COPD	8.0	(7.6	(7.6 , 8.5)	7.5		(7.0 , 7.9)	4.1		(3.4 , 4.9)	4.6		(3.9 , 5.5)	1.7	(1.0)	(1.0 , 2.6)	3.6	(3.5	(3.5 , 3.8)	2.3	(2.1	(2.1 , 2.5)
Ever told had asthma	8.9	(8.6	, 9.2)	9.7	(9.2	(9.2, 10.3)	9.9		(9.1 , 10.7)	) 10.4		(9.6 , 11.3)	9.2	(7.5	(7.5 , 11.4)	9.6	(9.4	, 9.8)	8.8	(8.5	, 9.1)
Mental Health																					
Serious Psychological Dis- tress, past month	11.3	(10.9	(10.9 , 11.6)	4.0		(3.8 , 4.2)	11.0	(10.2	, 11.8)	14.5	(13.4	11.0 (10.2 , 11.8) 14.5 (13.4 , 15.6)	2.7	(1.9	(1.9 , 3.7)	4.4	(4.2	(4.2 , 4.5)	4.5	(4.3	, 4.8)
Major Depressive Episode, past year	11.1	(10.7	(10.7 , 11.6)	6.5		(6.2 , 6.9)	10.7		(9.9 , 11.5)	12.8	(11.8	(11.8 , 13.9)	5.0	(3.8	(3.8 , 6.7)	6.1	(6.0	(6.0 , 6.3)	5.3	(5.1	(5.1 , 5.5)
Substance Dependence																					
Alcohol Dependence, past year	7.3	(7.0	(7.0 , 7.6)	3.3		(3.0 , 3.6)	8.4		(7.7 , 9.2)	9.6		(8.9 , 10.4)	7.3	(5.7	(5.7, 9.3)	1.9	(1.8	(1.8 , 2.1)	0.8	(0.7	(0.7 , 0.9)
Cannabis Dependence, past year	2.5	(2.3	(2.3 , 2.6)	0.7		(0.6 , 0.8)	5.3		(4.9 , 5.8)	7.4		(6.6 , 8.1)	1.3	(0.9	(0.9 , 1.8)	0.5	(0.5	(0.5 , 0.5)	0.2	(0.1	(0.1 , 0.2)
Illicit Drug <sup>a</sup> Dependence, past year	4.8	(4.5	, 5.1)	4.8	(4.5	(4.5 , 5.1)	4.5		(4.0 , 5.0)	5.8		(5.2 , 6.5)	1.9	(1.1	(1.1,3.1)	0.5	(0.4	(0.4 , 0.5)	0.2	(0.2	(0.2 , 0.3)
Pregnancy Status																					
Yes	0.6		(0.5 , 0.6)	0.7	(0.6	(0.6 , 0.8)	0.3		(0.2 , 0.5)	0.5		(0.3 , 0.7)	0.0	(0.0	(0.0, 0.1)	1.0		(1.0, 1.1)	1.1	(1.1 , 1.2)	, 1.2)
No	22.5	(22.0	22.5 (22.0 , 23.1)		(10.9)	11.3 (10.9 , 11.7)		(15.9)	16.7 (15.9 , 17.5)		(20.5	21.6 (20.5 , 22.7)	3.7	(2.9	(2.9 , 4.7)	22.7	(22.5	22.7 (22.5 , 23.0)	28.3	(27.9	(27.9 , 28.7)
$N/A^b$	76.9	(76.4	, 77.5)	87.9	(87.5	, 88.3)	83.0	(82.2	, 83.7)	( 77.9	(76.8	, 79.0)	96.3	(95.3	, 97.1)	76.2	(75.9	(75.9 , 76.5)	70.5	(70.1)	, 70.9)
$^a$ Other than cannabis. $^b$ Males and females respondents not aged 12 to 44 years.	ndents	not	aged 1	2 to 4	44 ye	ars.															

NOTE: NSDUH: National Survey on Drug Use and Health; CI: confidence interval.

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<b>ABLE C-5</b> Age- and sex-adjusted <sup><i>a</i></sup> associations between past-month premium cigar smoking and various	alth characteristics among US adults, 2015–2019 NSDUH
ge- and sex-adjusted <sup>a</sup> associations bet	iics among US adults, 2015–2019

	Pr Nonp	Premium vs. Nonpremium Cigar Smoking	L'remiun Cigar Si for esta	Cigar Smoking, adjusted for established smoking status <sup>b</sup>	Pre Smol	Premium Cigar Smoking vs. Never Tobacco Use	ing vs. Establ	rrennum Cigar Surok- ing vs. Current/Former Established Cigarette Smoking
	aOR	(95% CI)	aOR	(95% CI)	aOR	(95% CI)	aOR	(95% CI)
Ever told had cancer	1.83	1.83 (1.11 , 3.00)	1.67	(0.99 , 2.81)	1.47	1.47 (1.02 , 2.13)	1.09	(0.65 , 1.81)
Ever told had heart condition	0.80	(0.56 , 1.15)	0.78	(0.54, 1.13)	1.01	(0.73, 1.40)	0.69	(0.43 , 1.11)
Ever told had COPD	0.32	(0.19 , 0.52)	0.48	(0.28 , 0.82)	1.13	(0.69 , 1.84)	0.19	(0.08 , 0.46)
Ever told had asthma	1.19	(0.94, 1.50)	1.15	(0.90, 1.45)	1.22	(0.97, 1.55)	1.16	(0.84 , 1.62)
Mental Health								
Serious Psychological Distress, past month	0.23	(0.16 , 0.32)	0.30	(0.21 , 0.42)	0.67	0.67 (0.47 , 0.96)	0.29	(0.20 , 0.43)
Major Depressive Episode, past year	0.50	(0.38 , 0.67)	0.59	(0.44 , 0.79)	1.29	(0.95 , 1.76)	0.63	(0.41 , 0.97)
Substance Dependence								
Alcohol Dependence, past year	0.75	(0.57 , 0.98)	0.94	(0.72 , 1.22)	7.99	(5.67, 11.25)	0.93	(0.59, 1.48)
Cannabis Dependence, past year	0.26	(0.18, 0.38)	0.28	(0.19 , 0.42)	8.30	(4.98, 13.85)	0.35	(0.17, 0.73)
Illicit Drug <sup>c</sup> Dependence, past year	0.34	(0.20 , 0.57)	0.55	(0.33, 0.91)	7.22	(3.98 , 13.12)	0.08	(0.04, 0.18)
Pregnancy Status								
Yes vs. $no^d$	0.28	0.28 (0.06 , 1.36)	0.38	(0.08 , 1.87)	0.15	0.15 (0.03 , 0.66)	0.12	(0.02 , 0.89)

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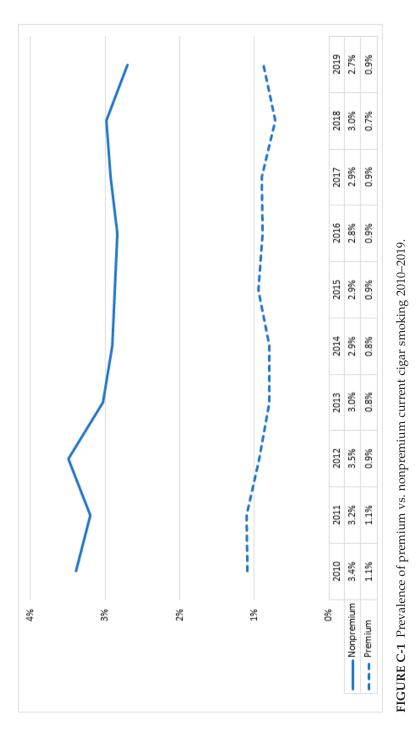
NOTE: aOR: adjusted odds ratio; CI: confidence interval; COPD: chronic obstructive pulmonary disorder.

 $^d$  Excludes males and females respondents not aged 12 to 44 years.

<sup>c</sup> Illicit drugs other than marijuana.

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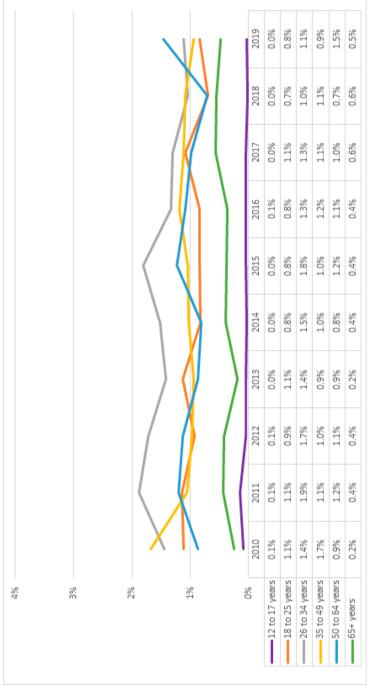


FIGURE C-2 Prevalence of premium cigar smoking by age group, 2010–2019 NSDUH.

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# Appendix D

# Cross-Sectional Patterns and Longitudinal Transitions of Cigar Use by Type in the PATH Study

Authored by:<sup>1</sup> Jihyoun Jeon<sup>2</sup> and Yoonseo Mok,<sup>3</sup> September 2021

#### INTRODUCTION

While premium cigar use is relatively common in the United States, studies of its prevalence and patterns are limited. The little evidence available comes from analyses of the National Adult Tobacco Survey and the Population Assessment of Tobacco and Health (PATH) study (Corey et al., 2014, 2018). In particular, Corey et al. analyzed adult cigar smoking patterns by cigar type, including premium cigars, and sociodemographic factors in PATH Wave 1 (2013–2014) (Corey et al., 2018). They found an overall adult past-30-day prevalence of premium cigar smoking in 2013–2014 of 0.7 percent (95 percent CI: 0.6–0.7) with use more common in men, non-Hispanic white people, those with some college education or more and with incomes of 200 percent of the federal poverty line or more.

Corey et al. also analyzed cigar use characteristics, such as the number of days smoked in the past 30 days, the number of cigars or cigarettes used per day, age at first regular use, duration of use and concurrent use of cigars and cigarettes. They found that compared with users of other cigar products, premium cigar users smoke fewer days in the past 30 days (median: 1.7; IQR: 0.0–4.8), smoke fewer cigars per day (median: 0.1; IQR: 0.0–0.2) and have a lower prevalence of concurrent cigarette smoking (29.9)

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<sup>&</sup>lt;sup>1</sup>Committee member Rafael Meza oversaw this analysis, reviewed the results for accuracy, provided regular feedback to the authors, and edited the final paper.

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percent; 95 percent CI: 25.5–34.3 percent). However, as this was a crosssectional study, no information was available on either rate of initiation or cessation of premium cigar or other cigar use or about transition rates between use of cigar types and cigarettes. Using PATH Waves 1–3, some studies have evaluated longitudinal patterns, such as initiation, cessation, reuptake and relapse of tobacco product use (cigarettes, electronic nicotine delivery systems [ENDS)], cigars, hookah and smokeless tobacco), although they did not look into differences by cigar type (Edwards et al., 2020; Kasza et al., 2020a,b).

In Corey et al., traditional cigar use was categorized as premium versus nonpremium based on the tobacco blends, components, manufacturing process and other characteristics associated with the usual brand reported by survey respondents. For traditional large cigar users with no brand information, the cutoff for premium was those who reported paying more than \$2 per cigar. Some brands classified as premium by Corey et al. have characterizing flavors, which would exclude them from the premium cigar category under some classifications (FDA, 2020).

To inform the committee about the patterns of use of premium and other cigars, we conducted analyses of PATH data from Waves 1–5 that extend Corey et al. in several ways. First, we replicated that analysis for Waves 1–5, providing annual estimates of premium cigar and other cigar type use prevalence and patterns of use for 2013–2014, 2014–2015, 2015–2016, 2016–2017 and 2018–2019. We then calculated longitudinal transitions between use of premium cigars and other cigar types and cigarettes, also differentiating premium cigar use by frequency (number of days used in the past 30 days). Lastly, we conducted analyses of tobacco dependence for different cigar use groups, including exclusive premium cigar users.

#### METHODS

#### Data<sup>4</sup>

PATH is a longitudinal study of the civilian, noninstitutionalized U.S. population age 12+ by the National Institutes of Health and the Food and Drug Administration beginning in 2013–2014. PATH participants answer periodically a series of detailed questions about tobacco product use using Audio Computer-Assisted Self-Interviewing. PATH collected data annually from Waves 1–4 but switched to biennially beginning in Wave 5. For this analysis, we used the PATH sample age 18+: Wave 1 (September

<sup>&</sup>lt;sup>4</sup> All supplemental materials cited in this paper are available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@ nas.edu.

2013–December 2014; N = 32,320; weighted response rate [WRR]: 74.0 percent), Wave 2 (October 2014–October 2015; N = 28,362; WRR: 83.2 percent), Wave 3 (October 2015–October 2016; N = 28,148; WRR: 78.4 percent), Wave 4 (December 2016–January 2018; N = 27,757 for Wave 1 cohort and 6,065 for Wave 4 replenishment sample; WRR: 73.5 percent for Wave 1 cohort and 68.0 percent for Wave 4 replenishment sample), and Wave 5 (December 2018–November 2019; N = 32,687; WRR: 88.0 percent) (HHS, 2021). Analyses relied on the PATH restricted-use file.

#### Measures

We followed similar procedures as Corey et al. (2018), extending their Wave 1 estimations to Waves 2-5, and updating the estimations for Wave 1. We briefly describe the variables and methods of the current analysis.

A question whether an individual has ever seen or heard of cigars, cigarillos, or filtered cigar before this study was asked of Wave 1 and replenishment Wave 4 participants at their study entry. Another set of questions assessed whether an individual smoked each cigar type, even one or two puffs in past 30 days. This second set of questions were asked of all adult respondents (continuing and aged-up adult respondents, or new cohort adult respondents who have ever seen or heard of traditional cigars, cigarillos, or filtered cigars) in Waves 2-5. These questionnaires in PATH display first images of traditional cigars with the physical characteristics and list examples of popular brands to all adult respondents ("Traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente [added Cohiba on Wave 3], but there are many others"). Then the questionnaires display images of cigarillos and filtered cigars with a description ("Cigarillos and filtered cigars are smaller than traditional cigars. They are usually brown. Some are the same size as cigarettes, and some come with tips or filters. Some common brands are Black&Mild, Swisher Sweets, Dutch Masters, Phillies Blunts, Prime Time, and Winchester [Cheyenne listed instead on Wave 3]"). Participants who reported smoking cigars "with a filter (like a cigarette filter)" were assigned as filtered cigar users, and those who reported "with a plastic or wooden tip" or "without a tip or filter" were assigned as cigarillos users.

#### Current Established Cigar and Cigarette Users

Current established cigar users were defined as those individuals who reported ever smoking the specific type "fairly regularly" and currently smoke every day or some days. Traditional cigar users were further differentiated into premium versus nonpremium with the usual brand smoked

(Supplement A). Traditional cigar brands reported by PATH participants were classified independently by three expert coders (Ganz, Villanti, and Sterling).<sup>5</sup> Coding was based on the following premium cigar characteristics identified by the National Academies of Sciences, Engineering, and Medicine (the National Academies) committee: a) handmade, b) filler at least 50 percent natural long-leaf filler tobacco, c) wrapped in whole leaf (i.e., not reconstituted tobacco), d) weighs at least 6lbs per 1,000, e) no filters/tips, and f) no characterizing flavor other than tobacco. Coders were able to look at brand and vendor websites. The three coders achieved 84 percent agreement (brands n = 110). Any disagreements (n = 21) were discussed among the three coders and an additional cigar expert (Delnevo).<sup>6</sup> Ultimately, the three coders and the additional expert could not determine whether the cigar should be categorized as premium or nonpremium for four brands: Marsh Wheeling, Isla Del Sol, Java and Acid. The group decided to treat these brands as nonpremium. Only three brands were coded differently from Corey et al. Specifically, Corey et al. categorized Acid, Optimo, and Marsh Wheeling as premium cigars, whereas these brands were coded as nonpremium for this analysis. In particular, Acid was classified as nonpremium because these cigars come in flavors. These decisions were consistent for both commissioned patterns of use studies. For individuals with missing usual brand information, those who reported paying ≥\$2 per cigar were classified as premium cigar users, while those who reported paying <\$2 per cigar were nonpremium. The analysis considered four cigar types: traditional premium cigars, traditional nonpremium cigars, cigarillos, and filtered cigars.

Current established cigarette users were defined as individuals who reported smoking at least 100 manufactured or roll-your-own cigarettes in their lifetime and now smoke cigarettes every day or some days.

## Cigar Smoking Patterns

The number of cigars smoked in lifetime was stratified into three categories: 10 or fewer, 11–50, and 51+. Information for the number of days smoked in the past 30 days was collected for some days smokers, with every day smokers assumed to smoke on all 30 days. Number of cigars smoked per day was calculated for both every day and some days smokers by multiplying the number of days smoked in the past 30 days by the average number of cigars smoked per day on such days divided by 30.

<sup>&</sup>lt;sup>5</sup>Ganz is an author of a commissioned paper for this report (see Appendix C); Villanti and Sterling are members of the NASEM committee.

 $<sup>^{6}</sup>$  Delnevo oversaw the development of the NSDUH analysis (see Appendix C) and is a member of the NASEM committee.

Duration of cigar smoking for current established smokers was calculated by subtracting age at first regular use from current age. Current use of  $\geq 1$ other noncigar, noncigarette products was defined as having ever used "fairly regularly" at least one of ENDS, pipe tobacco, hookah, smokeless tobacco, snus, or dissolvable tobacco and now using it every day or some days (Note: dissolvable tobacco was excluded in Waves 3–5).

## Cigar Purchasing

Cigar users reported whether they had a regular brand, the name of the brand of regular use or usually/last smoked, along with whether it was flavored or mentholated. They also specified how they purchase cigars (in person, from the Internet, by telephone, or do not buy their own cigars), where (cigar bar, convenience store/gas station, smoke shop/ tobacco specialty or outlet store, or somewhere else), and their usual purchase size (single stick or box/pack). Price per cigar was calculated as the reported usual price paid divided by the number of cigars in the usual purchase size unit. Similar measures were also reported and calculated for cigarette users.

## Reasons for Cigar Smoking

Total of 12 (Waves 1 and 2), 8 (Wave 3), 7 (Waves 4 and 5) reasons or beliefs for cigar smoking were asked to those reporting use (yes/no). The list of all items in each wave is available in Supplemental Table B5. Reasons that compared cigars with cigarettes were stratified by the participant's cigarette smoking status (current, former, never).

## Demographic Characteristics

Participants reported their demographic characteristics including sex (male, female), age in years (18–24, 25–34, 35–54, or 55+), race/ethnicity (non-Hispanic white, non-Hispanic Black/African American, non-Hispanic other/multi-race, or Hispanic), education (less than high school diploma, GED, high school diploma, some college/associate's degree, completed college or more). Poverty status was assigned based on annual household income and household size as <100 percent of the federal poverty level (FPL), 100–<200 percent FPL, and ≥200 percent FPL. Information for poverty status was available only in Wave 1.

## **Cross-Sectional Analyses by Wave**

Prevalence of cigar smoking by type (premium, nonpremium, cigarillos, and filtered cigars) and cigarette smoking were calculated using the "survey" package in the R statistical software version 4.1.1. Prevalence was calculated overall and according to sociodemographic characteristics, tobacco use patterns, purchasing behaviors, and reasons for use. APRs were calculated using a survey-weighted generalized linear models ("svyglm" function in R) with logit link function to examine associations between dual cigar and cigarette smoking versus cigar-only smoking, accounting for demographics and cigar use behaviors (daily versus nondaily smoking). To account for the complex survey design of PATH, all analyses used replicate weights and balanced repeated replication methods, Fay's method with a factor as recommended by PATH (HHS, 2021). Prevalence with denominator <50 observations or a relative standard error of >30 percent was suppressed. Missing values for >5 percent of all eligible responses were treated as a separate category (e.g., poverty status); otherwise observations with missing values were dropped.

For cross-sectional (per wave) analyses, we estimated weighted prevalence and CIs using cross-sectional single-wave weights and their corresponding 100 replicate weights in each wave.

## Longitudinal Transition Analyses

## Transition Analysis of Cigar and Cigarette Use

We calculated longitudinal transition rates (percentage of users transitioning from one use state to another) for each PATH wave pair, using cross-sectional weights at the end wave of each pair. For example, the analysis for Wave 1 to 4 looked at the transition rates between Wave 1 and 4 in people who participated in both waves, regardless of their participation in other waves. In this specific analysis, the cross-sectional Wave 4 weights were used in the transition rate calculations. We first considered the following nine cigar and cigarette use states: 1) never cigar and cigarette use, 2) noncurrent cigar and cigarette use, 3) exclusive current established premium cigar use, 4) exclusive current established use of other cigar types (nonpremium cigars, cigarillos, or filtered cigars), 5) exclusive current established cigarette use, 6) dual current established use of premium cigars and other cigar types, 7) dual current established use of premium cigars and cigarettes, 8) dual current established use of other cigar types and cigarettes, 9) poly tobacco use (i.e., current established use of premium cigars, other cigar types, and cigarettes). We also considered an alternative classification distinguishing premium cigar users by frequency (seven use states): 1) never cigar and cigarette use, 2) noncurrent

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cigar and cigarette use, 3) exclusive current established premium cigar use with <6 days of use in the past 30 days, 4) exclusive current established premium cigar use with 6+ days of use in the past 30 days, 5) exclusive current established other combustible tobacco use (nonpremium cigars, cigarillos, filtered cigars, or cigarettes), 6) dual current established use of premium cigar with <6 days of use in the past 30 days and other combustible tobacco use, 7) dual current established use of premium cigar with 6+ days of use in the past 30 days and other combustible tobacco use. Use of other tobacco products was not considered in these classifications.

For this longitudinal transition analysis, the sample consisted of all individuals who participated in Waves 1–5 (N = 18,925). Transition estimates were calculated using the all-wave weights for the Wave 1 cohort and the corresponding 100 replicate weights. We estimated the transition rates for all adults (ages 18+) and also stratified by age (18–34 and ages 35+).

#### Transition Analysis of Premium Cigar Users

To better assess the trajectories of premium cigar users, we conducted a second transition analysis restricting the sample to those who reported smoking premium cigar fairly regularly in at least one wave (N= 844). This analysis considered the same use states as in the previous analyses, with the addition of a "not in sample" state for individuals lost to followup or who did not participate in some waves. We used each individual baseline sample weight and the corresponding 100 replicate weights (i.e., the cross-sectional weights from the first wave in which the individual participated). We estimated the transition rates for all adults (ages 18+) and also stratified by age (ages 18–34 and 35+). As a sensitivity analysis, we also conducted the longitudinal trajectory analysis by limiting to Wave 1 cohort individuals who participated in all Waves 1–5 (N = 517) and who reported smoking premium cigars fairly regularly in at least one wave, using Wave 5 all-waves weights.

#### **Tobacco Dependence**

To compare the level of nicotine dependence of current established tobacco product users in PATH, we constructed a tobacco dependence score (TDS) based on the 16 items suggested by Strong et al. (Strong et al., 2017): the Wisconsin Inventory of Smoking Dependence Motives or WISDM (11 items), Nicotine Dependence Syndrome Scale or NDSS (4 items), and Diagnostic and Statistical Manual criteria (1 items). The nicotine dependence domains of these items consist of "Automaticity," "Craving," "Loss of Control," "Tolerance," "Negative Reinforcement,"

"Cognitive Enhancement," "Affiliative Attachment," and "Withdrawal." For the 15 items with five response categories in order of increasing symptom level (i.e., 1 being "no symptom" and 5 being "extremely true"), we recoded them as a three-category scale, placing 1, 2–3, and 4–5 into the categories 0, 1, and 2, respectively. We then rescaled the three-level items by multiplying them by 50, i.e.,  $(0,1,2) \times 50 = (0,50,100)$ . For the one item with binary response, we coded 0 for "No" and 1 for "Yes," then rescaled it by multiplying it by 100, i.e.,  $(0,1) \times 100 = (0,100)$ . We calculated a TDS per individual per wave as the linear average of these 16 responses. We then compared the mean and median TDS for the following exclusive tobacco product use categories: premium cigars, nonpremium cigars, cigarillos, filtered cigars, cigarettes, smokeless tobacco, and hookah. For each group, we also calculated the percentage of users reporting at least one dependence symptom, the difference in mean TDS between daily and nondaily users of each product, the difference in mean TDS between those who used it less than 6 days and 6+ days in the past 30 days, and the linear association of the number of days used in the past 30 days with TDS. Note that for tobacco dependence, some respondents might answer these questions with a specific product in mind, but if they are dual or poly users (even if that use is experimental and not established by the PATH study definition), then they could be answering these questions referring to their different tobacco products.

## RESULTS

## **Cross-Sectional Patterns of Use**

This study analyzed use patterns of four cigar types (premium, nonpremium, cigarillos, and filtered cigars) and cigarettes among U.S. adults across different periods from 2013 to 2019. For the purpose of illustration, we describe the results for PATH Wave 4 (2016–2017) in the main text (see Tables D1–D4). PATH Wave 4 added a new sample of users (replenishment sample) to address loss to follow-up in previous waves and produce a truly nationally representative sample as in Wave 1. Results for PATH Waves 1–5 are available in Supplemental Tables B1–B4. The analyses of reasons for cigar product use for Waves 1–5 are shown in Supplemental Table B5. Results using cigar use definitions without the fairly regularly restriction or the 100 cigarettes in their lifetime criteria for cigarette smoking are presented in Supplemental Table B6.

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## Demographic Characteristics of Cigar and Cigarette Users

The overall adult prevalence of current established adult tobacco use in PATH Wave 4 (2016–2017) was 0.7 percent (95 percent CI: 0.6–0.8 percent) for premium cigars, 0.5 percent (95 percent CI: 0.4 –0.5 percent) for nonpremium cigars, 1.5 percent (95 percent CI: 1.4-1.6 percent) for cigarillos, 0.8 percent (95 percent CI: 0.8-0.9 percent) for filtered cigars, and 17.7 percent (95 percent CI: 17.3–18.1 percent) for cigarettes (see Table D–1). The absolute use prevalence for each cigar type varies slightly by wave, but the general use patterns by sociodemographic groups for all cigar types are consistent across waves (see Figure D1 and Supplemental Table B1). The majority of adult cigar users were male (70.2–97.7 percent). In contrast, 53.9 percent (95 percent CI: 52.8–55.1 percent) cigarette users were male and 46.1 percent (95 percent CI: 44.9-47.2 percent) female. Cigarillos were smoked by young adults aged 18–34 years at relatively higher rates compared to other cigar types and cigarettes (54.8 percent versus 37.0 percent for premium cigar, 28.6 percent for nonpremium cigar, 31.5 percent for filtered cigar, and 34.4 percent for cigarette users). The use prevalence among non-Hispanic Black adults was higher for cigarillos (34.1 percent; 95 percent CI: 29.2–39.4 percent) compared to premium cigars (6.2 percent; 95 percent CI: 3.4–11.1 percent), and other cigar types and cigarettes (13.2-24.1 percent). The majority of the adult premium cigar users were non-Hispanic white people (79.5 percent; 95 percent CI: 73.5-84.5 percent). High school diploma, GED or less comprised 52.5 percent of nonpremium cigar, 54.2 percent of cigarillo, 62.8 percent of filtered cigar, and 57.4 percent of cigarette users but only 22.9 percent of premium cigar users. Premium cigar users were predominantly male, non-Hispanic white people, with some college or more education. Results for other waves are presented in Supplemental Table B1.

#### Cigar and Cigarette Smoking Patterns

Cigar smoking patterns and use behaviors varied by type (see Table D2). About half of the established premium, nonpremium cigar, and cigarillo users had smoked >50 cigars in their lifetime (46.1–51.8 percent), while filtered cigar users had similar distribution across the categories (only 35.3 percent smoked >50 filtered cigars in their lifetime). The prevalence of daily cigar smoking was highest for filtered cigar (39.6 percent; 95 percent CI: 35.2–44.3 percent) and lowest for premium cigars (5.2 percent; 95 percent CI: 2.2–11.4 percent). In contrast, the prevalence of daily use for cigarette users was 76.4 percent (95 percent CI: 75.4–77.4 percent).

The number of cigars smoked per day was greater for filtered cigars (median: 1.0 cigars/day; IQR: 0.0–8.3) compared with the other cigar types (median: 0.1–0.3 cigars/day), and lowest for premium cigars (median: 0.1

cigars/day, IQR: 0.0-0.2). For cigarette users, the number of cigarettes smoked per day had a median of 10.0 (IQR: 4.7-20.0). Age at first regular use was older for filtered cigars (median: 30.0 years) compared to the other cigar types (median range 19-25 years) and cigarettes (median: 17.0 years). The current use percentage of one or more other cigar types among cigar users was highest in nonpremium smokers (52.8 percent; 95 percent CI: 44.5-60.8 percent) and lowest in premium smokers (16.4 percent; 95 percent CI: 11.2-23.3 percent). This was lower for cigarette users (8.2 percent; 95 percent CI: 7.7-8.7 percent). The usage of one or more noncigar/noncigarette products was similar across users of all cigar types but lower for cigarette users. Concurrent cigarette smoking was lowest among premium cigar users (25.7 percent; 95 percent CI: 19.3–33.3 percent), with a prevalence of 50.1-70.5 percent for the other cigar type users. These patterns were consistent for the other PATH waves, except for the proportion of cigar users who smoked >50 cigars in their lifetime, which decreased over time, especially for premium and nonpremium cigar users (Supplemental Table B2).

## Tobacco Product Characteristics and Purchasing Behaviors

The majority of nonpremium cigar, cigarillo, filtered cigar and cigarette users reported having a regular brand (68.0-92.5 percent), while only 38.4 percent of premium cigar users did so (Table D3). Black & Mild was the leading brand of nonpremium cigars (23.6 percent; 95 percent CI: 16.0-31.2 percent), cigarillos (51.0 percent; 95 percent CI: 46.8-55.2 percent), and filtered cigars (20.7 percent; 95 percent CI: 14.8-26.7 percent). Swisher Sweets was reported as the second most commonly used brand among cigarillo users (21.1 percent; 95 percent CI: 16.9-25.4 percent). Acid, which was classified here as nonpremium, was the second most commonly used brand among nonpremium cigar users (12.7 percent; 95 percent CI: 8.0-17.5 percent). Cohiba (20.3 percent; 95 percent CI: 14.0-26.4 percent) and Arturo Fuente (17.9 percent; 95 percent CI: 11.4–24.5 percent) were the two most common brands reported by premium cigar users. Marlboro, Newport, Camel, Pall Mall, and American Spirit were the most common brands reported by cigarette users. Flavored or mentholated regular brands were less likely for users of premium cigars (7.6 percent; 95 percent CI: 5.5–10.5 percent) compared to other cigar types (48.4–55.7 percent). In comparison, 38.4 percent (95 percent CI: 36.8-40.0 percent) cigarette users reported using a mentholated brand. The majority of nonpremium cigar, cigarillo, filtered cigar, and cigarette users purchased in person (84.0-94.9 percent), and most of them bought in convenience store/gas stations (64.5-88.1 percent). In contrast, about a quarter of premium cigar users did not buy in person and mostly bought in smoke

shop/tobacco specialty or outlet stores (44.3 percent; 95 percent CI: 35.2– 53.8 percent) or cigar bars (35.4 percent; 95 percent CI: 28.4–43.1 percent). The median price paid per stick was lowest for filtered cigars (\$0.11; IQR: \$0.07–\$0.26) and highest for premium cigars (\$7.00; IQR: \$4.00–\$10.00). The median price paid per stick for cigarette users was higher than that of filtered cigars, but lower than that of other cigar products (\$0.30; IQR: \$0.25–\$0.35). Although the most popular cigar brands varied over time, the patterns of purchasing were consistent throughout all PATH waves (Supplemental Table B3).

# Factors Associated With Dual Cigar and Cigarette Smoking Versus Cigar-Only Smoking

Among current established cigar users, those smoking cigarillos or filtered cigars were more likely to be dual cigar and cigarette smokers (APR: 1.37; 95 percent CI: 1.17–1.59 for cigarillo users; APR: 1.58; 95 percent CI: 1.41–1.77 for filtered cigar users). On the other hand, those smoking premium or nonpremium cigars were less likely to be dual users (APR: 0.53; 95 percent CI: 0.41–0.69 for premium cigar users; APR: 0.80; 95 percent CI: 0.67–0.95 for nonpremium cigar users) (see Table D4). Cigar users who use other tobacco products (ENDS, pipe tobacco, hookah, smokeless tobacco, or snus) were more likely to smoke cigarettes (APR: 1.14; 95 percent CI: 1.04–1.25). Non-Hispanic Black cigar users were less likely to smoke cigarettes compared to non-Hispanic white people (APR: 0.85; 95 percent CI: 0.74–0.97). Cigar users with education level of GED, high school diploma, or less were more likely to be dual cigar and cigarette users than those who had some college/associate degree or more (APR: 1.38; 95 percent CI: 1.26–1.51). Daily cigar users were less likely to smoke cigarettes compared to nondaily cigar users (APR: 0.82; 95 percent CI: 0.72-0.92). These patterns were consistent across all PATH waves (Supplemental Table B4).

## Reasons for Using Cigar Products

While the reasons for cigar use varied by cigar type and cigarette smoking status, half or more of cigar users reported either "socializing while smoking" or "availability of products in favorite flavors" (see Supplemental Table B5). Affordability was another common reason for use reported by users of nonpremium cigars (range across waves 57.1–64.0 percent), cigarillos (range across waves 68.0–73.0 percent), filtered cigars (range across waves 73.8–80.2 percent) but not premium cigars (range across waves 21.6–30.2 percent). About half of filtered cigar users overall (range across waves 46.9–52.9 percent) indicated that they feel like smoking a regular cigarette while they smoke a filtered cigar; a smaller per-

centage of users of the other cigar types reported this as a reason for use (range across waves 2.7–6.7 percent in premium cigar, 22.6–25.8 percent in nonpremium cigar, and 24.9–28.6 percent in cigarillo users).

## Longitudinal Transition Analyses

## Transition Analysis of Cigar and Cigarette Use

Cross-sectional unweighted counts, weighted prevalence, and 95 percent CIs of cigar and cigarette use were estimated for adults (ages 18+) in PATH Waves 1–5. Stratified counts by age were also estimated (18–34 versus 35+). These estimates are shown in Supplement C1 (9 categories of tobacco use state) and Supplement C2 (7 categories of tobacco use state).

We present empirical weighted transition probabilities of tobacco use state between any wave pairs in 1-year, 2-year, 3-year, 4-year, or 5-year intervals (see Supplements C1 and C2). For example, 1-year transition probabilities were estimated from Wave 1 to 2, Wave 2 to 3, and Wave 3 to 4 and 5-year transition probabilities from Wave 1 to 5. Note that PATH collected data annually for Waves 1-4 but switched to biennially beginning in Wave 5; therefore, there is a two-year gap between Waves 4 and 5. We also calculated average 1-year (1-wave) transitions across Waves 1 to 4. Figure D2 shows a heatmap of the 1-year average transition probabilities for all adults (18+). About 75 percent of exclusive premium cigar users kept smoking premium cigars (sum of 69.2 percent as exclusive premium cigar users, 2.5 and 2.8 percent as dual users with other cigar types and cigarettes, respectively and 0.5 percent as poly tobacco users) in the following year (see Figure D2a). Most exclusive premium cigar users transitioning away do so to noncurrent use (18.8 percent) with only a small fraction transitioning to other products (6.1 percent). About 59 percent of exclusive other cigar type (nonpremium cigars, cigarillos, or filtered cigars) users kept smoking cigars as exclusive users (46.9 percent) or dual users with premium cigars (2.2 percent) or cigarettes (9.6 percent), or poly tobacco users (0.3 percent) in the following year. More than a quarter of exclusive other cigar type users discontinued use within a year (32.1 percent). Dual use of premium cigars with either other cigar types or cigarettes was relatively transient, with only slightly more than 40 percent of individuals staying as dual users in the following year. In particular, about 34 percent of dual users of premium cigars and cigarettes became exclusive cigarette users within a year.

About 68.2 percent of exclusive premium cigar users who smoke less than 6 days in the past 30 days continued smoking premium cigars in the following year as either exclusive users (63.0 percent) or dual users with other combustible tobacco products (5.2 percent) (see Figure D2b).

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While only 4 percent of less frequent exclusive premium cigar users (i.e., used less than 6 days in the past 30 days) increased use frequency within a year, about 20 percent of more frequent exclusive premium cigar users (i.e., 6+ days in the past 30 days) decreased use frequency. Less frequent exclusive premium cigar users were more likely to discontinue use within a year compared to more frequent users (22.7 versus 4.3 percent). Dual premium cigar use with other combustible tobacco products is relatively transient; only 44.5 percent of less frequent and 15.8 percent of more frequent premium cigar users remained as dual users. About 35.2 percent of less frequent and 40.9 percent of more frequent dual premium cigar users discontinued premium cigar use and became exclusive other combustible tobacco product users within a year.

Figure D3 shows longitudinal trajectories (alluvial plot) of adult exclusive premium cigar users at baseline (Wave 1). Slightly more than half remained as exclusive premium cigar users in all waves. About 35 percent of them discontinued use, and 7.2 percent switched to other tobacco products by Wave 5. Similar alluvial plots of longitudinal trajectories for other use categories at baseline and analyses stratified by age (18–34 versus 35+) are shown in Supplement C1. Alluvial plots for longitudinal trajectories based on the seven state categories differentiating frequency of premium cigar use are shown in Supplement C2.

#### Transition Analysis of Premium Cigar Use at Any Wave

Figure D4 shows longitudinal trajectories of cigar and cigarette use for those who smoked premium cigars fairly regularly in at least one wave. About 14 percent of adults included in this analysis were not present at Wave 1 but entered the study in following years (either aged up from the youth sample or included in the replenishment sample in Wave 4). Participants dropping from the study in the following years were categorized as "Not in sample" (28.8 percent in Wave 5). The distribution of tobacco use categories remained somewhat consistent across waves, with the exception of dual premium cigar users with cigarettes, whose prevalence kept decreasing (9.1 percent in Wave 1, 7.6 percent in Wave 2, 7.3 percent in Wave 3, 6.4 percent in Wave 4, and 5.1 percent in Wave 5). The overall percentage of premium cigar users (exclusive, dual, or poly users) remained similar across waves (42.7 percent in Wave 1, 36.2 percent in Wave 2, 42.1 percent in Wave 3, 40.1 percent in Wave 4, and 40.3 percent in Wave 5). We also provide the alluvial plot for longitudinal trajectory by limiting to the Wave 1 cohort that participated in Waves 1-5 and reported smoking premium cigar fairly regularly in at least one wave (see Supplement D1). In this sensitivity analysis, the overall percentage of premium cigar users was higher in recent waves (41.9 percent in Wave

1, 45.7 percent in Wave 2, 51.1 percent in Wave 3, 49.0 percent in Wave 4, and 53.8 percent in Wave 5). Supplements D1 and D2 present alluvial plots showing longitudinal trajectories of ever premium cigar users in alternative tobacco use categories (seven use states) and also stratified by age (18–34 versus 35+).

## **Tobacco Dependence among Exclusive Tobacco Users**

Table D5 shows the mean (95 percent CI) and median (IQR) of TDS estimated for each exclusive tobacco product use group: premium cigars, nonpremium cigars, cigarillos, filtered cigars, cigarettes, smokeless tobacco, hookah, and ENDS. Exclusive cigarette (mean: 51.1 and 95 percent CI: 50.6–51.5; median: 53.1; IQR: 28.1–75.0 in Wave 4) and smokeless tobacco (mean: 44.0 and 95 percent CI: 41.9–46.0; median: 43.8, IQR: 18.8–65.6 in Wave 4) users have the highest levels of TDS. Exclusive premium cigar (mean: 6.6 and 95 percent CI: 5.4–7.8; median: 0.0, IQR: 0.0–6.3 in Wave 4) users have the lowest levels of TDS. The mean and median TDS in the other exclusive tobacco product (nonpremium cigars, cigarillos, filtered cigars, and ENDS) users were 10.4–36.7 and 0.0–34.7, respectively. More than half of exclusive users of premium cigars and hookah did not report any dependence symptoms in Waves 3–5.

The difference in the level of tobacco dependence between nondaily and daily exclusive users was significant in all tobacco groups, except for premium cigar users in Waves 4 and 5. In Wave 4, the difference in mean TDS between nondaily and daily exclusive users was 13.5 (95 percent CI: 4.7–31.6) for premium cigars, 20.8 (95 percent CI: 8.0–33.6) for nonpremium cigars, 24.1 (95 percent CI: 18.9–29.3) for cigarillos, 17.1 (95 percent CI: 4.4–29.9) for filtered cigars, 36.6 (95 percent CI: 35.7–37.5) for cigarettes, 27.6 (95 percent CI: 23.8–31.4) for smokeless tobacco, 40.4 (95 percent CI: 34.3–46.5) for hookah, and 29.4 (95 percent CI: 26.0–32.8) for ENDS.

Similarly, the difference in the level of tobacco dependence between less frequent (less than 6 days in the past 30 days) and more frequent (6+ days in the past 30 days) exclusive users was significant in all tobacco groups, except for filtered cigars in Wave 4. For example, in Wave 4, the difference in mean TDS between less and more frequent exclusive users was 12.6 (95 percent CI: 4.0–21.2) for premium cigars, 15.7 (95 percent CI: 7.0–24.3) for nonpremium cigars, 17.1 (95 percent CI: 13.0–21.1) for cigarillos, 13.9 (95 percent CI: 2.6–30.5) for filtered cigars, 39.2 (95 percent CI: 37.6–40.7) for cigarettes, 29.6 (95 percent CI: 23.9–35.4) for smokeless tobacco, 13.8 (95 percent CI: 1.9–25.7) for hookah, and 30.2 (95 percent CI: 26.3–34.2) for ENDS.

Significant linear associations between the use frequency in the past 30 days and level of tobacco dependence were observed in all exclusive tobacco users, except for hookah users in Wave 4. Mean and median of TDS estimates for premium cigar users differentiated by frequency (less than 6 versus 6+ days used in the past 30 days) are presented in Supplemental Table B7.

#### LIMITATIONS

The main limitation of the study is that the designation of premium versus nonpremium traditional cigar use was based on the usual brand or price reported and not on direct assessment by study participants. While this approach was validated by Corey et al. (2018) and three experienced coders performed the brand classification, some traditional cigar users might have been misclassified. Like Corey et al. (2018), we did not adjust estimates of the number of cigars smoked by size or weight, precluding comparisons of exposure dose and amount smoked. Another important limitation is the lack of information in PATH about the cigar smokers' level of inhalation, which precluded characterization of inhalation patterns and analyses of dependence by inhalation. Inhalation has been shown to be an important determinant of health effects of cigar smoking (NCI, 1998), so understanding these behaviors is critical for health effects risk assessment. One more limitation is the relatively short period of analysis. While PATH allows for cross-sectional trend and longitudinal analyses of cigar use, it covers only 6 years (2013-2019), precluding analyses of long-term trends and patterns. Finally, while we evaluated patterns of use of different cigar types and cigarettes, we did not do so for other tobacco products, such as smokeless tobacco, e-cigarettes and other ENDS, hookah, or pipe. However, the analysis did evaluate the proportion of cigar users that use cigarettes or other tobacco products at each PATH wave.

#### SUMMARY OF KEY PATH RESULTS

- Premium cigars are predominantly consumed by male smokers, non-Hispanic white people, and individuals with some college or more education.
- The proportion of cigar users who smoked >50 cigars in their lifetime decreased over time, especially among premium and nonpremium cigar users.
- The majority of premium cigar users were nondaily cigar smokers.
- Premium cigar users were considerably less likely to smoke cigarettes or other cigar types in comparison with other cigar type users.

- In all waves, while other type cigars and cigarettes were purchased in convenience store/gas stations, premium cigars were purchased in either cigar bars or smoke shops/tobacco specialty or outlet stores. Premium cigar users were less likely to use flavored or mentholated brands compared to users of the other cigar types or cigarettes.
- Dual use of cigar and cigarettes was less likely among non-Hispanic Black people compared to non-Hispanic white people, daily smokers compared to nondaily smokers, and those who have some college/associate degree or more compared to those with education level of GED, high school diploma, or less.
- Two common reasons reported for smoking cigars were "socializing while smoking" or "availability of products in favorite flavors." Affordability was another common reason for smoking nonpremium cigars, cigarillos, and filtered cigars, but not for premium cigars.
- About three-quarters of exclusive premium cigar smokers remained so in the following year. Dual use of premium cigars with either other cigar types or cigarettes is somewhat transient.
- Exclusive premium cigar users who smoked less than 6 days in the past 30 days were more likely to discontinue use within a year compared to those who smoked 6+ days in the past 30 days. About 20 percent of 6+ days exclusive premium cigar users became <6 days users within a year.
- Among exclusive premium cigar users in Wave 1, slightly more than half remained as exclusive premium cigar users in Wave 5 and about 35 percent discontinued use by Wave 5.
- Among those who smoked premium cigars fairly regularly in at least one wave, the overall percentage of premium cigar users (exclusive, dual, or poly users) remained similar across waves, but the prevalence of dual premium cigar users with cigarettes decreased over time.
- The level of tobacco dependence is lowest in exclusive premium cigar and hookah users.
- The difference in the level of tobacco dependence in nondaily versus daily (or less versus more frequent) exclusive users is significant for all tobacco products, except for daily versus non-daily premium cigar users in Waves 4 and 5 and less versus more frequent filtered cigar users in Wave 4.

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Nonpremium), Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 4, 2016–2017	), Filtered Cigar, a	and Cigarette Smoke	ers, PATH Study	Wave 4, 2016–201	17
	Premium cigars <sup><i>a</i></sup> $(n = 338)$	Nonpremium cigars <sup><math>a</math></sup> ( $n = 238$ )	Cigarillos $(n = 992)$	Filtered cigars $(n = 486)$	Cigarettes $(n = 9,915)$
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Overall adult prevalence	0.7 (0.6–0.8)	0.5 (0.4–0.5)	1.5 (1.4–1.6)	0.8 (0.8–0.9)	17.7 (17.3–18.1)
Sex					
Male	97.7 (95.2–98.9)	86.6 (79.9–91.3)	70.2 (67.2–73.0)	71.7 (67.2–75.9)	53.9 (52.8–55.1)
Female	2.3 (1.1–4.8)	13.4 (8.7–20.1)	29.8 (27.0–32.8)	28.3 (24.1–32.8)	46.1 (44.9–47.2)
Age group (years)					
18–24	9.7 (6.3–14.7)	8.1 (4.9–13.1)	21.7 (18.5–25.2)	10.9 (8.2–14.5)	10.1 (9.4 - 10.8)
25–34	27.3 (21.4–34.3)	20.5 (15.5–26.4)	33.1 (28.9–37.5)	20.6 (16.9–25.0)	24.3 (23.2–25.6)
35-54	28.2 (22.1–35.2)	38.3 (29.7–47.8)	33.0 (28.5–37.8)	38.2 (32.8–43.9)	38.9 (36.8–41.0)
55+	34.8 (30.8–38.9)	33.1 (25.8–41.4)	12.2 (9.6–15.5)	30.3 (24.8–36.3)	26.6 (25.2–28.2)
Race/ethnicity					
White, non-Hispanic	79.5 (73.5–84.5)	60.9 (50.2–70.7)	47.4 (41.4–53.6)	57.6 (49.3–65.6)	68.4 (67.2–69.6)
Black/AA, non-Hispanic	6.2 (3.4–11.1)	24.1 (15.4–35.7)	34.1 (29.2–39.4)	20.2 (14.7–27.0)	13.2 (12.5–14.0)
Other or multi-race, non-Hispanic	5.0 (2.8–8.9)	4.0 (2.3–6.8)	4.6 (3.3–6.3)	5.2 (3.6–7.5)	5.6 (5.0–6.3)
Hispanic	9.2 (5.9–14.2)	11.1 (7.7–15.7)	13.9 (11.0–17.3)	17.0 (13.2–21.7)	12.7 (11.7–13.9)

TABLE D-1 Demographic Characteristics of Adult Current Established Traditional Cigar (Premium,

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Education

Less than high school diploma	4.0 (2.0–7.5)	14.2 (9.2–21.4)	17.0(14.8-19.4)	23.0 (18.8–27.8)	16.3 (15.3–17.3)
GED	4.6 (2.6–8.2)	7.9 (4.7–13.0)	9.2 (6.7–12.4)	12.0 (8.9–16.1)	11.5 (10.4–12.7)
High school diploma	14.3 (9.0–22.0)	30.4 (23.3–38.5)	28.0 (24.7–31.5)	27.8 (23.3–32.8)	29.6 (27.9–31.4)
Some college/associate degree	30.8 (25.5–36.6)	34.3 (27.1–42.4)	37.0 (32.5–41.8)	28.5 (25.8–31.3)	32.0 (30.1–34.0)
Complete college or more	46.3 (37.7–55.1)	13.1 (7.5–22.1)	8.9 (7.0–11.1)	8.7 (5.6–13.2)	10.5 (9.7–11.4)
NOTE: CI: logit-transformed Wald-type confidence interval; AA: African American; GED: General Education Development certificate. $^{a}$ Among traditional established cigar smokers, 4.8% ( $n = 29$ ) could not be assigned as either a premium or nonpremium smoker after	ld-type confidence inte d cigar smokers, 4.8%	rral; AA: African Ame (n = 29) could not be as	primed Wald-type confidence interval; AA: African American; GED: General Education Development certificate. established cigar smokers, 4.8% ( $n = 29$ ) could not be assigned as either a premium or nonpremium smoker after assessing	ucation Development ( ium or nonpremium sı	certificate. noker after assessing

responses to usual brand (Supplement A).

Nonpremium),	
(Premium, 1	
TABLE D-2 Smoking Patterns Among Adult Current Established Traditional Cigar (	arillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 4, 2016–2017
IA	Ciga

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<b>TABLE D-2</b> Smoking Patterns Among Adult Current Established Traditional Cigar (Premium, Nonpremium),Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 4, 2016–2017	Among Adult ( Sigarette Smoke	ing Patterns Among Adult Current Established Traditional Cig Cigar, and Cigarette Smokers, PATH Study Wave 4, 2016–2017	Traditional Cig ve 4, 2016–2017	ar (Premium, N	lonpremium),
	Premium cigars	Nonpremium cigars	Cigarillos	Filtered cigars	Cigarettes <sup>a</sup>
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Lifetime cigars smoked					
<1-10 cigars	5.5 (2.3–12.9)	23.9 (17.7–31.4)	14.0 (10.8–17.8)	28.8 (21.3–37.7)	NA
11–50 cigars	47.9 (38.2–57.8)	30.1 (19.3–43.6)	34.2 (30.5–38.2)	25.9 (18.6–34.8)	NA
51+ cigars	46.5 (36.5–56.8)	46.1 (36.4–56.1)	51.8 (47.6–55.9)	35.3 (37.6–53.3)	NA
Now smoke product every day	5.2 (2.2–11.4)	22.3 (14.8–32.1)	19.1 (16.7–21.8)	39.6 (35.2–44.3)	76.4 (75.4–77.4)
Days smoked in past 30 days <sup>b</sup> (median, IQR)	1.0 (0.0–4.0)	5.0 (1.0-25.1)	5.0 (1.0–25.0)	19.3 (1.0–30.0)	30.0 (30.0–30.0)
Number of cigars or cigarettes per day (median, IQR)	0.1 (0.0–0.2)	0.2 (0.0–1.0)	0.3 (0.0–1.5)	1.0 (0.0–8.3)	10.0(4.7-20.0)
Age (years) at first regular use <sup>d</sup> (median, IQR)	25.0 (20.0–31.0)	22.0 (18.0–35.0)	19.0 (16.0–25.0)	30.0 (19.0–43.1)	17.0 (15.0–19.0)
Duration (years) since first regular use (median, IQR)	13.0 (6.0–25.0)	18.0 (10.1–26.0)	11.0 (6.0–17.0)	9.0 (5.0–18.0)	24.0 (14.0–38.0)
Currently use other cigar type(s) $^{ef}$	16.4 (11.2–23.3)	52.8 (44.5–60.8)	32.8 (29.1–36.7)	42.2 (36.8–47.9)	8.2 (7.7–8.7)
Currently use noncigar, noncigarette product(s) <sup>g</sup>	26.1 (21.0–31.9)	28.8 (21.5–37.4)	28.3 (24.2–32.9)	26.8 (21.1–33.2)	15.4 (14.1–16.8)

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Cigarette smoking status <sup>h</sup>					
Current established smoker	25.7 (19.3–33.3)	50.1 (43.8–56.4)	60.2 (57.2–63.2)	70.5 (64.9–75.6)	NA
Former established smoker	40.6 (33.1–48.6)	25.9 (16.7–37.8)	15.1 (11.9–18.9)	12.4 (8.8–17.1)	NA
Never smoker	33.7 (26.4–41.8)	24.0 (14.7–36.8)	24.7 (21.9–27.8)	17.1 (13.1–22.0)	NA
NOTE: CI: logit-transformed Wald-type confidence interval; IQR: interquartile range (25th and 75th percentiles); NA: not applicable. <sup>a</sup> When a respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes ( <i>n</i> = 753), for certain topics, they were	e confidence interval; I ng both manufactured	QR: interquartile range cigarettes and roll-your	(25th and 75th percer- own (RYO) cigarette	ntiles); NA: not applicabl s ( $n = 753$ ), for certain top	e. ics, they were
asked separate questions about each product. For dual manuactured tigatetic and ALO survers, the responses to manuactured tigatetic products are provided; otherwise, responses reflect the single cigarette type the respondent reported smoking. <sup>b</sup> Number of days using the product in past 30 days was asked of those who now smoke cigars some days; every day smokers were assumed	ect the single cigarette in past 30 days was a	type the respondent ref sked of those who now	orted smoking. smoke cigars some d	avs; every day smokers <sup>1</sup>	vere assumed
to smoke on all 30 days.	-		D		
<sup><math>c</math></sup> Respondents reporting smoking less than one cigar per day on the days smoked were assigned as smoking 0.5 cigars per day. <sup><math>d</math></sup> Those reporting age at first regular use <6 years were assigned a value of 6 years.	is than one cigar per da use <6 years were assi	ay on the days smoked ' igned a value of 6 years	vere assigned as smo	king 0.5 cigars per day.	
<sup>c</sup> For current cigarette smokers, "currently use other cigar products" refers to current smoking of one or more cigar products. <sup>f</sup> If respondent was missing status for one cigar product and did not smoke the other cigar product, then they were treated as not smoking other	cently use other cigar product and	Joducts" refers to curre d did not smoke the othe	nt smoking of one or r cigar product, then	more cigar products. they were treated as not:	smoking other
cigar types.	· · ·	-			- - -
<sup>8</sup> Current use of noncigar, noncigarette product(s) defined as having ever used one or more of the following tobacco products "fairly regularly" and now using that product every or some days: ENDS, pipe tobacco, hookah, smokeless tobacco, or snus. If respondent reported not using any	te product(s) defined <i>z</i> ome days: ENDS, pipe	as having ever used one e tobacco, hookah, smok	or more of the follow eless tobacco, or snus	ing tobacco products "ta: 6. If respondent reported	rly regularly" not using any
other tobacco product or some combination of not using and missing tobacco product use status, then they were treated as not using any noncigar, noncigar, noncigarette products.	ttion of not using and r	nissing tobacco product	use status, then they	were treated as not using	any noncigar,
<sup>h</sup> Former established cigarette smokers had to have smoked at least 100 cigarettes in their lifetime and now smoke cigarettes not at all; never	ers had to have smoke	d at least 100 cigarettes	in their lifetime and	now smoke cigarettes no	ot at all; never
cigarette smokers nad to smoke rewer ti	to smoke lewer than 100 agarettes in their lifetime.	neir meume.			

TABLE D-3 Tobacco Product Characteristics and Purchasing Behaviors Among Adult Current Established	Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study	· ·
TABLE D-3 Tobacco Product Characteristics at	Traditional Cigar (Premium, Nonpremium), Ci	Wave 4, 2016–2017

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<b>TABLE D-3</b> Tobacco Product Characteristics and Purchasing Behaviors Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study	) Product Characte remium, Nonprem	rristics and Purcha ium), Cigarillo, Fil	cco Product Characteristics and Purchasing Behaviors Among Adult Current Established (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study	ong Adult Currer garette Smokers,	ıt Established PATH Study
VAVE 7, 2010-2011		Nonpremium			
	Premium cigars	cigars	Cigarillos	Filtered cigars	<b>Cigarettes</b> <sup><i>a</i></sup>
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Has a regular brand	38.4 (31.8-45.4)	73.8 (65.3–80.9)	74.8 (70.2–78.8)	68.0 (59.6–75.4)	92.5 (92.0–93.1)
Top 5 brands smoked <sup><math>b</math></sup>	Cohiba 20.3	Black & Mild 23.6	Black & Mild 51.0	Black & Mild 20.7	Marlboro 34.2
	(14.0-26.4)	(16.0 - 31.2)	(46.8 - 55.2)	(14.8 - 26.7)	(32.6–35.9)
	Arturo Fuente 17.9	Acid 12.7	Swisher Sweets 21.1	Cheyenne 18.5	Newport 15.9
	(11.4 - 24.5)	(8.0 - 17.5)	(16.9 - 25.4)	(12.3 - 24.8)	(14.6 - 17.2)
	Romeo y Julieta 7.8	Dutch Masters 11.8	Backwoods 5.3	Swisher Sweets 7.6	Camel 10.8
	(4.1 - 11.5)	(6.6 - 17.1)	(3.5-7.1)	(4.8 - 10.4)	(9.8–11.7)
	Montecristo 6.7	Swisher Sweets 11.6	White Owl 5.0	305's 7.3	Pall Mall 7.0
	(4.0 - 9.3)	(7.7 - 15.5)	(3.0-7.0)	(2.8 - 11.8)	(6.1 - 7.8)
	Macanudo 5.2	White Owl 5.9	Dutch Masters 2.4	Djarum 6.5	American Spirit 3.6
	(2.8–7.6)	(3.1 - 8.7)	(1.0-4.0)	(4.8 - 8.2)	(3.2 - 4.0)

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Regular brand flavored or mentholated <sup>b,c,d</sup>	7.6 (5.5–10.5)	50.3 (38.3–62.3)	55.7 (50.4–60.9)	48.4 (41.2–55.7)	38.4 (36.8–40.0)
Usually buy in person	76.4 (69.3–82.3)	84.0 (74.9–90.3)	92.5 (89.9–94.5)	90.0 (85.5–93.1)	94.9 (94.4–95.4)
Where buy tobacco product <sup>e</sup>					
Cigar bar	35.4 (28.4–43.1)	*	*	*	NA
Convenience store/gas station	*	64.5 (57.4–71.0)	85.2 (81.8–88.1)	73.7 (68.6–78.3)	88.1 (87.2–88.9)
Smoke shop/tobacco specialty or outlet store	44.3 (35.2–53.8)	*	11.3 (9.0–14.2)	22.1 (18.4–26.2)	10.0 (9.0–11.2)
Somewhere else	*	*	*	*	1.9 (1.3–2.6)
Usual purchase size <sup>f</sup>					
Single	71.5 (66.7–75.9)	41.9(35.1 - 49.0)	52.1 (48.4–55.8)	79.4 (74.4–83.7)	2.5 (2.1–2.9)
Box or pack	28.5 (24.1–33.3)	58.1 (51.0-64.9)	47.9 (44.2–51.6)	20.6 (16.4–25.6)	83.3 (82.0–84.5)
Carton	NA	NA	NA	NA	14.2 (13.1–15.4)
Price per stick <sup>68</sup> (median, IQR)	\$7.00 (4.00–10.00)	\$1.07 (0.71–2.00)	\$1.00 (0.66–1.08)	\$0.11 (0.07–0.26)	\$0.30 (0.25-0.35)
NOTE: CI: logit-transformed Wald-type confidence interval; IQR: interquartile range (25th and 75th percentiles); NA: not applicable. <sup><i>a</i></sup> When a respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes ( $n = 753$ ), for certain topics, they were asked separate questions about each product. For dual manufactured cigarette and RYO smokers, the responses to manufactured cigarette products are provided; otherwise, responses reflect the single cigarette type the respontent reported smoking. <sup><i>b</i></sup> Among those with a regular brand; if no regular brand prechased to taste like menthol, mint, clove, spice, candy, fruit, chocolate, <sup><i>c</i></sup> Cigar and RYO smokers were asked whether their regular brand was flavored to taste like menthol, mint, clove, spice, candy, fruit, chocolate,	Wald-type confidence ted smoking both man ut each product. For du onses reflect the single ular brand; if no regula were asked whether th	interval; IQR: interquar ufactured cigarettes and al manufactured cigaret c cigarette type the respo : brand, refers to last brr eir regular brand was fl	tile range (25th and 75th I roll-your-own (RYO) cig te and RYO smokers, the andent reported smoking and purchased. avored to taste like ment	percentiles); NA: not a jarettes ( <i>n</i> = 753), for ce responses to manufactu f, hol, mint, clove, spice, o	pplicable. rtain topics, they were ured cigarette products andy, fruit, chocolate,

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alcohol, or sweets.

<sup>d</sup> Manufactured cigarette and RYO smokers were asked whether their regular brand was mentholated.

" Only asked of those who usually buy in person. Where buy tobacco product refers where purchasing most of the time. "Convenience store/gas station" category also includes supermarket, grocery store, warehouse, or liquor store; "somewhere else" category also includes duty free shop, military commissary, bar/pub, restaurant, casino, friend, relative, swap meet/flea market, or store on an Indian reservation.

fFor cigar smokers, restricted to usually buy in person; for cigarettes, asked of manufactured cigarette smokers, irrespective of buying in person or not.

<sup>8</sup> Among filtered cigar smokers, price per stick is restricted to those who reported purchasing either 20- or 12-count packs (44% of all filtered cigar smokers).

\*The estimate has been suppressed because it is statistically unreliable. It is based on a (denominator) sample size of less than 50, or the relative standard error of the estimate (or its complement) is larger than 30 percent.

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	Prevalence <sup><i>a</i></sup> (95% CI) ( $n = 1,688$ )	Adjusted $PR^a$ (95% CI) ( $n = 1,628$ )	
Smoke premium cigars			
Yes	23.2 (17.3–30.4)	0.53 (0.41–0.69)	
No	59.8 (57.1–62.3)	Ref	
Smoke nonpremium cigars			
Yes	46.5 (39.1–54.0)	0.80 (0.67-0.95)	
No	51.5 (48.6-54.4)	Ref	
Smoke cigarillos			
Yes	60.3 (57.2–63.2)	1.37 (1.17–1.59)	
No	40.1 (36.2–44.0)	Ref	
Smoke filtered cigars			
Yes	70.5 (64.9–75.6)	1.58 (1.41–1.77)	
No	42.3 (39.3-45.4)	Ref	
Use other tobacco products $^b$			
Yes	59.6 (53.5–65.4)	1.14(1.04-1.25)	
No	47.7 (45.0–50.4)	Ref	
Sex			
Male	47.7 (45.2–50.2)	Ref	
Female	60.9 (56.9–64.8)	1.05 (0.97–1.13)	
		continued 2	

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	Prevalence <sup><i>a</i></sup> (95% CI) ( $n = 1,688$ )	Adjusted PR <sup>a</sup> (95% CI) ( <i>n</i> = 1,628)
Age group (years)		
18–34	54.1 (50.1–58.2)	1.01 (0.91–1.12)
35+	48.1 (44.6–51.6)	Ref
Race/ethnicity		
White, non-Hispanic	50.0 (45.9–54.1)	Ref
Black/AA, non-Hispanic	50.7 (45.4-56.1)	0.85 (0.74–0.97)
Other/multi-race, or Hispanic	53.7 (44.2-63.0)	0.93 (0.80–1.09)
Education		
GED, HS diploma or less	64.0 (60.1–67.7)	1.38 (1.26–1.51)
Some college/associate degree or more	38.2 (34.7-41.7)	Ref
Daily cigar smoking $^c$		
Yes	50.9 (44.3–57.4)	0.82 (0.72–0.92)
No	50.6 (46.9–54.4)	Ref
NOTE: CI: logit-transformed Wald-type confidence interval; PR: prevalence ratio; AA: African American; HS: high school; GED: General Education Development certificate. ${}^{a}$ There were $n = 1,688$ current established cigar smokers with information on current cigarette smoking status. The regression analysis included n = 1,628 participants ( $n = 774$ cigar only; $n = 854$ dual cigar + cigarette) after observations missing information for covariate were excluded. ${}^{b}$ Use of other tobacco products defined as having ever used one or more of the following tobacco products "fairly regularly" and now using	e ratio; AA: African American; HS: hig on on current cigarette smoking status fter observations missing information or of the following tobacco products	h school; GED: General Education . The regression analysis included for covariate were excluded. "fairly regularly" and now using
that product every day or some days: ENUD, pipe tobacco, hookah, smokeless tobacco, or snus.	eless tobacco, or snus.	

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<sup>c</sup> Daily cigar refers to smoking at least one cigar type on a daily basis.

ed exclusive <sup>a</sup> users of four cigar types, cigarette	dult population in U.S. PATH adults
ng current established exclusiv	ne overall a
TABLE D-5 Tobacco dependence among current established ex	smokers, users of smokeless tobacco and hookah, and th

		Nonpremium				Smokeless		
	<b>Premium cigars</b>	cigars	Cigarillos	Filtered cigars	Cigarettes	tobacco	Hookah	ENDS
Sample size, <i>n</i>	size, n							
Wave 1	165	70	289	79	8,223	945	451	415
Wave 2	145	46	162	60	7,118	776	258	518
Wave 3	160	37	152	56	6,828	712	217	620
Wave 4	181	58	254	77	7,663	662	209	677
Wave 5	177	45	262	72	6,387	644	160	1,639
Mean T	Mean TDS (95% CI)							
Wave 1	7.8 (6.4–9.1)	13.1 (10.4–15.9)	22.4 (20.1–24.8)	35.2 (30.7–39.6)	$13.1 \ (10.4 - 15.9)  22.4 \ (20.1 - 24.8)  35.2 \ (30.7 - 39.6)  52.4 \ (51.8 - 53.0)  45.4 \ (44.1 - 46.6)  52.4 \ (51.8 - 53.0)  45.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)  52.4 \ (52.1 - 56.6)$	45.4 (44.1–46.6)	8.1 (7.4–8.8)	25.7 (23.8–27.7)
Wave 2	7.1 (5.7–8.5)	12.9 (10.2–15.6)	21.2 (19.1–23.3)	31.5 (27.6–35.3)	31.5 (27.6–35.3) 49.6 (48.9–50.3) 42.9 (41.8–43.9)	42.9 (41.8–43.9)	4.9 (3.8–6.0)	21.1 (19.3–22.8)
Wave 3	6.0 (4.3–7.7)	16.9 (8.0–25.8)	17.1 (13.8–20.4)	36.3 (27.1–45.4)	50.6 (50.1–51.0) 44.1 (42.4–45.9)	44.1 (42.4–45.9)	5.2 (4.1–6.3)	32.9 (31.2–34.6)
Wave 4	6.6 (5.4–7.8)	10.4 (7.3–13.4)	20.3 (17.4–23.2)	36.6 (29.2-43.9)	$36.6 \ (29.2-43.9)  51.1 \ (50.6-51.5)  44.0 \ (41.9-46.0)$	44.0 (41.9-46.0)	6.8 (5.1–8.6)	36.7 (34.6–38.8)
Wave 5	4.8 (4.0–5.6)	16.7 (9.4–23.9)	20.2 (17.9–22.4)	34.7 (27.6, 41.8)	51.4 (50.7–52.2) 45.7 (44.4–47.1)	45.7 (44.4-47.1)	7.6 (6.3-8.9)	37.1 (35.6–38.6)
Median	Median TDS (IQR)							
Wave 1	3.1 (0.0–9.4)	3.1 (0.0–15.6)	12.5 (3.1–35.5)	31.3 (9.4–50.2)	53.1 (31.3–75.0) 43.8 (21.9–68.8)	43.8 (21.9–68.8)	3.1 (0.0–9.4)	18.8 (3.1–43.3)
Wave 2	3.1 (0.0–9.4)	6.3 (0.0–18.8)	12.5 (3.1–34.4)	27.9 (9.4–46.9)	50.0 (28.1–71.9) 40.6 (18.8–62.5)	40.6 (18.8–62.5)	3.1 (0.0-6.3)	12.5 (0.0–35.2)
Wave 3	0.0 (0.0–6.3)	3.1 (0.0–16.8)	9.0 (0.0–28.1)	33.6 (4.8–56.3)	53.1 (28.1–73.3) 46.9 (18.8–65.6)	46.9 (18.8–65.6)	0.0 (0.0-6.3)	31.3 (6.3–53.1)
Wave 4	0.0 (0.0–6.3)	0.0 (0.0–9.4)	12.5 (0.0–31.3)	34.7 (9.4–56.8)	53.1 (28.1–75.0) 43.8 (18.8–65.6)	43.8 (18.8–65.6)	0.0 (0.0-6.3)	34.4 (9.4–56.3)
Wave 5	0.0 (0.0–6.3)	3.1 (0.0–24.8)	12.5 (3.1–31.3)	21.5 (6.3–64.2)	53.1 (31.3–75.0) 46.9 (18.8–68.8)	46.9 (18.8–68.8)	0.0 (0.0-9.4)	34.3 (12.5–56.3)

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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		Nonpremium				Smokeless		
	Premium cigars	cigars	Cigarillos	Filtered cigars	Cigarettes	tobacco	Hookah	ENDS
Percenta	Percentage of report 1+ symptoms (95% CI): TDS >0	mptoms (95% CI)	): TDS >0					
Wave 1	59.6 (52.9–65.8)	63.8 (51.4–74.6)	59.6 (52.9–65.8) 63.8 (51.4–74.6) 76.5 (71.9–80.5) 92.5 (89.5–94.7) 96.1 (95.6–96.4) 95.6 (94.3–96.6) 63.0 (60.8–65.1) 79.4 (75.7–82.7)	92.5 (89.5–94.7)	96.1 (95.6–96.4)	95.6 (94.3–96.6)	63.0 (60.8–65.1)	79.4 (75.7–82.7)
Wave 2		67.8 (54.4–78.8)	59.7 (50.6–68.2) 67.8 (54.4–78.8) 78.6 (71.3–84.4) 87.3 (80.4–92.1) 95.2 (94.6–95.6) 94.0 (90.8–96.1) 50.1 (45.1–55.2) 71.8 (67.5–75.7)	87.3 (80.4–92.1)	95.2 (94.6–95.6)	94.0 (90.8–96.1)	50.1 (45.1–55.2)	71.8 (67.5–75.7)
Wave 3	Wave 3 49.1 (39.1–59.3) 64.0 (53.6–73.3) 70.8 (62.6–77.9) 81.7 (72.5–88.3) 94.5 (93.6–95.2) 91.1 (88.9–93.0) 44.3 (36.4–52.4) 82.8 (80.2–85.1)	64.0 (53.6–73.3)	70.8 (62.6–77.9)	81.7 (72.5–88.3)	94.5 (93.6–95.2)	91.1 (88.9–93.0)	44.3 (36.4–52.4)	82.8 (80.2–85.1)
Wave 4	Wave 4 46.9 (41.5-52.4) 46.6 (34.8-58.7) 73.0 (69.0-76.6) 85.6 (76.0-91.8) 95.2 (94.7-95.6) 94.7 (93.4-95.8) 47.5 (43.4-47.5) 90.0 (88.3-91.5)	46.6 (34.8–58.7)	73.0 (69.0–76.6)	85.6 (76.0–91.8)	95.2 (94.7–95.6)	94.7 (93.4–95.8)	47.5 (43.4–47.5)	90.0 (88.3–91.5)
Wave 5	Wave 5 43.3 (36.1–50.9) 54.2 (41.7–66.1) 75.5 (67.2–82.3) 87.2 (77.0–93.2) 94.7 (93.9–95.4) 95.8 (93.7–97.2) 48.4 (42.8–54.1) 89.1 (87.7–90.4)	54.2 (41.7-66.1)	75.5 (67.2–82.3)	87.2 (77.0–93.2)	94.7 (93.9–95.4)	95.8 (93.7–97.2)	48.4 (42.8–54.1)	89.1 (87.7–90.4)
Sample :	Sample size and difference in mean TDS between nondaily and daily users (95% CI)	e in mean TDS b	etween nondaily	and daily users	(95% CI)			
Wave 1	151/14 26.9 (21.3–32.6)	53/17 20.1 (10.0–30.2)	151/14         53/17         209/80         43/36           26.9 (21.3-32.6)         20.1 (10.0-30.2)         21.9 (15.0-28.9)         32.3 (24.2-40.5)		1607/6616 37.6 (36.6–38.5)	248/691 27.2 (24.7–29.7)	1607/6616         248/691         434/17         147/268           37.6 (36.6–38.5)         27.2 (24.7–29.7)         19.1 (14.5–23.8)         13.1 (10.7–15.5)	147/268 13.1 (10.7–15.5)
Wave 2	135/10 15.6 (6.1–25.1)	39/7 24.2 (15.0–33.5)	39/7 119/43 24.2 (15.0–33.5) 20.5 (15.2–25.7)	35/25 22.3 (15.7–28.9)	1425/5693 35.8 (34.9–36.7)	201/575 30.2 (27.3–33.1)	246/12 161/357 27.0 (13.9–40.0) 14.1 (11.7–16.4)	161/357 14.1 (11.7–16.4)
Wave 3	153/7 25.9 (8.2–43.7)	29/8 24.3 (5.0–43.7)	105/47 17.5 (9.7–25.2)	30/26 25.7 (17.0–34.5)	1266/5562 36.7 (35.6–37.8)	170/542 34.2 (32.2–36.3)	211/6 16.2 (1.1–31.2)	221/399 30.5 (28.1–33.0)
Wave 4	172/9 13.5 (-4.7-31.6)	40/18 20.8 (8.0–33.6)	183/71 24.1 (18.9–29.3)	40/37 17.1. (4.4–29.9)	1561/6102 36.6 (35.7–37.5)		205/594 205/4 27.6 (23.8–31.4) 40.4 (34.3–46.5)	260/519 29.4 (26.0–32.8)
Wave 5	166/11 9.4 (-2.8-21.6)		38/7         177/85         36/36         1304/5,083         163/481         151/9         633/1006           13.8 (0.8-26.8)         19.9 (13.1-26.7)         42.9 (34.9-50.9)         36.6 (35.7-37.5)         28.3 (25.3-31.4)         28.8 (19.5-38.0)         29.4 (27.4-31.4)	36/36 42.9 (34.9–50.9)	1304/ 5,083 36.6 (35.7–37.5)	163/481 28.3 (25.3–31.4)	151/9 28.8 (19.5–38.0)	633/1006 29.4 (27.4–31.4)

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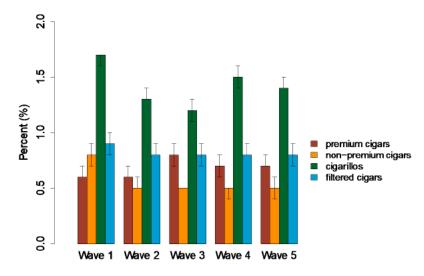
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Sample s	ize and difference	e in mean TDS b	etween users of <	<6 days and 6+ d <sup>2</sup>	ays used in the p	Sample size and difference in mean TDS between users of <6 days and 6+ days used in the past 30 days <sup>6</sup> (95% CI)	CI)	
Wave 1	123/40 14.6 (10.2–19.0)	34/34 13.1 (5.9–20.2)	$\frac{101/178}{20.0(15.8-24.2)}$	22/54 20.9 (11.1–30.7)	526/7633 43.4 (42.0–44.8)	70/832 31.1 (26.6–35.6)	163/84 9.1 (5.3–13.0)	66/345 15.6 (12.0–19.2)
Wave 2	117/25 9.0 (2.6–15.3)	28/16 16.1 (7.9–24.4)	72/85 20.1 (17.7–22.6)	23/35 13.9 (4.0–23.8)	436/6619 41.4 (39.7–43.1)	65/686 35.5 (31.0–40.1)	75/42 2.9 (0.7–5.1)	84/429 13.3 (9.5–17.1)
Wave 3	128/27 11.4 (6.5–16.4)	20/16 25.4 (3.8–47.0)	70/80 14.3 (8.8–19.8)	20/36 18.9 (9.5–28.2)	439/6344 38.8 (36.3–41.2)	64/626 35.1 (30.6–39.7)	64/19 12.0 (8.8–15.3)	102/510 26.5 (22.4–30.7)
Wave 4	144/33 12.6 (4.0–21.2)	29/28 15.7 (7.0–24.3)	97/151 17.1 (13.0–21.1)	27/50 13.9 (-2.6-30.5)	563/7044 39.2 (37.6–40.7)	65/701 29.6 (23.9–35.4)	62/33 13.8 (1.9–25.7)	120/652 30.2 (26.3–34.2)
Wave 5	145/30 5.9 (1.2–10.6)	30/15 10.9 (0.3–21.5)	95/163 17.6 (13.4–21.8)	21/51 30.9 (22.6–39.1)	499/5852 42.3 (40.5–44.1)	53/564 32.5 (29.1–35.9)	34/31 10.2 (3.4–17.0)	267/1362 29.4 (27.6–31.3)
Linear as	Linear association of the n	number of days u	the number of days used in the past 30 days $^b$ with TDS (95% CI)	days <sup>b</sup> with TDS	(95% CI)			
Wave 1	0.9 (0.7–1.1)	0.7 (0.4–1.0)	0.9 (0.7–1.1)	1.1 (0.7 - 1.4)	1.8(1.8-1.9)	1.4 (1.2–1.5)	0.0 (0.0-0.0)	0.6 (0.5–0.7)
Wave 2	0.5 (0.3–0.8)	0.9 (0.6–1.2)	0.9 (0.8–1.0)	0.7 (0.4–1.1)	1.8(1.7-1.8)	1.4 (1.3–1.6)	0.0 (0.0–0.2)	0.6 (0.5–0.7)
Wave 3	0.6 (0.2–0.9)	1.5 (0.8–2.3)	0.6 (0.4–0.9)	0.9 (0.5–1.3)	1.7(1.7-1.8)	1.5 (1.4–1.7)	0.5 (0.2–0.9)	1.3 (1.1–1.4)
Wave 4	0.6 (0.0–1.1)	0.7 (0.3–1.1)	0.9 (0.7–1.0)	0.6 (0.2–1.1)	1.7(1.6-1.7)	1.3 (1.1–1.6)	0.2 (-0.1-0.5)	1.3 (1.2–1.4)
Wave 5	0.3 (0.0–0.7)	0.8 (0.4–1.2)	0.7 (0.5–0.9)	1.5 (1.2–1.8)	1.7(1.7-1.8)	1.5 (1.3–1.7)	0.6 (0.4–0.7)	1.3 (1.2–1.4)
NOTE: CI: logit-tı delivery systems. <sup>a</sup> Exclusive mee	I: logit-transform systems. sive means that t	ed Wald-type con thev use only the	nfidence interval; at product current	IQR: interquartil tlv or in past 30	e range; TDS: tok davs but no othe	NOTE: CI: logit-transformed Wald-type confidence interval; IQR: interquartile range; TDS: tobacco dependence score; ENDS: electronic nicotine delivery systems. <sup><i>a</i></sup> Exclusive means that thev use only that product currently or in past 30 days but no other tobacco product. For cigar users, exclusive also	e score; ENDS: el :t. For cigar user	lectronic nicotine rs. exclusive also
eliminate <sup>b</sup> For h	iminates respondents wh <sup>b</sup> For hookah users, the f	no report using a requency inform	eliminates respondents who report using a second cigar product type ${}^b$ For hookah users, the frequency information was reported by the ${}^p$	luct type. d by the number	of "times" instea	ts who report using a second cigar product type. the frequency information was reported by the number of "times" instead of "days" used in the past 30 days in PATH data.	in the past 30 da	ys in PATH data.

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**FIGURE D-1** Overall prevalence of premium cigar, nonpremium cigar, cigarillo, and filtered cigar users by wave in the PATH data.

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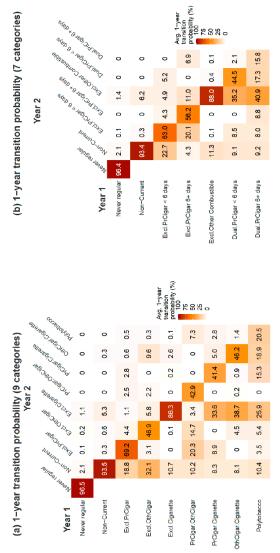
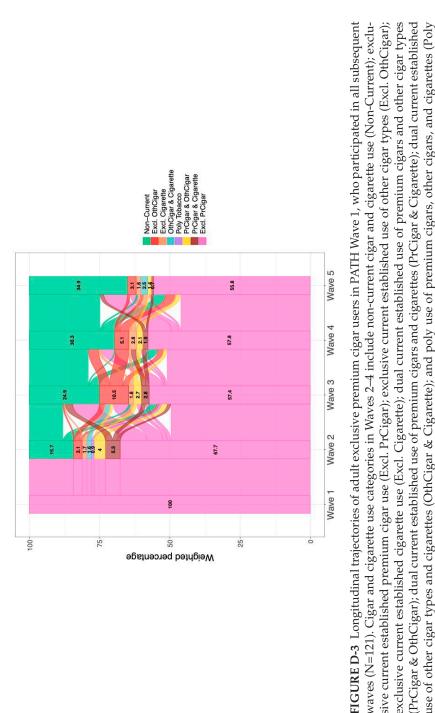


FIGURE D-2 Average 1-year transition probabilities based on longitudinal data from PATH Waves 1-4. Two alternative use 30 days (Excl.Prcigar <6 days), exclusive current established premium cigar use with 6+ days of use in past 30 days (Excl.PrCigar 6+ days), exclusive current established other combustible tobacco use (Excl.Other Combustible), dual current established use of premium cigar with <6 days of use in past 30 days and other combustible tobacco use (Dual.PrCigar <6 days), and dual current groupings were used: (a) never cigar and cigarette use (Never regular), non-current cigar and cigarette use (Non-Current), exclusive current established premium cigar use (Excl. PrCigar), exclusive current established use of other cigar types (Excl.OthCigar), exclusive current established cigarette use (Excl.Cigarette), dual current established use of premium cigars and other cigar types (PrCigar.OthCigar), dual current established use of premium cigars and cigarettes (PrCigar.Cigarette), dual current established non-current cigar and cigarette use (Non-Current), exclusive current established premium cigar use with <6 days of use in past use of other cigar types and cigarettes (OthCigar.Cigarette), and polytobacco use; (b) never cigar and cigarette use (Never regular), established use of premium cigar with 6+ days of use in past 30 days and other combustible tobacco use (Dual. PrCigar 6+ days)



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obacco use)

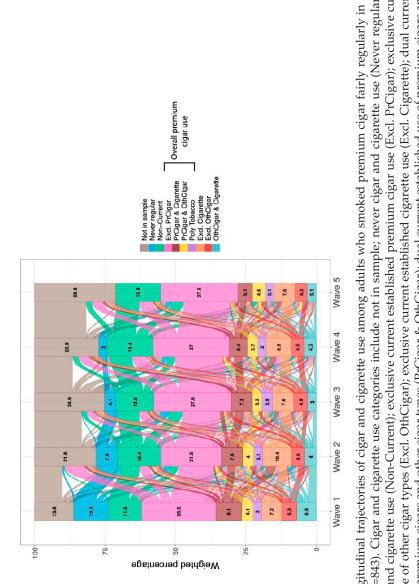


FIGURE D-4 Longitudinal trajectories of cigar and cigarette use among adults who smoked premium cigar fairly regularly in at least one wave (N=843). Cigar and cigarette use categories include not in sample; never cigar and cigarette use (Never regular); non-current cigar and cigarette use (Non-Current); exclusive current established premium cigar use (Excl. PrCigar); exclusive current established use of other cigar types (Excl. OthCigar); exclusive current established cigarette use (Excl. Cigarette); dual current established use of premium cigars and other cigar types (PrCigar & OthCigar); dual current established use of premium cigars and cigarettes (PrCigar & Cigarette); dual current established use of other cigar types and cigarettes (OthCigar & Cigarette); and poly use of premium cigars, other cigars, and cigarettes (Poly tobacco use)

**Supplemental Table A**. Assignment of adult current established traditional cigar smokers as either premium or nonpremium based on usual cigar brand, PATH Study, Waves 1–5

Since regulatory definitions of premium cigars do not exist, information about the brand's tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade), obtained through online searches, was used to distinguish premium from nonpremium brands.

Assignment	Brand name reported
Premium cigar brands	5 Star, 5 Vegas, Alec Bradley, Arturo Fuente, Ashton, Ben-Bay, Bolivar, Brickhouse, Buccanero, CAO, Casablanca, Chubb, Churchill, Cohiba, CubaLibre, Cuban, Davidoff, Don Tomas, Drew Estates, Durango, El Pita, Elverso, Excalibur, Flor de Oliva, Gurkha, H. Uppmanns, Hoya de Monterrey, Indio, Joya de Nicaragua, Kristoff, La Corona, La Gloria Cubana, Los Blan- cos, Macanudo, Makers Mark, Man of War, Montecristo, My Father, Nub, Oliva, Padron, Partagas, Perdomo, Professor Sila, Punch, Robert Burns Blackwatch, Rocky Patel, Romeo y Julieta, San Cristo, Tatuaje, Torano, Victor Sinclair, Zeno
Nonpremium cigar brands	Acid, Al Capone, Antonio y Cleopatra, Backwoods, Black and Mild, Blackstone, BLK, Djarum, Dutch Masters, El Producto, Entourage, Game, Garcia y Vega, Hav-A-Tampa, Isla Del Sol, Java, Kahula, King Edward, Marsh Wheeling, Miami Suites, Middletons, Munnimaker, Muriels, Optimo, Parodi, Phillies, Spliterillo, Supre Sweets, Supreme Blend Peach Cigars, Su- preme Menthol, Swisher Sweets, Tampa Nugget, Tampa Sweet, White Owl

- Based on web search conducted that suggested the product was either a filtered cigar or tipped cigarillo. The brands/sub-brands were 305's, 38 Special, Cheyenne, Clipper, Criss Cross, Dark Horse 100 Menthol, Deans, Gambler, King Edward Wood Tip, Phillies Black Max (plastic tip), Prime Time Large Filtered Cigar, Prime Time PT Tips!, Red Buck, Richwood, Santa Fe, Stampede, Supreme, Swisher Sweets Filter Tip, Wild Horse, Wrangler.
- These brands had insufficient information to assign as either premium or nonpremium traditional cigar: Cigar Factory, Helio, Hope, Imports, JR, Laquade, Local Made, Private Stock, Quimbo, Richmond, Thompson, VIP Cigars.
- For the traditional cigar smokers not assigned as either premium or nonpremium on the basis of brand name, based on the distribution of price paid, ≥\$2/cigar was used as premium.

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# Appendix E

# **Cigar Brands from PATH and NSDUH Analyses**

This appendix lists the brands of cigars considered by the committee to be premium for use in the commissioned PATH and NSDUH analyses. Three expert coders independently and manually coded brands from NSDUH and PATH data using brand and vendor websites (see Appendix C and D for more details). A cigar was defined as premium if it appeared to meet all the following criteria: 1) handmade, 2) filler at least 50 percent natural long-leaf filler tobacco, 3) wrapped in whole leaf tobacco, 4) weight of at least 6 pounds per 1,000 units, 5) no filter or tip, and 6) no characterizing flavor other than tobacco, per the committee's definition for the purpose of this report (see Chapter 1). Disagreements among coders were discussed with an additional expert, and codes were cross-referenced with those from Corey et al. (2018), on U.S. adult cigar use by type from the PATH study. The results of this coding process were applied throughout the report. It should be noted that the coders made their assessments based on information available online only. In addition, brands often make multiple products, and the coders considered multiple products in a brands line—if any of those products did not meet the definition of premium, the brand was considered nonpremium (e.g., if some of the brands cigar products used added flavors).

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## PREMIUM CIGARS

5 Star 5 Vegas Alec Bradley Arturo Fuento Ashton Baccarat Ben-Bay Bolivar Brickhouse Buccanero C.A.O. Casablanca Chubb Churchill Cohiba CubaLibre Cuban Cubana Cuesta-Rey Davidoff Diesel Don Tomas

Don Tomas Drew Estates Durango El Pita Elverso Excalibur Flor de Oliva Fuente Gurkha H. Uppmanns Hoya de Monterrey Indio Joya de Nicaragua K. Hansotia Gurhka Kristoff La Corona La Flor Dominicana La Gloria Cubana Los Blancos Macanudo Makers Mark Man of War

Montecristo Mv Father Nat Sherman Nub Oliva O Padron Partagas Perdomo Professor Sila Punch Puros Indios Robert Burns Black Watch Rocky Patels Romeo y Julieta Room101 305s Royal Jamaica San Cristo Tatuaje Torano Victor Sinclair Zeno

## NONPREMIUM

1839 305 s38 Special Acid Al Capone Antonio y Cleopatra Backwoods Black and Mild Blackstone BLK Captain Black Cheyenne Clipper Criss Cross Dark Horse100 Menthol

Deans Lil **Directors** Club Djarum Double Diamond **Dutch Masters** El Producto Entourage Fronto King Gambler Game Garcia y Vega Golden Harvest Good Times Grenadiers Havana Honey Hav-A-Tampa

Isla Del Sol Jackpot Java Kahula King Edward Little Nippers Marsh Wheeling Miami Suite Middletons Munnimaker Muriel Optimo Parodi Phillies Pom Pom Prime Time

#### APPENDIX E

Racer	Spliterillo	Tijuana Smalls
Red Buck	*	Vendetta
Red Duck	Stampede	vendetta
Remington	Supre Sweets	White Owl
Richwood	Supreme Blend	Wild Horse
Santa Fe	Supreme Menthol	Winchester
Seneca	Swisher Sweets	Wrangler
Show	Tampa Nugget	ZigZag
Smokers Best	Tampa Sweet	
Smokers Choice	Tatiana	

#### UNKNOWN/INSUFFICIENT INFORMATION TO DETERMINE

Blunts; brand unspecified Cigar/cigarillo; brand otherwise unspecified Cigar Factory Dominican; brand unspecified Habana/Havana; brand unspecified Helio Homemade cigars Honduran; brand unspecified Hope Imports JR Laquade Local made "Not a tobacco product" Pipe tobacco; brand otherwise unspecified Private stock Quimbo Richmond Smoker Friendly Thompson Tobacco replacement or tobacco-like product VIP cigars

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# Appendix F

# **Cigar Physical Characteristics**

Overall Paper Authored by:<sup>1</sup> Sundos Yassin and Jeremy Giberson<sup>2</sup> Additional authors:<sup>3</sup> Michelle Page<sup>4</sup>

#### INTRODUCTION AND TASK

To inform the Committee on Health Effects and Patterns of Use of Premium Cigars, a variety of premium cigars across the top 15 brands, including sub-brands within each, was purchased, weighed, measured, and photographed. An assortment of other products was included in the study, such as cigarillos and traditional cigars. Each product was weighed twice, measured by length and diameter, and photographed against a blue background with a measuring device beside it. All products were purchased within the San Francisco Bay Area in August 2021.

#### METHODS

NASEM provided a list of cigars, indicating the most popular premium brands and other types. An online search determined the local

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<sup>&</sup>lt;sup>1</sup>Committee member Neal Benowitz oversaw the cigar characteristics analysis, reviewed the results for accuracy, provided regular feedback to the authors, and edited the final paper.

<sup>&</sup>lt;sup>2</sup> Clinical Pharmacology Research Program, Division of Cardiology, Department of Medicine, University of California, San Francisco, CA, USA

<sup>&</sup>lt;sup>3</sup>Committee member Maciej Goniewicz oversaw the nicotine content analysis and reviewed the results for accuracy, provided regular feedback to the chemist conducting the analysis, and edited the summary of the findings.

<sup>&</sup>lt;sup>4</sup> Research Associate, Roswell Park Comprehensive Cancer Center, conducted the nicotine analysis and summarized the methodology and findings.

retail locations of cigar shops, and three tobacco stores, three convenience stores, and two chain markets were chosen. Products from the most popular brands were purchased first, including 2–4 sub-brands of each brand and 1–2 cigars from each sub-brand. Less popular brands were purchased second, given local availability.

Each cigar was compiled into a list, organized by brand and subbrand (Table F-1). The weight, length, and diameter of each cigar were recorded, in addition to photographs of the cigar with and without the original packaging.

A composite photograph of cigar brands was taken with the original packaging. Photographs of each individual cigar next to the measuring device were taken after removal of the original packaging. Additionally, composite photographs across cigar brands and sub-brands were taken, both with and without original packaging.

To measure weight, a clean beaker was placed on a digital scale and tared. The cigar was removed from its packaging and placed into the beaker. The weight was recorded in grams. These procedures were completed twice for each cigar. To measure diameter and length, a digital caliper was used. The diameter was taken from the middle portion of each cigar. The length was measured from the tip to the foot. Note that the caliper was not able to measure every cigar; the largest required a standard ruler. The diameter and length were both recorded in millimeters.

To analyze the nicotine content, a 3 gram sample was collected from 58 cigars of varying brands (one from each sub-brand) using a sterile scalpel. It was placed in a 50 mL plastic conical vial and labeled with a sample ID. All vials were sent to the Roswell Park Comprehensive Cancer Center in Buffalo, NY for analysis. Tobacco samples were analyzed for their respective nicotine content using gas chromatography-nitrogen phosphorus detector, using a modification of the CORESTA number 62 method.<sup>5</sup> (See the analytical report from Roswell Park for details.<sup>6</sup>)

## RESULTS

The weight, length, and diameter for all cigars analyzed are listed below, sorted by brand popularity. Average nicotine concentration and total nicotine per cigar are also listed for each sub-brand.

<sup>&</sup>lt;sup>5</sup> CORESTA. 2020. CORESTA Recommended Method No. 62: Determination of nicotine in tobacco and tobacco products by gas chromatographic analysis. Paris, France: Cooperation Centre for Scientific Research Relative to Tobacco.

<sup>&</sup>lt;sup>6</sup> Available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

Brand	Sub-Brands
Cohiba*	Serie M (Miami Limited Edition) Cohiba Robusto Red Dot (2) Black Robusto (2)
Romeo y Julieta*	1875 Reserva Real Toro 1875 Reserva Real Bully Short Story (2) 1875 Nicaragua
Arturo Fuente*	Hemingway Signature (3) Hemingway Short Story (2) Curly Head Natural
Macanudo*	Hyde Park Café (2) Baron de Rothschild Petit Corona (2)
Montecristo*	Classic Robusto White Series Court White Series Churchill
Padron*	Churchill 3000 Maduro "Handmade" (2) 2000 Maduro "Handmade" (2)
Rocky Patel*	1992 Vintage Sumatra Robusto 1990 Vintage Perfecto 1990 Vintage Robusto (2) 1999 Vintage Robusto (2)
Punch*	Clasico Double Corona (2) Clasico London Club Clasico Rothschild
Partagas*	Robusto (2) Black Bravo Black Magnifico
La Gloria Cubana*	Cubana Wavell Maduro (2) Cubana Wavell Natural (2) Cubana Churchill
K. Hansotia Gurkha*	Gurkha Cellar Reserve 15 Year Hedonism (2) Gurkha Cellar Reserve Ghost (2)
My Father*	Garcia & Garcia No. 1 Robusto El Centurion H-2K-CT (2) Flor de las Antillas (2)
Ashton*	Aged Maduro Virgin Sun Grown Virgin Sun Grown Eclipse

# TABLE F-1 All Cigars Purchased

continued

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Brand	Sub-Brands
CAO*	America Potomac (2) Gold Maduro
Davidoff*	Aniversario Special "R" (2) Aniversario No. 3 Churchill Robusto
Acid	Kuba Kuba (2) Blondie (2)
Black & Mild	Casino Cigar (plastic tip) (2) Original Cigar (wood tip) (2) Jazz Cigarillos (2)
Backwoods	Original Cigar Honey Berry Cigar (2)
Swisher Sweets	Blueberry Cigarillos (2) Grape Cigarillos (2) Leaf Original Cigar (2)
Dutch Masters	Dutch Blend—Silver Cigarillos (2) Palma Cigar (2)
Garcia y Vega	Irish Cream Cigar (2) Natural (Brown Leaf Cigar) (2)

#### TABLE F-1 Continued

NOTE: \* = premium brand as determined by the committee.

## **Brand: Cohiba**

Table F-2 shows Cohiba and selected sub-brands. The Cohiba Robusto Red Dot had a difference in weight, length, and diameter between the two samples of 1.3 grams, 0.71 mm, and 0.16 mm, respectively. The Black Robusto had a difference in weight, length, and diameter between the two samples of 2.8 grams, 1.55 mm, and 0.73 mm, respectively.

## Brand: Romeo y Julieta

Table F-3 shows Romeo y Julieta and selected sub-brands. The 1875 Reserva Real Bully Short Story had a difference in weight, length, and diameter between the two samples of 1.8 grams, 0.38 mm, and 0.39 mm, respectively.

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Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concentra- tion (mg/g tobacco)	Total Nico- tine per Cigar (mg)
Serie M (Miami Limited Edition)	17.1	17.1	146.66	19.12	37.70	33.26	568.75
Cohiba Robusto Red Dot	11.6	11.6	126.45	19.28	25.57	_	_
Cohiba Robusto Red Dot	12.9	12.9	127.16	19.12	28.44	16.47	212.46
Black Robusto	12.3	12.3	137.83	20.30	27.12	_	_
Black Robusto	15.1	15.1	139.38	19.57	33.29	18.56	280.26

#### TABLE F-2 Cohiba and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter. — Not calculated.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concentra- tion (mg/g tobacco)	Total Nico- tine per Cigar (mg)
1875 Reserva Real Toro	21.5	21.5	152.44	21.24	47.40	28.63	615.55
1875 Reserva Real Bully Short Story	15.1	15.1	126.79	19.56	33.29	26.12	394.41
1875 Reserva Real Bully Short Story	13.3	13.3	126.41	19.17	29.32	_	_
1875 Nica- ragua	10.4	10.4	126.19	19.32	22.93	9.78	101.71

# TABLE F-3 Romeo y Julieta and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

#### **Brand: Arturo Fuente**

Table F-4 shows Arturo Fuente and selected sub-brands. The Hemingway Short Story had a difference in weight, length, and diameter between the two samples of 0.4 grams, 0.95 mm, and 0.5 mm, respectively.

#### **Brand: Macanudo**

Table F-5 shows Macanudo and selected sub-brands. The Hyde Park Café had a difference in weight, length, and diameter between the two samples of 3.4 grams, 2.09 mm, and 0.17 mm, respectively. The Petit Corona had no difference in weight, but the length and diameter difference between the two samples was 1.71 mm and 0.35 mm, respectively.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Heming- way Signature	11.9	11.9	151.99	17.33	26.24		_
Heming- way Signature	10.4	10.4	151.99	17.25	22.93	21.65	225.16
Heming- way Signature	11.1	11.1	149.51	17.52	24.47	_	_
Heming- way Short Story	7.8	7.9	99.35	16.9	17.20	_	_
Heming- way Short Story	8.2	8.2	100.3	16.4	18.08	18.94	155.31
Curly Head Natural	10.3	10.3	170.1	16.10	22.71	12.70	130.81

#### TABLE F-4 Arturo Fuente and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

Not calculated.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Hyde Park Café	13.6	13.6	139.30	18.92	29.98	_	_
Hyde Park Café	17.0	17.0	141.39	18.75	37.48	17.40	295.80
Baron De Roth- schild	14.8	14.8	140.08	19.00	32.63	8.51	125.95
Petit Corona	6.6	6.6	126.29	14.40	14.55	_	_
Petit Corona	6.6	6.6	128.00	14.05	14.55	15.05	99.33

#### TABLE F-5 Macanudo and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter. Not calculated.

#### **Brand: Montecristo**

Table F-6 shows Montecristo and sub-brands. Cigars from this brand were difficult to locate, so only one from each sub-brand listed above were included in the study.

#### Brand: Padron

Table F-7 shows Padron and selected sub-brands. The 3000 Maduro "Handmade" had a difference in weight, length, and diameter between the two samples of 0.8 grams, 1.03 mm, and 0.5 mm, respectively. The 2000 Maduro "Handmade" had a difference in weight, length, and diameter between the two samples of 0.4 grams, 0.24 mm, and 0.01 mm, respectively.

## **Brand: Rocky Patel**

Table F-8 shows Rocky Patel and selected sub-brands. The 1990 Vintage Robusto had a difference in weight, length, and diameter between the two samples of 4 grams, 0.01 mm, and 1.41 mm, respectively. The 1999

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Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Classic Robusto	16.9	16.9	127.90	19.73	37.26	26.76	452.24
White Se- ries Court	11.4	11.4	139.58	16.67	25.13	17.62	200.89
White Series Churchill	25.8	25.8	176.2	20.29	56.88	24.39	629.26

## **TABLE F-6**Montecristo and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Churchill	11.6	11.6	171.01	17.24	25.57	14.74	170.98
3000 Maduro "Hand- made"	14.3	14.3	138.87	19.26	31.53	21.63	309.31
3000 Maduro "Hand- made"	13.5	13.5	139.90	19.76	29.76	_	_
2000 Maduro "Hand- made"	12.2	12.2	126.34	18.74	26.90	22.73	277.31
2000 Maduro "Hand- made"	11.8	11.8	126.58	18.73	26.01	_	_

## **TABLE F-7**Padron and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

Vintage Robusto had a difference in weight, length, and diameter between the two samples of 0.6 grams, 0.78 mm, and 1.2 mm, respectively.

#### **Brand: Punch**

Table F-9 shows Punch and selected sub-brands. The Clasico Double Corona had a difference in weight, length, and diameter between the two samples of 0.1 grams, 0.08 mm, and 0.67 mm, respectively.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
1992 Vintage Sumatra Robusto	14.8	14.8	139.39	18.93	32.63	14.14	209.27
1990 Vintage Perfecto	9.2	9.2	101.15	17.5	20.28	10.72	98.62
1990 Vintage Robusto	16.3	16.3	139.66	19.93	35.94	23.12	376.86
1990 Vintage Robusto	12.3	12.3	139.67	18.52	27.12		_
1999 Vintage Robusto	15.1	15.1	139.67	19.75	33.29	25.02	377.80
1999 Vintage Robusto	14.5	14.5	138.89	18.55	31.97	—	—

#### TABLE F-8 Rocky Patel and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

- Not calculated.

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Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Clasico Double Corona	15.1	15.1	170.04	18.92	33.29		_
Clasico Double Corona	15.2	15.2	170.12	18.25	33.51	24.22	368.14
Clasico London Club	8.3	8.3	126.20	15.40	18.30	13.03	108.15
Clasico Roths- child	10.9	10.9	116.29	20.06	24.03	16.07	175.16

#### TABLE F-9 Punch and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter. — Not calculated.

#### **Brand: Partagas**

Table F-10 shows Partagas and selected sub-brands. The Robusto had a difference in weight, length, and diameter between the two samples of 1 gram, 0.29 mm, and 0.27 mm, respectively.

#### Brand: La Gloria Cubana

Table F-11 shows La Gloria Cubana and selected sub-brands. The Cubana Wavell Maduro had a difference in weight, length, and diameter between the two samples of 2.6 grams, 1.18 mm, and 1.55 mm, respectively. The Cubana Wavell Natural had a difference in weight, length, and diameter between the two samples of 1.8 grams, 0.14 mm, and 1.03 mm, respectively.

#### Brand: K. Hansotia Gurkha

Table F-12 shows K. Hansotia Gurkha and selected sub-brands. The Gurkha Cellar Reserve 15 Year Hedonism had a difference in weight, length, and diameter between the two samples of 0.5 grams, 1.1 mm, and

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Robusto	10.0	10.0	113.28	18.54	22.05	14.44	144.40
Robusto	11.0	11.0	112.99	18.81	24.25		_
Black Bravo	14.4	14.4	114.41	20.56	31.75	32.28	464.83
Black Mag- nifico	19.1	19.1	151.62	21.72	42.11	15.10	288.41

# TABLE F-10 Partagas and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter. — Not calculated.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Cubana Wavell Maduro	13.5	13.5	125.63	18.35	29.76		_
Cubana Wavell Maduro	16.1	16.1	126.81	19.90	35.49	24.02	386.72
Cubana Wavell Natural	13.9	13.9	127.12	19.43	30.64	_	_
Cubana Wavell Natural	12.1	12.1	127.26	18.40	26.68	19.10	231.11
Cubana Churchill	18.6	18.6	178.21	19.03	41.01	25.37	471.88

## TABLE F-11 La Gloria Cubana and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

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0.11 mm, respectively. The Gurkha Cellar Reserve Ghost had a difference in weight, length, and diameter between the two samples of 3.6 grams, 0.14 mm, and 0.36 mm, respectively.

#### **Brand: My Father**

Table F-13 shows My Father and selected sub-brands. The El Centurion H-2K-CT had a difference in weight, length, and diameter between the two samples of 0.7 grams, 0.03 mm, and 0.25 mm, respectively. The Flor de las Antillas had a difference in weight, length, and diameter between the two samples of 2.9 grams, 1.99 mm, and 0.33 mm, respectively.

Sub-	Weight #1	Weight #2	Length	Diameter	1	Average Nicotine Concen- tration (mg/g	Total Nicotine per Cigar
Brand	(g)	(g)	(mm)	(mm)	sand (lb)	tobacco)	(mg)
Gurkha Cellar Reserve 15 Year Hedo- nism	16.1	16.1	150.86	20.69	35.49	_	_
Gurkha Cellar Reserve 15 Year Hedo- nism	16.6	16.6	151.96	20.58	36.60	31.90	529.54
Gurkha Cellar Reserve Ghost	16.2	16.2	152.31	20.52	35.71	16.38	265.36
Gurkha Cellar Reserve Ghost	19.8	19.8	152.17	20.88	43.65	_	_

TABLE F-12 K. Hansotia Gurkha and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter. — Not calculated.

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Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Garcia & Garcia No. 1 Robusto	16.3	16.3	132.60	20.10	35.94	18.81	306.60
El Cen- turion H-2K-CT	14.0	14.0	139.32	20.07	30.86	15.73	220.22
El Cen- turion H-2K-CT	13.3	13.3	139.29	19.82	29.32	_	_
Flor de las Antil- las	14.6	14.6	150.00	20.85	32.19	13.34	194.76
Flor de las Antillas	17.5	17.5	151.99	21.18	38.58	_	_

#### TABLE F-13 My Father and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

- Not calculated.

#### **Brand: Ashton**

Table F-14 shows Ashton and sub-brands. Cigars from this brand were difficult to locate, so only one from each sub-brand listed was included in the study.

#### Brand: CAO

Table F-15 shows CAO and selected sub-brands. The America Potomac had a difference in weight and length between the two samples of 0.1 grams and 0.01 mm; there was no difference in diameter.

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Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Aged Maduro	12.1	12.1	171.11	16.74	26.68	18.21	220.34
Virgin Sun Grown	12.6	12.6	111.32	24.23	27.78	19.67	247.84
Virgin Sun Grown Eclipse	15.3	15.3	150.88	19.96	33.73	17.52	268.06

## **TABLE F-14**Ashton and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

## TABLE F-15 CAO and Sub-Brands

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
America Potomac	18	18	126.5	19.75	39.68	20.61	371.98
America Potomac	17.9	17.9	126.49	19.75	39.46	_	_
Gold Maduro	17.8	17.8	166.7	18.85	39.24	12.44	221.43

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

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#### **Brand: Davidoff**

Table F-16 shows Davidoff and selected sub-brands. The Aniversario Special "R" had a difference in weight, length, and diameter between the two samples of 0.6 grams, 0.2 mm, and 0.15 mm, respectively.

#### **Brand: Acid**

Table F-17 shows Acid and selected sub-brands. The Kuba Kuba had a difference in weight, length, and diameter between the two samples of 0.6 grams, 0.82 mm, and 0.9 mm, respectively. The Blondie had no difference in weight, but the length and diameter difference between the two samples was 1.68 mm and 0.49 mm, respectively.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
	.0,		. ,		. , ,	,	
Aniversario Special "R"	14.9	14.9	124.69	20.13	32.85	27.78	413.92
Aniversario Special "R"	15.5	15.5	124.49	19.98	34.17	_	_
Aniversario No. 3	19.2	19.2	153.48	19.6	42.33	28.92	555.26
Churchill Robusto	15	15	134.85	19.38	33.07	23.00	345.00

## TABLE F-16 Davidoff and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Kuba Kuba	12.5	12.5	126.96	20.68	27.56	20.45	255.63
Kuba Kuba	13.1	13.1	126.14	19.78	28.88		_
Blondie	5.3	5.3	102.86	14.37	11.68	_	
Blondie	5.3	5.3	101.18	13.88	11.68	16.06	85.12

#### TABLE F-17 Acid and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

Not calculated.

#### Brand: Black & Mild

Table F-18 shows Black & Mild and selected sub-brands. Tips were removed from the Casino Cigar (plastic tip) and Original Cigar (wood tip) prior to measurements. The Casino Cigar had a difference in weight, length, and diameter between the two samples of 0.2 grams, 2.3 mm, and 0.61 mm, respectively. The Original Cigar had a difference in weight, length, and diameter between the two samples of 0.6 grams, 0.58 mm, and 0.21 mm, respectively). The Jazz Cigarillos had no difference in weight, but the length and diameter difference between the two samples was 1.29 mm and 0.37 mm respectively.

#### **Brand: Backwoods**

Table F-19 shows Backwoods and selected sub-brands. The Honey Berry Cigar had a difference in weight, length, and diameter between the two samples of 0.1 grams, 0.8 mm, and 0.06 mm, respectively.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Casino Cigar (plastic tip)*	2.7	2.7	96.20	8.67	5.95	12.29	33.18
Casino Cigar (plastic tip)*	2.5	2.5	93.90	9.28	5.51	_	_
Original Cigar (wood tip)*	2.5	2.5	93.46	8.84	5.51	10.49	26.23
Original Cigar (wood tip)*	3.1	3.1	92.88	9.05	6.83	—	_
Jazz Cigarillos	2.9	2.9	108.64	9.96	6.39	11.54	33.47
Jazz Cigarillos	2.9	2.9	107.35	10.33	6.39	_	

#### TABLE F-18 Black & Mild and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

Not calculated.

\* Tips were removed prior to measurements.

#### **Brand: Swisher Sweets**

Table F-20 shows Swisher Sweets and selected sub-brands. The Blueberry Cigarillo had a difference in weight, length, and diameter between the two samples of 0.1 grams, 0.12 mm, and 0.05 mm, respectively. The Grape Cigarillo had no difference in weight, but the length and diameter difference between the two samples was 0.1 mm and 0.22 mm, respectively. The Leaf Original Cigar had a difference in weight, length, and diameter between the two samples of 0.2 grams, 9.18 mm, and 2.14 mm, respectively.

Sub- Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Original Cigar	2.1	2.1	105.23	8.86	4.63	13.30	27.93
Honey Berry Cigar	2.6	2.6	107.48	9.98	5.73	_	_
Honey Berry Cigar	2.7	2.7	108.28	9.92	5.95	18.68	50.44

## **TABLE F-19** Backwoods and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Blueberry Cigarillos	2.8	2.8	108.67	10.33	6.17	10.52	29.46
Blueberry Cigarillos	2.7	2.7	108.79	10.28	5.95	—	_
Grape Cigarillos	2.9	2.9	108.85	10.55	6.39	10.69	31.00
Grape Cigarillos	2.9	2.9	108.75	10.77	6.39	_	
Leaf Original Cigar	2.8	2.8	114.42	8.39	6.17	30.64	85.79
Leaf Original Cigar	2.6	2.6	105.24	10.53	5.73	—	_

#### TABLE F-20 Swisher Sweets and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

— Not calculated.

#### **Brand: Dutch Masters**

Table F-21 shows Dutch Masters and selected sub-brands. The Dutch Blend-Silver Cigarillos had a difference in weight, length, and diameter between the two samples of 0.5 grams, 0.4 mm, and 0.35 mm, respectively. The Palma Cigar had a difference in weight, length, and diameter between the two samples of 0.4 grams, 0.07 mm, and 0.43 mm, respectively.

#### Brand: Garcia y Vega

Table F-22 shows Garcia y Vega and selected sub-brands. The Irish Cream Cigar had a difference in weight, length, and diameter between the two samples of 0.1 grams, 1.02 mm, and 0.59 mm, respectively. The Natural (Brown Leaf Cigar) had a difference in weight, length, and diameter between the two samples of 0.4 grams, 0.69 mm, and 0.43 mm, respectively.

Sub-Brand	Weight #1 (g)	Weight #2 (g)	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar (mg)
Dutch Blend- Silver Cigarillos	2.7	2.7	111.08	10.68	5.95	15.42	41.63
Dutch Blend- Silver Cigarillos	3.2	3.2	111.48	11.03	7.05	_	_
Palma Cigar	3.2	3.2	113.13	10.41	7.05	11.24	35.97
Palma Cigar	2.8	2.8	113.06	10.84	6.17	_	—

#### TABLE F-21 Dutch Masters and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

- Not calculated.

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Sub-Brand	0	Weight #2	Length (mm)	Diameter (mm)	Pounds per Thou- sand (lb)	Average Nicotine Concen- tration (mg/g tobacco)	Total Nicotine per Cigar
	(g)	(g)	(11111)	(11111)	Sand (ID)	(004000)	(mg)
Irish Cream Cigar	2.8	2.8	113.44	9.02	6.17	20.38	57.06
Irish Cream Cigar	2.9	2.9	112.42	8.43	6.39	_	_
Natural (Brown Leaf Cigar)	2.5	2.5	108.36	9.72	5.51	_	_
Natural (Brown Leaf Cigar)	2.9	2.9	109.05	9.29	6.39	12.67	36.74

#### **TABLE F-22** Garcia y Vega and Sub-Brands

NOTE: g = gram; lb = pound; mg = milligram; mm = millimeter.

- Not calculated.

#### DISCUSSION

This commissioned analysis by the Committee on the Health Effects and Patterns of Use of Premium Cigars provides data on the variations between brands of cigars and within the sub-brands of each. Some interesting observations can be noted. First, each cigar varied significantly in smell. Three cigars for the Davidoff line, which were among the most expensive (see Appendix 1 for the cost of premium cigars per stick), were the most pleasant. Each cigar came packaged in a sealed tin with an aromatic cedar wrapper surrounding it. This brand of cigar also had the most consistency within sub-brands for the advertised measurements of each cigar.

Additionally, some cigars were visibly fresher once removed from the packaging. Two cigars from the Macanudo Hyde Park Café sub-brand were analyzed, for example; each was purchased from different smoke or specialty tobacco stores within the same week. One of them, however, was significantly drier. The wrapper was much darker in color, and the texture was dry and brittle. Their measurements also differed significantly: the drier cigar was 3.4 grams lighter.

Cigarillos and traditional cigars were also analyzed. These were extremely potent in smell, regardless of flavor, and had great inconsis-

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tency in weight, length, and diameter among sub-brands, despite the fact that many of these are sold in packs.

#### LIMITATIONS

As mentioned, cigar brands and sub-brands had slight variations in texture and overall freshness. As cigars must be stored at a proper humidity in a humidor to maintain freshness, the variation in weight of the Macanudo Hyde Park Café cigars may be due to the differences in storage methods between each purchase location.

Additionally, due to the flavored tobacco ban within the city of San Francisco, it proved difficult to locate a variety of cigarillos and traditional cigars. The top brands of little/filtered cigars could not be located at many stores in the San Francisco Bay Area. Limited inventory at various smoke and tobacco shops made it difficult to purchase and analyze two subbrands within each premium cigar brand. By increasing the geography or purchasing products online, more robust conclusions may be possible.

Brand	Sub-Brand	Price
Cohiba*	Serie M (Miami Limited Edition) Cohiba Robusto Red Dot Black Robusto	\$38.99 \$29.99 \$31.99
Romeo y Julieta*	1875 Reserva Real Toro 1875 Reserva Real Bully Short Story 1875 Nicaragua	\$26.00 \$13.99 \$13.99
Arturo Fuente*	Hemingway Signature Hemingway Short Story Curly Head Natural	\$18.99** \$13.99 \$7.99
Macanudo*	Hyde Park Café Baron de Rothschild Petit Corona	\$18.99 \$13.49 \$13.99
Montecristo*	Classic Robusto White Series Court White Series Churchill	\$18.99 \$18.99 \$21.99
Padron*	Churchill 3000 Maduro "Handmade" 2000 Maduro "Handmade"	\$12.99 \$11.99 \$11.99
Rocky Patel*	1992 Vintage Sumatra Robusto 1990 Vintage Perfecto 1990 Vintage Robusto 1999 Vintage Robusto	\$17.99 \$13.99 \$13.99 \$12.99
Punch*	Clasico Double Corona Clasico London Club Clasico Rothschild	\$15.99 \$11.99 \$12.99
Partagas*	Robusto Black Bravo Black Magnifico	\$15.99 \$11.00 \$11.00
La Gloria Cubana*	Cubana Wavell Maduro Cubana Wavell Natural Cubana Churchill	\$12.99 \$13.99 \$17.99
K. Hansotia Gurkha*	Gurkha Cellar Reserve 15 Year Hedo- nism Gurkha Cellar Reserve Ghost	\$19.99 \$12.99
My Father*	Garcia & Garcia No. 1 Robusto El Centurion H-2K-CT Flor de las Antillas	\$15.99 \$13.99 \$13.99
Ashton*	Aged Maduro Virgin Sun Grown Virgin Sun Grown Eclipse	\$17.99 \$24.99 \$22.99
CAO*	America Potomac Gold Maduro	\$11.99 \$14.99

## APPENDIX 1 COST OF PREMIUM CIGARS PER STICK

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Brand	Sub-Brand	Price
Davidoff*	Aniversario Special "R" Aniversario No. 3 Churchill Robusto	\$32.99 \$39.99 \$29.99
Acid	Kuba Kuba Blondie	\$16.99 \$9.99
Black & Mild	Casino Cigar (plastic tip) Original Cigar (wood tip) Jazz Cigarillos	\$0.99 \$0.99 \$0.99 (2/pack- age)
Backwoods	Original Cigar Honey Berry Cigar	\$7.50 (5/pack- age) \$5.50 (3/pack- age)
Swisher Sweets	Blueberry Cigarillos Grape Cigarillos Leaf Original Cigar	\$4.89 (5/pack- age) \$4.89 (5/pack- age) \$4.49 (3/pack- age)
Dutch Masters	Dutch Blend—Silver Cigarillos Palma Cigar	\$1.49 (2/pack- age) \$3.49 (3/pack- age)
Garcia y Vega	Irish Cream Cigar Natural (Brown Leaf Cigar)	\$7.99 (5/pack- age) \$1.29 (2/pack- age)

\* = premium brand as determined by the committee.

\*\* = Three Hemingway Signature cigars are included in this summary; two were purchased at \$18.99 and one at \$15.99.

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# Appendix G

# Exploratory Spatial Analyses of the Locations of 2019–2021 Premium Cigar Association (PCA) Retailers, United States

Authored by: Amanda Y. Kong, Ph.D., M.P.H.<sup>1</sup>

## BACKGROUND

This exploratory analysis calculated the census tract retailer density of premium cigar retailers (per 1,000 people) and examined correlations between tract sociodemographic characteristics and retailer density in the United States. It also explored associations between sociodemographic characteristics and the presence (versus absence) of a retailer in a census tract.

## DATA SOURCES AND METHODS

## Sociodemographic Characteristics

Sociodemographic variables at the census tract level from the 2015–2019 5-Year American Community Survey were downloaded from Social Explorer.<sup>2</sup> Variables included total population; percent of non-Hispanic White (white), non-Hispanic Black or African American (Black), and Hispanic or Latino (Hispanic/Latino) individuals; percent of population 65+, and median household income.

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<sup>&</sup>lt;sup>1</sup>Assistant Professor, University of Oklahoma Health Sciences Center.

<sup>&</sup>lt;sup>2</sup> ACS 2019 (5-Year Estimates). Social Explorer; 2019. Available at https://www.social explorer.com/tables/ACS2019\_5yr (accessed October 18, 2021).

## Premium Cigar Association (PCA) Retailer Members

The Premium Cigar Association (PCA) provided a retailer-level dataset that included current members in 2019 through 2021, with all physical brick-and-mortar retailers that are PCA members and where the majority of sales were for premium cigars or pipe tobacco,<sup>3</sup> retailer types, such as convenience stores, hookah/head shops, and vape stores, were excluded.

The original dataset included 1,316 unique retailers. However, upon review of the address fields and states, further cleaning of several observations was performed in consultation with the National Academies of Sciences, Engineering, and Medicine, briefly described below and detailed in Supplement A:<sup>4,5</sup>

- 1. 25 observations were removed:
  - a. Not in the USA or territory (n = 21)
  - b. Store closed upon review of address (n = 1)
  - c. Could not determine address (n = 3)
- 2. Addresses corrected from PO Box to retailer address using Google (n = 10)
- 3. Listed address corrected using Google (n = 4)

After cleaning the dataset, 1,291 unique retailers remained. Using ArcMap 10.8.1, all retailers were geocoded and assigned a latitude and longitude (see Figure G-1).

## Calculating Premium Cigar Retailer Density

All premium cigar retailers were spatially joined to their respective census tract and corresponding sociodemographic data, and the number of retailers per 1,000 people in a tract was calculated (Figure G-2). Tracts with zero population (n = 611; two PCA members) were omitted from analysis (total number of PCA members n = 1,289).

<sup>&</sup>lt;sup>3</sup> Personal communication, email from Scott Pearce (Premium Cigar Association) to National Academies study staff, August, 16, 2021. Available by request from the National Academies Public Access Records Office at PARO@nas.edu.

<sup>&</sup>lt;sup>4</sup> The final data set and codebook are available by request from the National Academies Public Access Records Office at PARO@nas.edu.

<sup>&</sup>lt;sup>5</sup> See Supplement A for more details on the removed and corrected observations. Supplements are available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

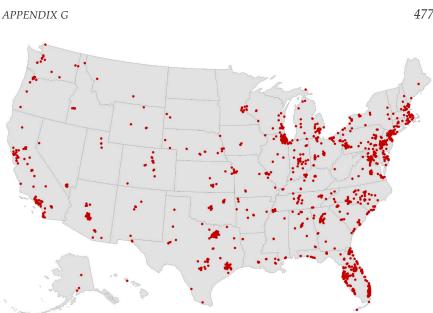


FIGURE G-1 Locations of 2019–2021 U.S. Premium Cigar Association retailers (n = 1,291)

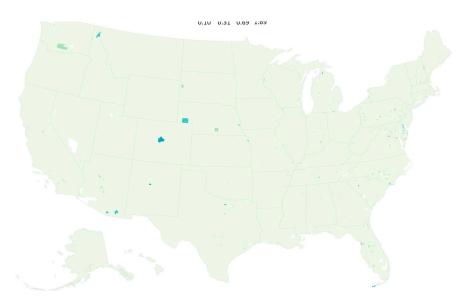


FIGURE G-2 2019–2021 Premium Cigar Association member retailer density (retailers per 1,000 people), U.S. census tracts (n = 72,410) NOTE: Census tracts with zero population (white) were omitted from the analysis (n = 611).

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#### Analysis

Using SAS 9.4, Spearman correlations between each tract-level sociodemographic variable and premium cigar retailer density were calculated. In additional exploratory analyses, a binary variable indicating the presence (=1) of at least one premium cigar retailer (versus none = 0) was created. Unadjusted associations between sociodemographic characteristics and this binary indicator were fit. Tract-level age, race, and ethnicity variables were scaled to tens (e.g., 10 percent is coded 1.0) so that estimates may be interpreted as the expected difference for a census tract that has a 10-percentage point greater value in the sociodemographic variable. Median household income was scaled to \$1,000. As census tracts are nested within states (and Washington DC), general estimating equation (GEE) methods with an exchangeable working correlation matrix were used, which adjust both estimates and standard errors to account for this geographic nesting.

#### RESULTS

#### PCA Members Retailer Density

Figure G-2 shows very little variation in premium cigar retailer density (mean = 0.00, SD = 0.06), largely due to minimal variation in the total retailer count (Tables G-1 and G-2). Supplements B–D provide state-level maps and a table of the total count of retailers and density per 1,000,000 residents.<sup>6</sup>

Spearman correlations (see Table G-3) indicated very small positive correlations, though caution should be taken interpreting these results due to the large sample size (statistical significance is likely) and because geographic nesting is not accounted for in analyses.

Further exploration indicated that only 16 census tracts had a premium cigar retailer density of 1.00 or more, and this may be due to lower population sizes in the tract (Supplement E). These observations had no apparent patterns in sociodemographic characteristics.

#### Presence of Absence of Retailer

With so little variation in the total retailer count, unadjusted associations between each sociodemographic characteristic and the presence (versus absence) of a retailer were investigated. As indicated in Table

<sup>&</sup>lt;sup>6</sup> Supplements are available in the project's public access file and upon request from the National Academies Public Access Records Office at PARO@nas.edu.

#### APPENDIX G

(		
Count	Frequency	Percent
0	71,164	98.3
1	1,205	1.6
2	39	0.1
3	2	0.0

**TABLE G-1** Total count of Premium Cigar Association member retailers, U.S. census tracts (n = 72,410)

**TABLE G-2** Distribution of Premium Cigar Association member retailer density (per 1,000 people), U.S. census tracts (n = 72,410)

Level	Quantile
100% Max	8.20
99%	0.20
95%	0.00
90%	0.00
75% Q3	0.00
50% Median	0.00
25% Q1	0.00
10%	0.00
5%	0.00
1%	0.00
0% Min	0.00

**TABLE G-3** Spearman correlation coefficients between Premium Cigar Association member retailer density (per 1,000 people) and sociodemographic characteristics of U.S. census tracts (n = 72,410)

	% aged 65+	% white	% Black	% Hispanic/ Latino	Median household income (\$USD)
Retailor density	0.00755	0.00754	0.01450	0.00602	0.01740
<i>p</i> value	0.0423	0.0425	<.0001	0.1051	<.0001

G-2, 71,164 of census tracts (98.3 percent) did not have a premium cigar retailer, while 1,246 (1.7 percent) had one or more. Descriptive analyses indicating the average value of each sociodemographic characteristic are presented in Table G-4.

Results from the GEE models (see Table G-5) indicate that tracts with a higher percent of white residents had greater odds of having at least one (versus none) premium cigar retailer (OR = 1.06; 95 percent CI: 1.03-1.09). In contrast, tracts with a higher percent of Black (OR = 0.92; 95 percent CI: 0.88-0.96) and Hispanic/Latino residents (OR = 0.90; 95 percent CI: 0.84-0.96) had lower odds of having at least one premium cigar retailer. Adjusted models including all sociodemographic characteristics were not fit due to multicollinearity.

**TABLE G-4** Average values of sociodemographic characteristics by presence or absence of at least one Premium Cigar Association member retailer, U.S. census tracts (n = 72,410)

Contra domenta in Champataniatia	No Retailer		≥ 1 Re	≥ 1 Retailer	
Sociodemographic Characteristic	Mean	SD	Mean	SD	
% aged 65+	16.4	8.1	17.4	9.6	
% white	61.2	30.1	65.6	23.2	
% Black	13.5	21.6	11.5	15.9	
% Hispanic/Latino	16.7	21.5	14.0	15.7	
Median household income (\$USD)	66,664	33,729	70,314	32,995	

**TABLE G-5** Associations between sociodemographic characteristics and the presence (vs. absence) of at least one Premium Cigar Association member retailer, U.S. census tracts (n = 72,410)

Contradiction of the contradiction	Unadjusted		
Sociodemographic Characteristic	OR	95% CI	
% aged 65+	1.03	0.96–1.11	
% white	1.06	1.03-1.09	
% Black	0.92	0.88-0.96	
% Hispanic/Latino	0.90	0.84-0.96	
Median household income (\$USD)	1.00	1.00-1.01	

NOTES: Tract-level age, race, and ethnicity variables were scaled to tens (e.g., 10 percent is coded 1.0) so that estimates may be interpreted as the expected difference for a census tract that has a 10-percentage point greater value in the sociodemographic variable. Median household income was scaled to \$1,000. All models account for the nesting of tracts within states. Bolding indicates statistical significance.

APPENDIX G

## CONCLUSION

The majority of U.S. census tracts do not have a premium cigar retailer. However, the percentage of white residents in a tract is associated with greater odds of at least one retailer compared to none. In contrast, a higher percentage of Black or Hispanic/Latino residents is associated with lower odds of at least one retailer compared to none.

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Premium Cigars: Patterns of Use, Marketing, and Health Effects

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# Appendix H

# **Public Meeting Agendas**

## FIRST PUBLIC MEETING

#### March 9, 2021 Videoconference via Zoom

2:00	<ul><li>Welcome</li><li>Steve Teutsch, Committee Chair</li></ul>
2:05–3:00	<ul> <li>Presentation of the statement of task, background, and discussion</li> <li>Benjamin Apelberg Office of Science, Center for Tobacco Products, Food and Drug Administration On behalf of Matthew Holman Director, Office of Science, Center for Tobacco Products, Food and Drug Administration</li> </ul>

### 3:00 Closing remarks/open session adjourn

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#### SECOND PUBLIC MEETING

#### April 20, 2021 Videoconference via Zoom

#### 1:00–1:10 Welcome

• Steve Teutsch, Committee Chair

#### 1:10–2:10 Public comment

The National Academies of Sciences, Engineering, and Medicine invites the public to provide comments to be considered by the Committee on Health Effects and Patterns of Use of Premium Cigars.

At this meeting (April 20, 2021), the committee welcomes input on the draft research questions provided to the committee by the report sponsors (the Food and Drug Administration and the National Institutes of Health)—available here. If you would like to provide oral comments at the meeting, please send an email with your name and affiliation to PremiumCigars@nas.edu (each individual will have up to 5 minutes).

Members of the public may also submit written comments for consideration by the study committee (as individuals or on behalf of an organization) via email to PremiumCigars@nas.edu.

All materials and comments received will be placed in the committee's public access file and may be provided to the public upon request. Materials and comments received may also be included in the committee's report.

#### 2:10–2:15 Closing remarks/open session adjourn

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APPENDIX H

## April 23, 2021 Videoconference via Zoom

1:00–1:10	<ul><li>Welcome</li><li>Steve Teutsch, Committee Chair</li></ul>
1:10-2:00	<ul> <li>Tobacco Science</li> <li>David L. Ashley Research Professor, Georgia State University School of Public Health</li> <li>K. Michael Cummings Professor, Medical University of South Carolina</li> </ul>
2:00-3:15	<ul> <li>Perspectives of Premium Cigars from Producers, Retailers, and Consumers</li> <li>Thomas Lindegaard Senior Vice President of Scientific and Regulatory Affairs, Scandinavian Tobacco Group; Coordinator, CORESTA Sub-Group on Cigar Smoking Methods</li> <li>Richard Voith President, Econsult Solutions, Inc.</li> <li>Gerald Long Manager of Scientific Affairs, ITG Brands, LLC</li> <li>Scott Pearce Executive Director, Premium Cigar Association</li> <li>Mike Copperman Legislative Director, Cigar Rights of America</li> <li>Drew Newman (<i>Discussant</i>) Owner and General Counsel, J.C. Newman Cigar Company</li> <li>Barry S. Schaevitz (<i>Discussant</i>) Partner, Fox Rothschild, LLP</li> </ul>
3:15-3:30	Break
3:30-4:30	<ul> <li>Tobacco Control and Policy Perspectives</li> <li>Ann Boonn Director of Research, Campaign for Tobacco-Free Kids</li> <li>Barbara Schillo Senior Vice President, Truth Initiative Schroeder Institute</li> </ul>

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- Joelle M. Lester Director of Commercial Tobacco Control Programs, Public Health Law Center at Mitchell Hamline School of Law
- Dennis A. Henigan (*Discussant*)
   Vice President for Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids

#### 4:30 Closing remarks/open session adjourn

### THIRD PUBLIC MEETING

### May 28, 2021 Videoconference via Zoom

2:00-2:10	Welcome
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• Steve Teutsch, Committee Chair

#### 2:10–3:15 Tobacco Product Chemistry and Science

- Clifford Watson
   Director of Tobacco Products Laboratory, Centers for
   Disease Control and Prevention
- Benjamin Blount Research Chemist, Centers for Disease Control and Prevention
- Bartosz Koszowski Division Manager of Individual and Population Health, Battelle

## 3:15-4:05 Health Effects of Premium Cigars

- Benjamin Chaffee Associate Professor, University of California, San Francisco School of Dentistry
- Mia Hashibe
  - Professor, Department of Family and Preventive Medicine, University of Utah; Scientific Coordinator, International Head and Neck Cancer Epidemiology (INHANCE) Consortium

#### 4:05–4:20 Break

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4:20–4:50	<ul> <li>Tobacco Use Data and Surveys</li> <li>Neal D. Freedman Senior Investigator, National Cancer Institute</li> </ul>
4:50–5:00	<b>Public comment</b> Note that given the webinar format of the meeting, attendees will need to type their comments into the Q&A box on Zoom, and staff will read them aloud. Note that comments should be related to the committee's statement of task.
5:00	Closing remarks/open session adjourn

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## Appendix I

## **Committee Member and Staff Biographies**

Steven M. Teutsch, M.D., M.P.H. (Chair), is an adjunct professor at the UCLA Fielding School of Public Health and Senior Fellow at the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California. Until 2014, he was the chief science officer for Los Angeles County Public Health, where he continued his work on evidence-based public health and policy. Previously, Dr. Teutsch worked at Merck, where he was responsible for scientific leadership in developing evidence-based clinical management programs, conducting outcomes research studies, and improving outcomes measurement to enhance quality of care. Prior to joining Merck, he was director of the Division of Prevention Research and Analytic Methods at the Centers for Disease Control and Prevention, where he was responsible for assessing the effectiveness, safety, and cost-effectiveness of disease and injury prevention strategies. Dr. Teutsch has served as a member of the Community Preventive Services Task Force, U.S. Preventive Services Task Force, Americas Health Information Community Personalized Health Care Workgroup, and Evaluation of Genomic Applications in Prevention and Practice Workgroup. He chaired the Secretary's Advisory Committee on Genetics Health and Society and served on or chaired several National Academies panels, Medicare's Evidence Development and Coverage Advisory Committee, and several subcommittees of the Secretary's Advisory Committee on Healthy People 2020 and 2030. Dr. Teutsch has published more than 200 articles and 8 books in a broad range of fields in epidemiology, including parasitic diseases, diabetes, technology assessment, health services

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research, and surveillance. He received his undergraduate degree in biochemical sciences at Harvard University, M.P.H. in epidemiology from the University of North Carolina School of Public Health, and M.D. from Duke University School of Medicine. He was certified by the American Board of Internal Medicine in 1977 and the American Board of Preventive Medicine in 1995 and is a Fellow of the American College of Physicians and American College of Preventive Medicine.

**Wei Bao, M.D., Ph.D.,** is an assistant professor of epidemiology in the College of Public Health at the University of Iowa. His broad epidemiological interests include research into diabetes and obesity, diet and lifestyle, tobacco use, chronic disease epidemiology, and molecular epidemiology. At the university, Dr. Bao is a member of the Fraternal Order of Eagles Diabetes Research Center, Obesity Research and Education Initiative, and Center for Global and Regional Environmental Research and an associate member of the Environmental Health Sciences Research Center. He received his medical degree and Ph.D. from Tongji Medical College, Huazhong University of Science and Technology, China. Dr. Bao also completed a postdoctoral fellowship at the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health. *Resigned from the committee on August 20, 2021.* 

Neal Benowitz, M.D., is emeritus professor of medicine, Division of Cardiology, at the University of California, San Francisco, where he was chief of the Division of Clinical Pharmacology for more than 35 years. He is a leading authority on the human pharmacology of nicotine in relation to pathogenesis of and individual differences in vulnerability to tobacco-related disease and the use of pharmacologic data as a basis for public health policies to prevent and reduce it. Dr. Benowitz has served on a number of national and international committees addressing issues in tobacco-related diseases and smoking cessation, including several with the National Academies. He has authored more than 700 publications, including a state-of-the-art review on nicotine addiction in the New England Journal of Medicine. Dr. Benowitz is the former president of the SRNT, recipient of the Ove Ferno SRNT Award for Clinical Research on Nicotine and Tobacco, and former president of the American Society for Clincal Pharmacology and Therapeutics. He has been a contributing author or editor for six U.S. Surgeon General reports on tobacco. Dr. Benowitz is currently on retainer to serve as an expert witness for litigation related to cigarettes. He also serves on the data safety monitoring board for Achieve Health Sciences. He earned his M.D. from the University of Rochester.

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Cristine D. Delnevo, Ph.D., M.P.H., FAAHB, is the founding director of the Center for Tobacco Studies at Rutgers University and Professor of Health Behavior, Society, and Policy at the Rutgers School of Public Health. She also serves as the senior advisor on Tobacco Control at the Rutgers Cancer Institute of New Jersey. She has held numerous grants from NIH and FDA and focuses on the population epidemology of tobacco use, in particular noncigarette products, such as electronic cigarettes and cigars; the impact of product characteristics, such as menthol or flavoring in tobacco products, on patterns of use; tobacco communication and marketing; and monitoring market trends for rapid surveillance-all in the context of tobacco control policy and regulatory science. She is the recipient of the Society for Research on Nicotine and Tobacco (SRNT) John Slade Award for outstanding contributions to public health and tobacco control through science-based public policy and public advocacy. She has published more than 200 scientific articles and book chapters and been recognized by Clarivate in 2020 and 2021 with their "Highly Cited Researcher Award." She was appointed to the Tobacco Products Scientific Advisory Committee at FDA in March 2021. Dr. Delnevo received her M.P.H. from the Rutgers School of Public Health and Ph.D. in health studies from Temple University.

Pebbles Fagan, Ph.D., M.P.H., is a professor in the Department of Health Behavior and Health Education. She is also the director of the Center for the Study of Tobacco at the Fay W. Boozman College of Public Health at the University of Arkansas for Medical Sciences director of research in the Office of Health Initiatives and Disparities Research, Department of Surgery, College of Medicine. Dr. Fagan is a behavioral scientist with more than 25 years of experience in conducting research that aims to increase knowledge on how to reduce tobacco- and cancer-related health disparities in racial/ethnic, socially disadvantaged, and marginalized communities. She uses team-based science to examine social, behavioral, and biobehavioral factors associated with health disparities. Formerly, she was a health scientist at the Tobacco Control Research Branch at the National Cancer Institute, where she cofounded the Tobacco Research Network on Disparities, the first national research network designed to stimulate novel collaborative research in such disparities. In 2011, Dr. Fagan became an associate professor and program director for the Cancer Prevention and Control Program at the University of Hawaii Cancer Center. In 2016, she joined the faculty at Fay W. Boozman as a professor and director of the Center for the Study of Tobacco. Dr. Fagan was instrumental in advancing a series of papers that informed the content of several reports that describe the impact of menthol cigarettes on the public's health. Dr. Fagan earned her Ph.D. in Health Education and Community Health from

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Texas A&M University and her M.P.H. from the Tulane University School of Public Health and Tropical Medicine.

**Maciej Goniewicz, Ph.D., Pharm.D.,** is a full member of the Department of Health Behavior, Division of Cancer Prevention and Population Sciences at Roswell Park Comprehensive Cancer Center. Dr. Goniewicz's primary research area is nicotine pharmacology and toxicology, with a focus on nicotine dependence and smoking cessation. He has research experience in smoking cessation behavioral treatment, pharmacotherapy, and pharmacokinetics in both clinical and community-based settings. He has authored more than 170 scientific papers on topics related to tobacco control, biomarkers, and nicotine-containing products. Dr. Goniewicz is a member of the SRNT, Society of Toxicology, and American Association for Cancer Research and was on the National Academies committee on the Public Health Consequences of E-Cigarettes. He earned his Pharm.D. and Ph.D. from the Medical University of Silesia, Poland. He completed his postdoctoral fellowships at the University of California, San Francisco and Queen Mary University of London, UK.

Stephen S. Hecht, Ph.D., is the Wallin Land Grant Professor of Cancer Prevention in the Department of Laboratory Medicine and Pathology and a professor at the Masonic Cancer Center at the University of Minnesota Medical School. Dr. Hecht's research is focused on understanding the ways tobacco smoke constituents cause cancer. His research focuses on carcinogens, such as tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons, and certain volatiles, such as formaldehyde, acetaldehyde, and acrolein. He is a fellow of the American Association for the Advancement of Science and the American Chemical Society. Dr. Hecht has received the Joseph Cullen Award from the American Society of Preventive Oncology, Merit Award from the National Cancer Institute, and Award for Excellence in Cancer Prevention Research from the American Association for Cancer Research, Dr. Hecht was a member of the National Academies committee on scientific standards for studies on modified risk tobacco products. He earned his Ph.D. from the Massachusetts Institute of Technology.

**Miranda R. Jones, Ph.D.,** is an assistant professor of epidemiology at the Johns Hopkins Bloomberg School of Public Health. Dr. Jones is an epidemiologist whose research focuses on environmental and social determinants of chronic diseases. She is specifically interested in the health impacts of environmental exposures, including tobacco, secondhand smoke, air pollution, and heavy metals, and their role in racial and ethnic disparities in cancer and cardiovascular disease. Dr. Jones earned her B.A.

in Health Administration and Policy from the University of Maryland, Baltimore County and her M.H.S. and Ph.D. in Epidemiology from the Johns Hopkins Bloomberg School of Public Health. She completed a postdoctoral fellowship in Cancer Epidemiology, Prevention, and Control in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health.

**Grace Kong, Ph.D.,** is an assistant professor in the Department of Psychiatry at Yale School of Medicine. Dr. Kong's current research interests include understanding substance use health disparities among youth, the use of social media for tobacco marketing, novel tobacco use behaviors among youth, and developing innovative adolescent tobacco/cessation interventions for youth. Dr. Kong received her Ph.D. in clinical psychology (child and adolescent track) at St. John's University in 2009 and completed her NIDA T32 postdoctoral fellowship focused on adolescent addictions in the Division of Substance Abuse at Yale School of Medicine in 2012.

Adam Leventhal, Ph.D., professor within the Keck School of Medicine of the University of Southern California (USC), is a clinical psychologist and public health scientist who aims to understand and prevent addiction. He is founding director of the USC Institute for Addiction Science, which supports transdisciplinary collaborative addiction research and education, including 63 faculty members across eight schools. Having been awarded more than \$40M in grant funding from NIH and other agencies, his laboratory focuses on (1) adolescent and young adult tobacco, cannabis, and opioid use; (2) addiction among populations with mental illness, from racial/ethnic minority backgrounds, with socioeconomic disadvantage, and other groups subject to health disparities; (3) the development of medications to treat nicotine addiction; (4) science to inform public policies for regulating tobacco and other addictive consumer products; and (5) cancer and cardiovascular disease prevention. Dr. Leventhal has authored more than 250 peer-reviewed scientific articles, including publications in JAMA, New England Journal of Medicine, and other journals. His work has been covered by the Associated Press, NBC Nightly News, New York Times, and other media outlets. Dr. Leventhal has served on expert panels on the health effects of tobacco products for the National Academies, FDA, and the U.S. Surgeon General. He is a member of the FDA Tobacco Products Scientific Advisory Committee, an elected fellow of the American Academy of Health Behavior and American Psychological Association, and recipient of awards for contributions to addiction science and mentoring.

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Darren Mays, Ph.D., M.P.H., is as an associate professor in the Division of Medical Oncology at The Ohio State University College of Medicine. Dr. Mays is a behavioral scientist with more than 10 years of experience in behavioral cancer prevention and control research, with a major emphasis on tobacco prevention and cessation. Dr. Mays' research investigates the uptake and progression of tobacco use among young people, risk factors for tobacco use, and behavioral prevention and cessation interventions. He also focuses on tobacco policy and regulation, such as policies targeting tobacco packaging, labeling, and advertising. Dr. Mays has published more than 100 peer-reviewed research articles and presented his research widely. Dr. Mays is a longstanding member of several professional organizations, including the SRNT, Society of Behavioral Medicine, and American Public Health Association. Dr. Mays received his M.P.H. from the Rollins School of Public Health at Emory University and Ph.D. from the Rollins School of Public Health & James T. Laney School of Graduate Studies at Emory University.

**Rafael Meza**, **Ph.D.**, is a professor in the Department of Epidemiology at the University of Michigan. Dr. Meza is principal investigator of the UM/ Georgetown TCORS Center for the Assessment of Tobacco Regulations and coordinating principal investigator of the Cancer Intervention and Surveillance Modeling Network lung cancer working group. Dr. Meza's research focuses on the use of simulation modeling and quantitative methods to assess the impact of disease prevention and control interventions, particularly for tobacco control and lung cancer. Dr. Meza received his B.Sc. in applied mathematics from the Instituto Tecnologico Autonomo de Mexico and Ph.D. in applied mathematics from the University of Washington. After his Ph.D., Dr. Meza completed a 2-year fellowship at the Fred Hutchinson Cancer Research Center and a 3-year fellowship at the University of British Columbia Center for Disease Control.

**Kymberle Landrum Sterling, Ph.D., M.P.H.,** is an associate professor of health promotion and behavioral sciences at the University of Texas (UT) Health School of Public Health, Dallas Regional Campus. Dr. Sterling is a tobacco control behavioral scientist, with expertise in youth and young adult cigarette and novel tobacco product use, tobacco-related health disparities, and smoking cessation. She has served as the principal investigator of two FDA-/NIH-funded tobacco control regulatory sciences research grants that assessed flavored cigar smoking and identified risk perceptions of it among racially/ethnically diverse young adults. Her research has informed federal tobacco control policies, specifically FDA's expansion of its regulatory authority to cigars. She is the principal investigator of an FDA/NIH tobacco regulatory sciences research grant

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examining the effects of implied modified risk statements on flavored cigar advertising on cigar use behaviors among young adults. An important methodological feature of her research is community-based research principles to engage with vulnerable communities to assess their health needs and develop culturally tailored, evidence-based interventions to optimize their health behavior outcomes and mitigate health disparities. She also has methodological expertise in mixed-methods (survey and qualitative research) and experimental study designs and latent variable modeling. Dr. Sterling was trained as a cell and molecular biologist at Tulane University in New Orleans, Louisiana, before receiving her doctor-ate in health promotion and behavioral sciences at the UT Health School of Public Health, Houston.

Andrea Villanti, Ph.D., M.P.H., was an associate professor of psychiatry and psychology at the University of Vermont through December 2021. Beginning January 18, 2022, Dr. Villanti serves as associate professor at the Rutgers School of Public Health and as Deputy Director of Rutgers Center for Tobacco Studies. Her primary research focus is young adult tobacco use, including predictors and patterns of and interventions to reduce use. She also has expertise in translational research to improve tobacco control policy and program decision making, including tobacco regulatory science. Her work focuses on design, collection, and analysis of population survey data and conducting experiments and intervention trials in large, online samples. Dr. Villanti's current NIH-funded research projects include testing a nicotine corrective messaging intervention, evaluating the substitutability of plausible menthol cigarette alternatives, and evaluating state-level policy and communication efforts to prevent substance use in youth and young adults. Dr. Villanti earned her M.P.H. from the Mailman School of Public Health at Columbia University and Ph.D. from the Johns Hopkins Bloomberg School of Public Health.

#### STAFF

**Amy Geller, M.P.H.**, is a senior program officer in the Health and Medicine Division (HMD) on the Board on Population Health and Public Health Practice. During her 19 years at the National Academies, she has staffed committees spanning many topics, including advancing health equity, reducing alcohol-impaired driving fatalities, workforce resilience, vaccine safety, reducing tobacco use, drug safety, and treating post-traumatic stress disorder. She was and is the study director, respectively, for the recently released HMD report *Sexually Transmitted Infections: Adopting a Sexual Health Paradigm* and the HMD Committee on Health Effects and Patterns of Use of Premium Cigars. She also directs the DC Public Health

Case Challenge, a joint activity of HMD and the National Academy of Medicine that aims to promote interdisciplinary, problem-based learning for college students at universities in the DC area.

Aimee Mead, M.P.H., is an associate program officer on the Board on Population Health and Public Health Practice. She has staffed National Academies' consensus reports confronting a variety of public health challenges, including eliminating hepatitis B and C in the United States, reducing alcohol-impaired driving, reviewing the public health consequences of e-cigarettes, and preventing sexually transmitted infections. She has also supported the Roundtable on Environmental Health Sciences, Research, and Medicine. Before joining the National Academies, she worked at the National Heart, Lung, and Blood Institute. She received her M.P.H. from the Yale School of Public Health and B.S. from Cornell University.

**Sophie Yang** is a research associate in the Health and Medicine Division on the Board on Population Health and Public Health Practice. She has staffed National Academies' consensus studies on prevention and control of sexually transmitted infections, promoting health equity in the prenatal through early childhood periods, reducing fatalities from alcoholimpaired driving, eliminating hepatitis B and C in the United States, promoting health equity through community-based solutions, and improving access and affordability of hearing health care for adults. She also staffs the DC Public Health Case Challenge, a joint activity of the Health and Medicine Division of the National Academies and the National Academy of Medicine. Sophie graduated from Bowdoin College in 2013 with a B.A. in Asian Studies and Economics.

**Maggie Anderson** is a research assistant in the Health and Medicine Division on the Board on Population Health and Public Health Practice. Before joining the National Academies, Ms. Anderson worked at Program Savvy Consulting as an independent contractor and as an intern with the Food Policy Council of Buffalo and Erie County. She received a B.A. in biology with a minor in environmental studies from Mount Holyoke College.

Harika Dyer was a research assistant in the Health and Medicine Division on the Board on Population Health and Public Health Practice from April 2020 through July 2021. She is an M.P.H. student in epidemiology at the University of Pittsburgh Graduate School of Public Health (GSPH), 2021 Diversity Scholar, and student research assistant in GSPH's Center for Health Equity. Before joining the National Academies, Ms. Dyer worked as a medical scribe and as a sustainability program associate at Booz Allen

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Hamilton. She received her L.L.B. from the University of the West Indies and B.A. in political science from Georgia State University.

Rose Marie Martinez, Sc.D., is the senior director of the National Academies' Board on Population Health and Public Health Practice (1999present). The board has a vibrant portfolio of studies on high-profile and pressing issues that affect population health. It addresses the science base for population health and public health interventions and examines the capacity of the health system, particularly the public health infrastructure, to support disease prevention and health promotion activities, including educating and supplying the health professionals necessary for carrying them out. The board has examined such topics as the safety of childhood vaccines and other drugs; systems for evaluating and ensuring drug safety after marketing; pandemic influenza planning; the health effects of cannabis and cannabinoids; the health effects of environmental exposures; the integration of medical care and public health; women's health services; health disparities; health literacy; tobacco control strategies; and chronic disease prevention. Dr. Martinez was a senior health researcher at Mathematica Policy Research (1995–1999), where she conducted research on the impact of health system change on the public health infrastructure, access to care for low-income populations, managed care, and the health care workforce. Dr. Martinez is a former assistant director for health financing and policy with the U.S. General Accounting Office, where she directed evaluations and policy analysis in the area of national and public health issues (1988-1995). Her experience also includes 6 years directing research studies for the Regional Health Ministry of Madrid, Spain (1982–1988). Dr. Martinez is a member of the Council on Education for Public Health, the accreditation body for schools of public health and public health programs. Dr. Martinez received her Sc.D. from the Johns Hopkins School of Hygiene and Public Health.

**Y. Crysti Park** is an administrative assistant in the Health and Medicine Division on the Board on Population Health and Public Health Practice and was a senior program assistant for the Board on Health Sciences Policy. Earlier, she was an executive in the garment industry.

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