

PCA'S NASEM STUDY NOTES & NOTEWORTHY: THE GOOD, THE BAD AND THE INCONCLUSIVE



On March 10th the National Academy of Sciences, Engineering, and Medicine released a study on Premium Cigars: Patterns of Use, Marketing, And Health Effects. This study was broken down into those three categories, patterns of use, marketing, and health effects. These categories highlight the major areas of concern for tobacco products as a whole but, as you will see, the conclusions of NASEM's research committee sets a path for future considerations by regulators and does not necessarily have an immediate impact on premium cigar regulations.

There are several conclusions that the NASEM Report makes that we would like to highlight. The conclusions regarding their accepted definition, price points, interdepartmental streamlined regulation, FTC Reports, and Health Consequences of premium cigar use. The conclusions made by the NASEM Committee highlighted here represent many of the positive aspects of the study. Instead of reading through the full 521-page report, below are some of the main takeaways from the PCA Government Affairs team on topics of interest.

DEFINITIONS

"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."¹

This definition used by the NASEM Committee diverges from the conclusion Judge Mehta's conclusion in several keyways. As a reference, Judge Mehta's definition is as follows: "a cigar that:

1. is wrapped in whole tobacco leaf;
2. contains a 100 percent leaf tobacco binder;
3. contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar);
4. 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);
5. has no filter, non-tobacco tip, or non-tobacco mouthpiece;
6. does not have a characterizing flavor other than tobacco;
7. contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weighs more than 6 pounds per 1,000 units."

¹ National Academies of Sciences, Engineering, and Medicine. 2022., 2

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These two definitions are close in nature and may be used in regulatory actions. Though, the NASEM Committee does note:

“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.”²

So, even with the clear definition used by the NASEM Committee, it will not necessarily be adopted by all or any regulatory or legislative bodies. With all of that said, the committee did state:

“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.”³

This statement is completely contradictory of what the committee had set out to do with setting their definition. This ought to be noted due to the potential regulatory or legislative implications of this report.

Lastly on the definitions front, the use of “primary users” is referenced several times in regard to the health effects. Primary users are defined as “those who were never established cigarette users”.⁴

FLAVORS

As noted, “the committee’s definition of premium cigars excludes flavors. However, cigars otherwise matching the definition of premium used by the committee are sometimes flavored.”⁵

“(…) 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.”⁶

“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.).”⁷

2 National Academies of Sciences, Engineering, and Medicine. 2022., 37

3 Ibid., 72

4 Ibid., 17

5 Ibid., 93

6 National Academies of Sciences, Engineering, and Medicine. 2022., 93

7 National Academies of Sciences, Engineering, and Medicine. 2022., 93

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PRICE POINT

A conclusion reached by the NASEM Committee is that a definition including price point is problematic due to a variety of factors including taxation and potential industry manipulation. NASEM concluded the following regarding price point:

“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.”⁸

This conclusion is impactful due to the potential adoption of a price point-centered definition by regulatory and legislative bodies. The conclusion highlights the ways in which price point centered definitions could create an issue with nonpremium cigars adjusting price point and weight to be included with the price point centered definition.

The committee also noted that absent a definition based price point, premium cigars are already intrinsically higher priced than other tobacco products.

STREAMLINE DEPARTMENTS

The NASEM Committee concluded that the lack of an accepted definition among courts, industry, public, legislative and regulatory bodies. This lack of definition leads to a lack of comprehensive data of premium cigar use and the associated health risks, as was highlighted by the NASEM Committee’s lack of conclusions on said patterns of use and associated health risks. It was the recommendation of the NASEM Committee that 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.⁹ The NASEM Committee stated the following:

“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).”¹⁰

“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.**¹¹

8 Ibid., 37

9 National Academies of Sciences, Engineering, and Medicine. 2022., 19

10 Ibid., Abstract, xx

11 Ibid., 19

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If TTB's definition is used, the premium cigar industry risks opening up the industry to further taxation. As reference, the TTB definition of a premium cigar is:

“Cigar: Any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of paragraph (2) of the definition for cigarette).

- **Small cigars.** Cigars weighing not more than three pounds per thousand.
- **Large cigars.** Cigars weighing more than three pounds per thousand.”¹²

TTB's definition is wide and overly general which could include a wide range of products that the NASEM Committee and Judge Mehta definitions would exclude.

PATTERNS OF USE

The committee noted that patterns of use for premium cigar users vary from study to study due to the inconsistency with definitions of premium cigars. The patterns of use, and conclusions thereof, also largely depend on whether smoke was inhaled and the depth of inhalation. Another key aspect is the generally infrequent usage pattern of premium cigars among premium cigar users. Such factors also impact the health effects and associated risk, highlighted in the health effects section of the report.

“In general, and in contrast to cigarette smoking, cigar use has historically been less frequent and referred to as an “occasional” behavior (...) 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) (...) Daily use was rare (3.5 percent) among premium cigar users (...)”¹³

This conclusion of non-daily use for the greater majority of premium cigar users supports the Premium Cigar Association's rhetoric of frequency of use being a leading factor for being treated distinctly differently than other tobacco products. The Premium Cigar Association's rhetoric surrounding the frequency of use of premium cigars was first put forth by the NIH/FDA PATH study and is now further supported by this study.

“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.”¹⁴

12 Bugher, Tim. “TTB: Tobacco: Products.” TTBGov - Products.

13 National Academies of Sciences, Engineering, and Medicine. 2022.,113-114

14 Ibid., 167

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The table below was referenced by the study depicting the reasoning for premium cigar users choosing to smoke premium cigars, the overwhelming majority of survey respondents stating that they use cigars in a social setting.¹⁵

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

	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)

SOURCE: Corev et al., 2018.

16

15 Ibid., 182

16 National Academies of Sciences, Engineering, and Medicine. 2022., 182

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Noted in the study is that premium cigars are unlikely to be consumed or purchased by youth and that most users only consume cigars occasionally.¹⁷ The occasional usage is noted to change if price point were to change due to local state and federal taxes.¹⁸ This affirms the work the National Association of Tobacco Outlets did on the elasticity of tobacco products, specifically cigars. This report produced by NATO has been used in the pursuit of defeating tobacco tax legislation on the federal and state levels, noting the loss of business due to extreme tax swings.

“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.”¹⁹

Lastly, the consideration that premium cigars are largely only available in age gated locations and are especially tailored to meet the demands of premium cigar consumers, in simple terms, premium retail tobacconists. Noted in the report “Premium cigars are not as widely available for purchase as other cigar types or tobacco products.”²⁰ This further supports the Premium Cigar Association’s position that specialty retail tobacconists serve their consumers and do not attract youth.

“**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 committees 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”²¹

17 Ibid., 314

18 Ibid., 314

19 National Academies of Sciences, Engineering, and Medicine. 2022., 314

20 Ibid., 314

21 Ibid., 314

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SOPHISTICATION OF THE CONSUMER

The sophistication of the consumer is mentioned in the report, though no conclusive evidence was found, that consumers of premium cigars may not fully understand the difference between premium and nonpremium cigars. Though, as noted in the report, there is no evidence that this assumed conclusion is correct.

“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.”²²

ADDICTION

For the conclusions relating to premium cigars and addiction, no conclusive results were presented. Only a vague mention of premium cigars having the potential of being addictive because of so-called biological plausibility.²³ This plausibility is noted to be dependent on frequency of use which, as noted previously, is largely occasional among cigar smokers.^{24,25} It is not an unreasonable conclusion to draw, from the data and conclusions presented in the study, that premium cigars have a very low assumed addiction level mostly due to the frequency of use by the consumer.

“(…)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).”²⁶

MARKETING

One of the most impactful conclusions made by the committee was that “the tobacco industry does not self-regulate its marketing practices for any product”.²⁷ This conclusion highlights the need for self-regulation within the premium cigar industry. The FDA and other regulatory bodies will take note of this message made by NASEM. This conclusion could be the most impactful conclusion made by the committee.

“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 decreasing exposure among targeted populations and the deceptive or misleading nature of marketing (NCI, 2008).”²⁸

22 National Academies of Sciences, Engineering, and Medicine. 2022.,188

23 Ibid., 256

24 Ibid., 256

25 Ibid., 314

26 Ibid., 256

27 Ibid., 138

28 Ibid., 138

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YOUTH USAGE OF PREMIUM CIGARS

The committee concluded that usage among youth was very unlikely, stating:

“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.”²⁹

This is a conclusion worth highlighting because it supports the position of the Premium Cigar Association that there is little to no youth access issue within the premium cigar industry.

HEALTH CLAIMS IN MARKETING

In the findings of the report, it mentioned that some of the marketing materials surveyed had made positive health claims for the usage of premium cigars. Upon further research, the assumed positive health claims were made in reference to the relaxing nature of cigar smoking and not marketing materials covering any supposed health benefits past that.³⁰

“No articles mentioned health risks related to premium cigars; two (7 percent) [of articles surveyed] mentioned positive health effects (i.e., using premium cigars as stress relief, such as Rush Limbaugh’s interview stating, “Cigars relax me. They help me to think”).”³¹

TERMINOLOGY

One note made by the study is that there was use of so-called “low-harm” health terms within the marketing of premium cigars.³² Upon further research, it was noted in the report that phrases such as natural, organic and light were noted to be these so-called “low-harm health terms”.³³ These terms are regularly used to describe the taste profile of a premium cigar, such as light, mild and strong, as it relates to the blend of tobacco. These terms do not indicate that a product is any healthier than a stronger blend but notes the strength to ensure the consumer is purchasing the product they enjoy. This also justifies the need for self-regulation in regard to marketing. If no action is taken, these so-called low harm terms are at risk for restriction by the FDA or other regulatory bodies.

“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.”³⁴

29 National Academies of Sciences, Engineering, and Medicine. 2022.,19

30 Ibid., 147

31 Ibid., 147

32 Ibid., 147

33 Ibid., 147

34 National Academies of Sciences, Engineering, and Medicine. 2022., 147

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Other marketing terms were covered such as relating to high quality (hand-crafted), luxury terms, success, and taste. These terms are largely associated with lifestyle marketing for cigars. The table below depicts the survey results for these lifestyle terms used in premium cigar marketing.

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

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 technology, 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	Scantly dressed women	1 (2%)

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).

35 Ibid., 148

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CIGARS AS A LIFESTYLE

Another section of the report focuses on the use of lifestyle targeted marketing within the premium cigar space. As stated in the report:

“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.”³⁶

HEALTH EFFECTS

Though the NASEM Committee has concluded that there is no comprehensive definition on premium cigars, the committee did conclude the following:

“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 non-daily or occasional users and because they are less likely to inhale the smoke.”³⁷

This is consistent, though not as conclusive, with the FDA/NIH PATH study that concluded: “No statistically significant increase in risk for smoking related diseases can be found between non-daily premium cigar smokers and non-smokers in general.”

“Conclusion 5-4: There is insufficient evidence to determine if occasional or nondaily exclusive cigar use in general is associated with increased health risks.”³⁸

“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.”³⁹

“No data are published on secondhand smoke exposure to cigars overall or premium cigars in particular.”⁴⁰

“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

36 National Academies of Sciences, Engineering, and Medicine. 2022., 150

37 Ibid., 16, 244-245

38 Ibid., 16

39 Ibid., 16

40 Ibid., 117

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speculate that former cigar use might be explained by smoking cessation in response to disease onset.”⁴¹

“The literature search found no studies evaluating the specific lung cancer risks from premium cigar use.”⁴²

“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. (...)** 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.”⁴³

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41 National Academies of Sciences, Engineering, and Medicine. 2022., 219

42 Ibid., 220

43 Ibid., 223