

Regulation of “Premium” Cigars

FDA Should Not Create a Separate Category for So-Called “Premium Cigars” Because it has Already Correctly Concluded that there is No Appropriate Public Health Justification to Exclude Premium Cigars from Regulation

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FDA specifically explored the question of whether its authority should extend to so-called “premium” cigars when it published its proposed “deeming rule” in April 2014, and “after carefully considering the public comments on the rule,” FDA concluded that “there was no appropriate public health justification to exclude premium cigars from regulation.”

Specifically, FDA concluded that:

- (1) all cigars pose serious negative health risks,
- (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and
- (3) premium cigars are used by youth and young adults. FDA noted that, although some premium cigar smokers might smoke these products infrequently or report that they do not inhale, these behaviors do not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others.

Consequently, FDA included premium cigars in the scope of the final deeming rule published on May 10, 2016 (81 FR 28974 at 29020) to more effectively protect the public health.” (See Regulation of Premium Cigars, 83 FR 12901 at 12902)

This was the correct conclusion and there is no scientific basis to reverse this decision.

Nevertheless, in March 2018 FDA issued an advance notice of proposed rulemaking (ANPRM) to obtain information related to the regulation of premium cigars. Based on FDA’s previous conclusions based on its comprehensive consideration of the “premium cigar” issue, there is no rationale for FDA’s revisiting this issue now. Since all cigars – including so-called “premium cigars” – meet the definition of “tobacco products,” they should be regulated as tobacco products, and there is no rational basis (other than responding to political pressure) for the FDA to make any kind of distinction for different types of cigars.

By analogy, the FDA did not make any regulatory distinction for different sizes of cigarettes (e.g., “slims,” “ultra longs,” etc.) or e-cigarettes of different sizes and shaped (e.g., cigalikes, tanks). Additionally, it would send an exceptionally bad precedent for FDA to define different types of cigars based on considerations such as the presence or absence of filters or mouthpieces, especially in light of the variety of new heated tobacco products being introduced to the market, some of which seem to have mouthpieces (JT’s PloomTECH), and some of which do not (PM’s IQOS, BAT’s glo).

Of particular concern, there is no rational basis for making a distinction for how a tobacco product – including cigars – is packaged or marketed, as this would only create an incentive for manufacturers to game the system by labeling their product in whatever way would result in the least restrictive regulations as they did by creating flavored little cigars after most flavors were prohibited in cigarettes. In particular, manufacturers have wrapped the tobacco in a wrapper made with tobacco leaf, rather than paper, making a cigarette into a “cigar” by the terms of the legal definition.¹ Similarly, brown-papered cigarettes could be called “premium cigars” to avoid more severe restrictions that are placed on regular cigars or cigarettes, including restrictions on flavors, youth access, and taxes.

Moreover, if so-called “premium cigars” were unregulated or faced limited restrictions, there is a danger that consumers as well as potential consumers, especially youth and young adults, would migrate to “premium cigars” using flavors, nicotine content tuned to attract and addict users, and bypassing restrictions on sales to youth.

Indeed, while use patterns of “premium” cigars are currently different from cigarettes, in part because of the pH of the smoke, exempting them would create a loophole that tobacco companies could exploit by lowering the pH of large cigars and adding flavors, much as they did to exploit little cigars when characterizing flavors (except menthol) were prohibited in cigarettes.² ***An exemption for premium cigars would leave the door open for tobacco companies to turn premium cigars into giant cigarettes.***

UCSF submitted four public comments specifically considering the question of whether premium cigars should be exempted from regulations that apply to other tobacco products, which we incorporate by reference³ (copies are also appended to this comment). Because these

¹ Goel R, Muscat J, Trushin N et al., PennState Hershey Tobacco Center of Regulatory Science. Comment submitted to Docket No. FDA-2017-N-6189 for “Tobacco Product Standard for Nicotine Level of Certain Tobacco Products.”

² Henningfield JE, Fant RV, Radzius A, Frost S. Nicotine concentration, smoke pH and whole tobacco aqueous pH of some cigar brands and types popular in the United States. Nicotine Tob Res. 1999 Jun;1(2):163-8.
Brunnemann KD, Hoffmann D.. The pH of tobacco smoke. Food Cosmet Toxicol. 1974 Feb;12(1):115-24.

³ FDA’s Proposed Exception for Premium Cigars and Weak Warning Labels for Cigars Do Not Protect the Public Health:

<https://tobacco.ucsf.edu/fda%E2%80%99s-proposed-exception-premium-cigars-and-weak-warning-labels-cigars-do-not-protect-public-health>

FDA’s Proposed Exception for Premium Cigars (Option 2) Does Not Protect the Public Health and Should Be Rejected:

<https://tobacco.ucsf.edu/fda%E2%80%99s-proposed-exception-premium-cigars-option-2-does-not-protect-public-health-and-should-be-rejected>

FDA inappropriately discounts health benefits of regulating ecigs and cigars by 70% because of lost pleasure of smoking:

<https://tobacco.ucsf.edu/fda-inappropriately-discounts-health-benefits-regulating-ecigs-and-cigars-70-because-lost-pleasure-smoking>

previously submitted comments address many of the specific questions currently posed by FDA, we are not responding to several of the questions that FDA posed. We do respond to questions where there is substantial new information that further buttresses FDA's decision not to exempt premium cigars from regulation as tobacco products.

Specific questions for comment

A. Definition of Premium Cigars

- 1. Explain what data may be used to assess (a) the universe of cigar products that are currently available to consumers and (b) their relevant characteristics, including "premium" status. How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?**

For the reasons described above, the FDA should not change its policy. Trying to develop a definition of "premium cigars" would merely create opportunities for tobacco companies to manipulate their products to the detriment of public health.

- 2. Explain what you believe to be the particular defining characteristics of premium cigars. These characteristics could include, but not be limited to:**
 - a. Size (e.g., length, ring gauge, total weight).**
 - b. Tobacco filler type and minimum required percentages of each filler per cigar.**
 - c. Fermentation type.**
 - d. Wrapper and binder composition (e.g., whole leaf, reconstituted or homogenized tobacco leaf).**
 - e. Where the tobacco used for premium 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.**
 - f. Presence or absence of a filter.**
 - g. Presence or absence of a mouthpiece.**
 - h. Manufacturing and assembly process (e.g., including any production by hand or by machine).**
 - i. Rate of production (e.g., "produced at no more than [insert number] units per minute").**
 - j. Presence or absence of flavor imparting compounds, flavor additives, or characterizing flavors other than tobacco.**
 - k. Presence or absence of any additives other than cigar glue.**
 - l. Nicotine content.**
 - m. Tar delivery amounts (and how this should be defined and measured).**
 - n. Carbon monoxide delivery amounts (and how this should be defined and measured).**
 - o. Retail price.**
 - p. Frequency with which price changes are initiated by particular levels in the distribution chain (retailers, manufacturers, importers, and/or distributors).**
 - q. Packaging quantity and size.**
 - r. Any action directed to consumers, by a retailer or manufacturer, such as through**

White House significantly weakened FDA's proposed rules for cigars and ecigs:
<https://tobacco.ucsf.edu/white-house-significantly-weakened-fdas-proposed-rules-cigars-and-ecigs>

labeling, advertising, or marketing, which would reasonably be expected to result in consumers believing that the tobacco product is a premium cigar.

As the introductory comments and response to Question 2 indicate, all these details simply create opportunities for tobacco companies to exploit so they can more easily develop and market new products that will prolong or worsen the tobacco epidemic.

- 3. If available to you, provide annual sales data, including market size and volume, for products that you believe should be categorized as premium cigars, along with the information's source and the definition of "premium cigar" used in the data provided.**

See previous comment.

B. Use Patterns of Premium Cigars

If available to you, provide the following information related to the use patterns of premium cigars generally and among youth and young adults specifically:

- 1. Studies or information regarding the potential role of premium cigars on tobacco initiation and progression to use of other tobacco products, especially compared and contrasted against the potential roles of other cigars.**
- 2. Studies or information regarding behavioral data related to dual use of premium cigars and other tobacco products, especially compared and contrasted against dual use of other cigars.**
- 3. Studies or information regarding the frequency and intensity (e.g., number of cigars smoked per day, depth of smoke inhalation, number of days smoking during a particular time period) of premium cigar use, especially compared and contrasted against other cigars.**

These questions are not relevant to whether or not premium cigars should be regulated as tobacco products. The Family Smoking Prevention and Tobacco Control Act (FSPTCA) amended the Federal Food, Drug, and Cosmetic Act⁴ to define "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption..."⁵ When the FSPTCA was enacted, FDA's authority to regulate tobacco products extended to cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and to any other tobacco products that FDA deems to be subject to its tobacco regulatory authorities.⁶ In FDA's proposed rule to extend its tobacco product authorities, FDA specifically considered two separate options for the scope of cigar products that would be deemed subject to FDA tobacco product regulation: "Option 1" would extend FDA's authority to all products that meet FSPTCA's statutory definition of "tobacco product," and "Option 2" would exclude a subset of so-called "premium cigars" from regulation.⁷ In May 2016 FDA's "Deeming Rule" rejected Option 2 and extended

⁴ Federal Food, Drug, and Cosmetic Act, section 201(rr)(1), 21 U.S.C. 321.

⁵ Family Smoking Prevention and Tobacco Control Act, section 101(a), Pub. L. 111-31, 21 U.S.C. 387 et seq. (2009)

⁶ Family Smoking Prevention and Tobacco Control Act, section 901(b), Pub. L. 111-31, 21 U.S.C. 387 et seq. (2009)

⁷ Proposed Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 FR 23142 at pp. 23150-23152, 23202-23207 (April 25, 2014).

its tobacco regulatory authorities to include all cigars, including so-called “premium cigars,” finding no appropriate public health justification to exclude so-called “premium cigars” from regulation.⁸ FDA stated:

After thorough review of the comments and the scientific evidence, FDA has concluded that deeming all cigars, rather than a subset, more completely protects the public health and therefore has adopted Option 1 in the final rule. FDA has concluded that: (1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults. The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Therefore, we find there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them.⁹

Because FDA has already determined, premium cigars are dangerous, even if no kids used them. Just as there was “no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule,” there is no appropriate public health justification for FDA to consider regulating premium cigars differently now.

4. Studies or information regarding the proportion of premium cigar smokers showing symptoms of dependence, especially compared and contrasted against other cigars.

Regardless of whatever might be available in the current literature, this would likely change if “premium cigars” were regulated differently than other cigars and/or tobacco products because it would open up a loophole similar to what happened when characterizing flavors were prohibited in cigarettes but not little cigars.

5. Studies or information regarding the abuse liability of premium cigars compared with other tobacco products, especially compared and contrasted against other cigars.

There is no reason to expect the nicotine from premium cigars would have different biological effects than nicotine inhaled from other tobacco products.

6. Studies or information regarding the impact of premium cigar labeling, advertising, and marketing efforts on patterns of use, especially compared and contrasted against other cigars.

No comment.

⁸ Final Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28973 (May 10, 2016).

⁹ Final Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 FR 28973 at p. 29020 (May 10, 2016).

- 7. Information on the extent to which users of other tobacco products might switch to premium cigars if FDA were to exempt premium cigars from regulation or to regulate premium cigars differently from other cigars, and the measures that could be taken to prevent this from occurring. Where you discuss the potential effects of FDA regulating premium cigars differently from other cigars, please describe the specific different treatment that you envision.**

When youth perceive a tobacco product as safer (and by extension, if products are not regulated, they can be considered safer), they are more likely to use it.

C. Public Health Considerations

If available to you, provide the following information related to public health considerations:

- 1. Studies or information on any applicable manufacturing, marketing, sale, distribution, advertising, labeling, and/or packaging requirements and restrictions in the FD&C Act and its implementing regulations, and whether they should be applied differently to premium cigars compared to other tobacco products, including other cigars.**
- 2. Studies or information regarding nicotine concentrations for premium cigars compared to other tobacco products, including other cigars.**

No comment.

- 3. Studies or information regarding the risk of oral cancer, esophageal cancer, laryngeal cancer, lung cancer, or any other form of cancer associated with premium cigars, especially compared and contrasted with risks for other cigars.**

In the National Cancer Institute Monograph on the health effects of cigars, the NCI concluded that cigar smoke, like cigarette smoke, contains toxic and cancer-causing chemicals and that cigar smoke is possibly equally or even more toxic than cigarette smoke.¹⁰ Compared to cigarette smoke, cigar smoke contains a higher level of nitrosamines and more tar per gram of tobacco. Cigars are also associated with more incomplete combustion and longer smoking time than cigarettes, which could contribute to greater toxin exposure to users.

The NCI monograph found that cigar smoking causes cancer of the oral cavity, larynx, and esophagus, with the risk of oral cancer 7-10 times higher among cigar smokers compared to non-smokers. Risks of cancers of the oral cavity and esophagus are similar among cigarette and cigar smokers, probably due to the similar doses of tobacco smoke delivered directly to these areas by cigars and cigarettes.¹¹

¹⁰ National Cancer Institute. 2012 Cigars: Health Effects and Trends. Bethesda, MD: US Dept of Health and Human Services, Public Health Service. Smoking and Tobacco Control Monograph No. 9. NIH publication 98-4302. Available at: http://rex.nci.nih.gov/NCI_MONOGRAPHS/MONO9.HTM.

¹¹ National Cancer Institute. 2012 Cigars: Health Effects and Trends. Bethesda, Md: US Dept of Health and Human Services, Public Health Service. Smoking and Tobacco Control Monograph No. 9. NIH publication 98-4302. Available at: http://rex.nci.nih.gov/NCI_MONOGRAPHS/MONO9.HTM.

Multiple individual studies were cited in the NCI report, including:

- A case-control study of 185 squamous cell carcinomas of the upper aerodigestive tract, including larynx, tongue, oropharynx, floor of mouth, and other cancers of the oral cavity, demonstrated an odds ratio of 2.8 (95% CI: 1.5, 5.5) for cigar use and all oral cancer sites combined.¹²
- Over 12 years of follow-up of the American Cancer Society's Cancer Prevention Study (CPS) II cohort, cigar smoking at baseline, as compared with never smoking, cigar smoking was associated with an increased risk of death from cancers of the oral cavity/pharynx (relative risk: 4.0; 95% CI: 1.5, 10.3).¹³
- In CPS I and II: there was elevated risk of oral cancer mortality for cigar smokers who had never smoked cigarettes or pipes, as well as for cigar smoking overall (mortality ratios from 4 to 7.9). Cigar-only smokers reporting no inhalation also had significantly elevated risk of oral cancer mortality in CPS-I (MR: 7.0; 95% CI: 4.1, 11.0).¹⁴
- In a case-control study of cancer of the oral cavity-oropharynx in Italy, male cigar smokers, with or without the combination of other tobacco products, had higher risk of oral cavity cancer than cigarette-only smokers (OR: 14.6; 95% CI: 4.7, 46), compared to an OR of 3.9 (95% CI: 1.6, 9.4) for cigarette smokers.¹⁵

In a more recent meta-analysis that pooled five cohort studies,¹⁶ ever use of cigars and/or pipes was associated with increased risk for head and neck cancer (hazard ratio: 1.5; 95% CI: 1.2, 1.9), and this association persisted among cigar-only (not pipe) smokers, as well (HR: 1.4; 95% CI: 1.0, 2.0).

In terms of oral cancer risk, the 2012 NCI report did not specifically separate large/premium cigars from filtered, small, or non-premium large cigars. However, whether cigar smoke depth of inhalation potentially affects cancer risk was considered. Users of premium cigars tend not to inhale the smoke as deeply as users of small or filtered cigars. Based on reported data from the CPS-I cohort, oral cancer mortality (relative to tobacco non-smokers) was highest among cigar smokers who reported inhaling the smoke moderately or deeply. However, oral cancer mortality was also substantially elevated among cigar smokers who reported none or slight inhalation.

¹² Spitz MR, Fueger JJ, Goepfert H, Hong WK, Newell GR. Squamous cell carcinoma of the upper aerodigestive tract. A case comparison analysis. *Cancer*. 1988 Jan 1;61(1):203-8.

¹³ Shapiro JA, Jacobs EJ, Thun MJ. Cigar smoking in men and risk of death from tobacco-related cancers. *J Natl Cancer Inst*. 2000 Feb 16;92(4):333-7.

¹⁴ Shanks TG, Burns DM. Disease consequences of cigar smoking. National Cancer Institute, Smoking and Tobacco Control, Monograph 9: Cigars Health Effects and Trends 1998,105-160.
<http://cancercontrol.cancer.gov/brp/tcrb/monographs/>

¹⁵ Merletti F, Boffetta P, Ciccone G, Mashberg A, Terracini B. Role of tobacco and alcoholic beverages in the etiology of cancer of the oral cavity/oropharynx in Torino, Italy. *Cancer Res*. 1989 Sep 1;49(17):4919-24.

¹⁶ Malhotra J, Borron C, Freedman ND, Abnet CC, van den Brandt PA, White E, Milne RL, Giles GG, Boffetta P. Association between Cigar or Pipe Smoking and Cancer Risk in Men: A Pooled Analysis of Five Cohort Studies. *Cancer Prev Res (Phila)*. 2017 Dec;10(12):704-709.

This suggests that even cigars that do not involve deep inhalation of smoke are capable of increasing oral cancer mortality. The Table reporting these differences by inhalation depth is reproduced below (originally presented in the 1998 NCI report).¹⁷

Table 1: Mortality ratios (and 95% confidence intervals), for select causes of death in male cigar only vs. cigarette only smokers by amount smoked daily and depth of inhalation. Cancer Prevention Study I, 12-year follow-up							
Amount Smoked Daily							
Cause of death	Non Smoker	Cigars per Day			Cigarettes per Day		
		1-2 cigars	3-4 cigars	5+ cigars	<1 pack	1 pack	>1 pack
Cancer of buccal cavity & pharynx	1	2.12 (0.43-6.18)	8.51 (3.66-16.77)	15.94 (8.71-26.75)	5.93 (4.28-8.02)	6.85 (5.37-8.62)	12.04 (9.81-14.63)
Self-Reported Depth of Inhalation							
	Non Smoker	Cigars			Cigarettes		
		None	Slight	Moderate to Deep	None, Slight	Moderate	Deep
Cancer of buccal cavity & pharynx	1	6.98 (4.13-11.03)	7.83 (1.57-22.88)	27.88 (5.60-81.46)	6.26 (4.47-8.53)	8.43 (7-10.06)	12.48 (9.61-15.94)
Source: National Cancer Institute. Chapter 1: Cigar Smoking: Overview and Current State of the Science Cigars: Health Effects and Trends. Bethesda, Md: US Dept of Health and Human Services, Public Health Service. Smoking and Tobacco Control Monograph No. 9: Cigars Health Effects and Trends 1998,105-160. http://cancercontrol.cancer.gov/brp/tcrb/monographs/							

4. Studies or information regarding the risk of heart disease associated with premium cigars, especially compared and contrasted with risks for other cigars.
5. Studies or information regarding the risk of aortic aneurysm associated with premium cigars, especially compared and contrasted with risks for other cigars.

No comment.

6. Studies or information regarding the risk of periodontal disease associated with premium cigars, especially compared and contrasted with risks for other cigars.

¹⁷ Shanks TG, Burns DM. Disease consequences of cigar smoking. National Cancer Institute, Smoking and Tobacco Control, Monograph 9: Cigars Health Effects and Trends 1998,105-160. <http://cancercontrol.cancer.gov/brp/tcrb/monographs/>

The use of tobacco, particularly combustible tobacco products, is the major preventable risk factor in the onset and progression of periodontal diseases.¹⁸ In addition, tobacco use greatly reduces the success of periodontal treatments and surgical procedures.¹⁹

Few publications specifically consider cigar use as a risk factor for periodontal disease separately from cigarette smoking, but the studies that have examined cigar use show similar adverse risks for periodontal disease and tooth loss from cigars as from cigarettes. No published epidemiologic evidence is available to show a difference in periodontal disease risk between premium/large cigars and filtered or small cigars.

In an assessment of 690 dentate adult men who were part of the Veterans Affairs Dental Longitudinal Survey,²⁰ after adjustment for age, education, number of teeth at baseline, cigar smokers were at elevated risk of tooth loss over 20+ years (relative risk: 1.3; 95% confidence interval: 1.2, 1.5) compared to tobacco non-users. The increased risk among cigar smokers was similar to the risk among cigarette smokers. Cigar smoking was likewise associated with progression of alveolar bone loss.

Among 705 adults who took part in the Baltimore Longitudinal Study of Aging,²¹ those who were former or current smokers of cigars or pipes were compared to daily cigarette smokers, former daily cigarette smokers, and non-smokers. In this study, former or current cigar or pipe smokers demonstrated a higher prevalence of moderate or severe periodontitis (18%) compared to non-smokers (13%); although, this prevalence was lower than among daily cigarette smokers (26%). In this study, cigar/pipe use was also associated with elevated levels of attachment loss, probing depth, gingival recession, dental calculus, and tooth loss.

Neither of the two above studies was able to separate differences in periodontal outcomes by type of cigar smoked (e.g., premium/large cigars vs. filtered or small cigars).

- 7. Studies or information regarding the risk of stroke associated with premium cigars, especially compared and contrasted with risks for other cigars.**
- 8. Studies or information regarding the risk of chronic obstructive pulmonary disease associated with premium cigars, especially compared and contrasted with risks for other cigars.**
- 9. Studies or information regarding risk of cancers of the mouth and throat for premium cigar users who do not inhale or who report that they do not inhale, especially compared and contrasted with risks for other cigars.**

No comment.

¹⁸ Genco RJ, Borgnakke WS. Risk factors for periodontal disease. *Periodontol* 2000. 2013 Jun;62(1):59-94.
Nociti FH Jr, Casati MZ, Duarte PM. Current perspective of the impact of smoking on the progression and treatment of periodontitis. *Periodontol* 2000. 2015 Feb;67(1):187-210.

¹⁹ Heasman L, Stacey F, Preshaw PM, McCracken GI, Hepburn S, Heasman PA. The effect of smoking on periodontal treatment response: a review of clinical evidence. *J Clin Periodontol*. 2006 Apr;33(4):241-53.

²⁰ Krall EA, Garvey AJ, Garcia RI. Alveolar bone loss and tooth loss in male cigar and pipe smokers. *J Am Dent Assoc*. 1999 Jan;130(1):57-64.

²¹ Albandar JM, Streckfus CF, Adesanya MR, Winn DM. Cigar, pipe, and cigarette smoking as risk factors for periodontal disease and tooth loss. *J Periodontol*. 2000 Dec;71(12):1874-81.

10. Studies or information on the impact of premium cigar use on other public health endpoints, including users and non-users, especially compared and contrasted with the impact of other cigars.

Premium cigars produce more secondhand smoke than cigarettes or little cigars because the mass of tobacco that is burned is so much larger.

Secondhand smoke, including both the sidestream smoke from the smoldering tip and the mainstream smoke that is released from the mouth despite lack of inhalation/exhalation, is still a major health concern that the FDA is required to consider when evaluating health effects of tobacco products. Indeed, FSPTCA section 904 requires tobacco product manufacturers to submit all information to FDA relating to the health, toxicological, behavioral, or physiologic effects of all tobacco products and their constituents, *including smoke constituents*, and requires FDA to establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents (HPHCs), *including smoke constituents*.²² In April 2012, FDA published its first list of HPHCs, which included harmful and potentially harmful constituents in tobacco smoke.²³ At the time the initial HPHC list was published, FDA had not yet extended its tobacco regulatory authorities to cigars. However, FDA updated its January 2011 guidance on HPHCs²⁴ in August 2016 to “better reflect the current range of tobacco products subject to [FDA] authority,” including cigars.²⁵

Importantly, FDA recognizes that constituents that have the potential to cause direct or indirect harm to *non-users* of tobacco products (such as those emitted in secondhand smoke) are also harmful. In its 2016 revised guidance, FDA defined the phrase “harmful and potentially harmful constituent” to include any chemical or chemical compound in a tobacco product or *in tobacco smoke* that:

a) is, or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and

b) causes or has the potential to cause direct or indirect harm to users *or non-users of tobacco products*. Examples of constituents that have the “potential to cause direct harm” to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds. Examples of constituents that have the “potential to cause indirect harm” to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by: 1) potentially facilitating initiation of the use of tobacco products; 2) potentially impeding cessation of the use of tobacco products; or 3) potentially

²² Family Smoking Prevention and Tobacco Control Act, section 904, Pub. L. 111-31, 21 U.S.C. 387 et seq. (2009)

²³ Harmful and Potentially Harmful Constituents in Tobacco Products, and Tobacco Smoke; Established List, 77 FR 20034 (April 3, 2012).

²⁴ Guidance for Industry and Food and Drug Administration Staff; “‘Harmful and Potentially Harmful Constituents’ in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act”; Availability, 76 FR 5387 (January 31, 2011).

²⁵ “Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised), Guidance for Industry and FDA Staff (August 2016), available at <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM241352.pdf>.

increasing the intensity of tobacco product use (e.g., frequency of use, amount consumed, depth of inhalation). Another example of a constituent that has the “potential to cause indirect harm” is a constituent that may enhance the harmful effects of a tobacco product constituent.²⁵ [Emphasis added]

Indeed, to the extent that premium cigar users do not inhale, they would generate more secondhand smoke because the exhaled mainstream smoke has not been through the natural filtration system of the airways and lungs that comes with inhaled tobacco products, and therefore would be expected to have higher levels of toxic chemicals than mainstream smoke that has been inhaled and exhaled. Not only is this a concern to bystanders, but even the cigar smokers themselves will inhale the secondhand smoke in the room despite not actively inhaling the mainstream smoke, and are still subjected to the same adverse health effects of the smoke that are experienced by nonsmoking bystanders.

Sidestream smoke from filtered little cigars (Swisher Sweets) impairs endothelial function as measured by arterial flow-mediated dilation after brief exposures was comparable to that from Marlboro Red cigarettes.²⁶ While tobacco in filtered little cigars is not identical to that in premium cigars by virtue of different pH, the results indicate that this potential adverse effect on endothelial function is a general effect of both cigarette tobacco and cigar tobacco, supporting the concern that adverse health effects of premium cigars transcend the difference between inhaling smoke into the lungs or holding it in the mouth.

- 11. Studies or information regarding the addictiveness of premium cigars.**
- 12. Studies or information regarding consumer perceptions of the health risks of premium cigars when compared to other tobacco products, including other cigars.**
- 13. Studies or information regarding consumer perceptions of the addictiveness of premium cigars, especially compared and contrasted with perceptions for other cigars.**
- 14. Studies or information on the required warning statements, shown below and which will be required to appear on cigar packaging and advertising in the near future (21 CFR 1143.5(a)(1)). Comment on whether any additional or alternative warning statements would be appropriate and provide your suggested language and any relevant studies or information.**
 - a. WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.**
 - b. WARNING: Cigar smoking can cause lung cancer and heart disease.**
 - c. WARNING: Cigars are not a safe alternative to cigarettes.**
 - d. WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.**
 - e. WARNING: Cigar use while pregnant can harm you and your baby.; or
SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility,
Stillbirth and Low Birth Weight.**
 - f. WARNING: This product contains nicotine. Nicotine is an addictive chemical.**

²⁶ Liu J, Wang X, Narayan S, Glantz SA, Schick SF, Springer ML. Impairment of endothelial function by little cigar secondhand smoke. *Tob Regul Sci* 2016;2(1):56-63 (PMC 4703945)

UCSF previously submitted a public comment specifically considering the importance of requiring strong and appropriate warning labels for all cigars, including so-called “premium cigars.”²⁷ A. copy is appended to this comment.

D. Healthcare Costs Attributable to Cigar Smoking

The healthcare costs attributable to cigar smoking in the U.S. are substantial.²⁸ We used a Zero-Inflated Poisson regression model to analyze data from the 2000, 2005, 2010, and 2015 National Health Interview Surveys on 89,638 adults aged 35+. Cigar smokers had statistically significantly greater utilization of hospital care, emergency room visits, and home care visits. Considering those who only smoked cigars currently or formerly and never used any other tobacco products, the cost amounted to \$625 per cigar smoker in 2014 dollars. This compares to a cost per ever cigarette smoker aged 35+ of \$1,131 for California for 2014 (US figures not available).²⁹ Note that the cigar costs include only 3 types of healthcare utilization while the cigarette estimates include hospital care, ambulatory care, prescriptions, home health care, and nursing home care. We were unable to separate premium cigars from other types of cigars, but our cost estimates nonetheless indicate that healthcare costs attributable to cigar smoking are large and while smaller than those attributable to cigarette smoking, are of the same order of magnitude. Our estimates suggest that cigars have a substantial impact on human health, thus indicating the importance of regulating all types of cigars.

Conclusion

Since the FDA appropriately included premium cigars in the final deeming rule published in May 2016, the evidence to support the correctness of this decision has only grown. Moreover, creating a separate category for premium cigars only creates potential loopholes for the tobacco companies to exploit to undermine public health. As FDA correctly concluded in the May 2016 rule, “there is no appropriate public health justification to exclude premium cigars from regulation.”

²⁷ FDA’s Proposed Exception for Premium Cigars and Weak Warning Labels for Cigars Do Not Protect the Public Health:

<https://tobacco.ucsf.edu/fda%E2%80%99s-proposed-exception-premium-cigars-and-weak-warning-labels-cigars-do-not-protect-public-health>

²⁸ Wang Y, Sung HY, Yao T, Lightwood J, Max W. Health care utilization and expenditures attributable to cigar smoking among US adults, 2000-2015. *Public Health Rep.* 2018 May/Jun;133(3):329-337. doi: 10.1177/0033354918769873. Epub 2018 Apr 24.

²⁹ Max W, Sung H-Y, Shi Y, Stark B. The cost of smoking in California. *Nicotine & Tobacco Research*, 2015, 1–8. doi:10.1093/ntr/ntv123. These estimates were inflated to 2014 dollars using the Personal Health Care Index.