



July 25, 2018

Dockets Management Staff (HFA-305)
 U.S. Food and Drug Administration
 5630 Fishers Lane, Rm. 1061
 Rockville, MD 20852

RE: Docket No. FDA-2017-N-6107, Advance Notice of Proposed Rulemaking, Regulation of Premium Cigars

The undersigned organizations submit these comments in the above-designated docket regarding the Advance Notice of Proposed Rulemaking on Regulation of Premium Cigars, 83 Fed. Reg. 12901 (March 26, 2018) (ANPRM). In its final Deeming Rule, the Food and Drug Administration (FDA) made the appropriate determination that there is no public health justification for exempting so-called “premium cigars” from the Rule. No data or other information has emerged since the final Rule was issued in May, 2016 that should cause FDA to reconsider that conclusion.

I. PARAMETERS OF THIS ANPRM

In this ANPRM, FDA established important parameters limiting its inquiry regarding the regulation of premium cigars. By its plain terms, this ANPRM is not for the purpose of reconsidering the agency’s judgment that, based on the information available and in the administrative record at the time of the final Deeming Rule, there is no public health rationale for excluding premium cigars from regulation. Indeed, the ANPRM reiterates FDA’s key conclusions leading to its decision to reject any such exemption from regulation for any category of cigars: “(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.”¹

Moreover, as the ANPRM notes, even if the patterns of use of premium cigars may differ from other categories of cigars, this would not justify an exemption from regulation: “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.”² The ANPRM states that those conclusions followed careful consideration of the public comments submitted on the Rule.³

Rather than reconsidering the evidence supporting its Deeming Rule decision to regulate premium cigars, the ANPRM is intended only to allow the agency to receive any information that may not have been available prior to the final Deeming Rule, or otherwise not considered by FDA in the Deeming Rule proceedings. The ANPRM notes, in particular, that “the comments against regulation provided little data to support the opinions expressed and where studies were submitted, provided little information about the studies cited.”⁴ Thus, the agency explains that it “is seeking comments, evidence, information, data, and analysis *that were not submitted in response to the proposed deeming rule, or that may have become available since then*, that could further inform FDA’s thinking about the regulation of premium cigars.”⁵ In our view, the fact that supporters of a regulatory exemption for premium cigars were unable to support such an exemption with valid science is an insufficient reason to issue this ANPRM and conduct these proceedings. Nevertheless, it is clear that FDA is seeking only information not presented to the agency in the Deeming Rule proceedings and those supporting a regulatory exemption have the burden of justifying it based on *newly presented evidence*.

The limited parameters of this ANPRM proceeding are further underscored by representations made on FDA’s behalf to a federal court by the U.S. Department of Justice (DOJ), in successfully defending the cigar health warnings mandated by the Deeming Rule against industry attack. In a brief filed in *Cigar Association of America et al. v. U.S. Food and Drug Administration*, DOJ discussed the meaning of the ANPRM and its implications for the application of the Deeming Rule cigar warnings to premium cigars, explaining that “the ANPRM in fact underscores that the FDA’s decision not to craft a special exemption for premium cigars was made only after a thorough review of the then-available evidence, not before.”⁶ Thus, the DOJ brief observed that “the FDA has agreed to accept additional information that may bear on

¹ ANPRM at 12902.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.* (emphasis added).

⁶ Defendants’ Response to Plaintiffs’ Response to the Government’s Notice of Publication of Advance Notice of Publication of Advance Notice of Proposed Rulemaking, *Cigar Association of America et al. v. U.S. Food and Drug Administration* (DDC CA No. 16-1460) (April 10, 2018), at 2.

the issue – but only ‘new and different’ information that was not already submitted in comments on the proposed deeming rule.”⁷ In upholding the Deeming Rule’s cigar health warnings, the court, relying on FDA’s representations concerning the parameters of the ANPRM, commented that “[b]y so limiting the scope of the information and comments requested, the FDA does not concede, or even hint, that the prior rulemaking record was deficient in any respect.”⁸ Again, according to the text of the ANPRM and the government’s representations in court characterizing the ANPRM (relied on by a federal court), this proceeding is not a reconsideration of the agency’s Deeming rule decision against exempting premium cigars from regulation, but simply a means for the agency to receive new and different information it did not consider in the Deeming rule proceedings.

As the following discussion indicates, the studies and data that have emerged since the final Deeming rule was issued in May, 2016 in no way undercut the FDA’s well-reasoned decision against a premium cigar exemption; indeed, they strengthen the scientific support for regulating all cigars.

II. SUMMARY OF RECENT MAJOR CIGAR-RELATED RESEARCH

Though not purporting to be all-inclusive, this section summarizes the findings of major research since the final Deeming Rule was issued relevant to the questions asked about premium cigars in the ANPRM. Although this research establishes the great variability in cigar characteristics and patterns of use, no recent research supports a regulatory exemption for any category of cigars, including so-called “premium” cigars.

The PATH Study Does Not Support a Regulatory Exemption for Premium Cigars but Rather Shows that a Significant Portion of Premium Cigar Smokers Engage in Dual Use Behavior, Which Increases their Risk of Disease (ANPRM Questions B2 and B3)

The ANPRM cites, as an example of new recent data that may be relevant to the regulation of premium cigars, a study from Corey, et al., using data from the Population Assessment of Tobacco and Health (PATH) Study indicating that those who smoked premium cigars tended to report smoking them on fewer days compared with smokers of other cigar types and reported consuming fewer cigars per day than smokers of other cigar types.⁹

First, the Corey, et al., study does not assess the relative health risks of smoking premium cigars vs. other cigars and thus furnishes no basis to question the FDA’s Deeming Rule conclusion that, whatever the use patterns associated with premium cigars, they do not sufficiently reduce the health risks to users to justify a regulatory exemption.

⁷ *Id.* at 3.

⁸ *Cigar Association of America et al. v. U.S. Food and Drug Administration*, 2018 WL 2223653 (May 15, 2018), at 22.

⁹ Corey, C.G., E. Holder-Hayes, A.B. Nguyen, et al. “U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014, *Nicotine & Tobacco Research* [Epub ahead of print] doi:10.1093/ntr/ntx209, September 15, 2017 (“Corey, et al.”).

Second, even if premium cigars were shown to pose a risk of a different nature and degree than other cigars due to different usage patterns, the appropriate regulatory response would not be to exempt them from regulatory oversight, but for FDA to consider whether there is a way to apply its regulatory authority in a manner that fits the risk posed, given the nature of the products, who uses them, and how they are used. In no way would a different level of risk itself justify a complete exemption from FDA jurisdiction or key public health protections like the Deeming Rule's minimum age and age verification provisions, mandatory health warnings, ingredient disclosure requirements, harmful and potentially harmful constituent disclosure requirements and other important protections.¹⁰ Experience demonstrates that if a product is exempted from FDA's authority, industry will take undue advantage of any such loophole, as occurred after FDA banned cigarettes with characterizing flavors and industry responded by recharacterizing such products as cigars.

Third, even if some premium cigar users smoke fewer cigars and less often, the PATH data in Corey, et al., show that a significant percentage of premium cigar smokers engage in risky dual use behavior. The data show that one in six (16.8%) of premium cigar smokers also currently smoked other cigar products and nearly one in three (29.9%) of premium cigar smokers also currently smoked cigarettes.¹¹

All Cigars Expose Smokers to Hazardous Levels of Toxins and Addictive Levels of Nicotine (ANPRM Questions C2-11)

Recent studies support the FDA's Deeming Rule conclusion that, although some smokers may smoke large or premium cigars less frequently than other cigars or cigarettes, all cigar smokers are exposed to dangerous levels of toxins and a risk of addiction.

As a general matter, research continues to demonstrate that cigar smokers have an elevated risk of disease and mortality than never smokers¹² and all cigars, including large cigars

¹⁰ See generally Comments of 24 Public Health Groups in Docket No. FDA-2014-N-0189, RIN 0910-AG38, Proposed Rule on Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act (August 8, 2014) ("Public Health Comments on Proposed Deeming Rule"), at 15.

¹¹ Corey, et al., at 12.

¹² Malhotra, J. et al., "Association between Cigar or Pipe Smoking and Cancer risk in Men: A Pooled Analysis of Five Cohort Studies," *Cancer Prevention Research*, DOI:10.1158/1940-6207. CAPR-17-0084 (Published OnlineFirst September 28, 2017) (finding increased risk of smoking-related cancers with exclusive use of cigars or pipe when compared to never smokers, with both products contributing independently to cancer risk; lung cancer showed strongest association with smoking both these products); Christensen, C.H. et al., "Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population," *JAMA Internal Medicine* 178(4):469-476, 2018 (finding exclusive cigar smokers "had higher all-cause mortality risks than never tobacco users" and "had an elevated risk of dying from a tobacco-related cancer (including bladder, esophagus, Larynx, lung, oral cavity and pancreas).")

(some of which are premium cigars) deliver significant amounts of toxins and nicotine.¹³ Thus, one recent study of dual use of cigarettes and various categories of cigars found that “in efforts to achieve levels of nicotine, cigar smokers (especially cigarillo and large cigar users) expose themselves to toxicant levels of CO [carbon monoxide] and potentially other components of mainstream tobacco smoke,” concluding that “it is clear that all cigar products delivered significant and addictive quantities of nicotine and CO – findings that support the rationale for their regulation.”¹⁴

A second recent study, of dual users of cigarettes and large cigars, examined toxicant delivery and addictive potential. It found that by smoking large cigars, dual users expose themselves to toxic components that have been linked with the addiction risk, morbidity, and mortality of cigarette smoking.¹⁵ The study concluded that “[t]he results of the present and previous studies indicate that all cigar products (little cigars, cigarillos, and large cigars), like cigarettes, rapidly deliver nicotine and CO to their consumers which represents a significant public health concern.”¹⁶ “These findings,” the authors continued, “support the rationale for regulation of cigar products as has recently been enacted by the FDA.”¹⁷

The FDA has previously addressed the claim of the International Premium Cigar and Pipe Retailer’s Association (IPCRA) that the vast majority of premium cigar smokers do not inhale the smoke (79 Fed Reg at 23152). A recent review authored by FDA scientists concluded that “even when no inhalation of cigar smoke is reported, risks of death from cancers of the upper aerodigestive tract (oral cavity, larynx, esophagus) are still highly elevated.”¹⁸ The review included 22 studies from 16 prospective cohorts, with the evidence on cancer risk among cigars smokers who report not inhaling derived primarily from the American Cancer Society Cancer Prevention Study I (CPS-I) and Cancer Prevention Study II (CPS-II). No other prospective studies have examined risk of specific cancers among exclusive cigar smokers (those who never smoked cigarettes or pipes) by reported degree of inhalation. As summarized in the review by FDA scientists, not only was risk of death from cancers of the upper aerodigestive tract elevated in CPS-I and CPS-II, but in both CPS-I and CPS-II, exclusive cigar smokers who reported no inhalation were at a statistically significant 2 to 3-fold increased risk of developing fatal lung cancer compared to never smokers.¹⁹ Furthermore, the review notes evidence from CPS-II

¹³ Pickworth, WB, et al., “Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure,” *Tobacco Regulatory Science* 3(Supp. 1): S72-S83, April 2017.

¹⁴ *Id* at 7, 8.

¹⁵ Rosenberry, ZR, Pickworth, WB, and Koszowski, B., “Large Cigars: Smoking Topography and Toxicant Exposure,” *Nicotine & Tobacco Research* 20(2):183-191, 2018.

¹⁶ *Id* at 188.

¹⁷ *Id* at 188.

¹⁸ Chang CM, Corey CG, Rostron BL, Spielberg BJ. Systematic review of cigar smoking and all cause and smoking related mortality. *BMC Public Health*. 2015;24;15:390.

¹⁹ Shanks TG, Burns DM. Disease consequences of cigar smoking. In: Burns DM, Cummings KM, Hoffman D, editors. *Cigars: health effects and trends*. Monograph 9. Bethesda (MD): U.S. Department of Health and Human Services, National Institutes of Health; 1998. DHHS Publ No.

concerning stomach cancer mortality, an outcome that has not been examined in CPS-I. In CPS-II, cigar smoking was associated with significantly increased risk of fatal stomach cancer,²⁰ with two-fold increased risk observed in exclusive cigar smokers who reported not inhaling, as well as a larger increase in risk in exclusive cigar smokers who reported inhaling.

In CPS-I, risks of fatal cancers of three upper aerodigestive cancers (oral cavity and pharynx, larynx, and esophagus) were significantly increased among exclusive cigar smokers who reported not inhaling, with relative risks compared to never smokers that ranged from 3 to 10, depending on the cancer site.²¹ In CPS-II, generally similar elevations in risk for mortality from these cancers were observed among cigar smokers who did not inhale, although the number of cigar smokers was smaller than in CPS-I and relative risks were not formally statistically significant.²² No new evidence has been published using cohort data disputing the conclusion that cigar smoking, even without inhalation, increases the risk of certain cancers.

Cigar Smoking is Perceived to be Less Dangerous than Cigarette Smoking

There was substantial evidence in the Deeming Rule administrative record of a widespread misperception, particularly among young people, that cigar smoking is less hazardous than cigarette smoking,²³ evidence relied upon by a federal court in upholding the Deeming Rule's requirement of health warnings for all cigars.²⁴ The data from the PATH study in Corey, et al., confirm this misperception among significant numbers of premium cigar smokers, showing that nearly one-third (31.4%) of premium cigar smokers smoked them because they believe "they might be less harmful than cigarettes."²⁵ The clear health hazards of premium cigars, and the public's misperception of them as "safer," support continued FDA regulation of all cigars. Exempting cigars would only reinforce this misperception.

98-4302. p. 105–58. Shapiro JA, Jacobs EJ, Thun MJ. Cigar smoking in men and risk of death from tobacco-related cancers. *J Natl Cancer Inst* 2000;92:333-337.

²⁰ Chao A, Thun MJ, Henley SJ, Jacobs EJ, McCullough ML, Calle EE. Cigarette smoking, use of other tobacco products, and stomach cancer mortality in U.S. adults – the Cancer Prevention Study II. *Int J Cancer* 2002;101:380-389.

²¹ Burns DM. Cigar smoking: Overview and current state of the science. In: Burns DM, Cummings KM, Hoffman D, editors. *Cigars: health effects and trends*. Monograph 9. Bethesda (MD): U.S. Department of Health and Human Services, National Institutes of Health; 1998. DHHS Publ No. 98-4302. p. 1–19.

²² Shapiro JA, Jacobs EJ, Thun MJ. Cigar smoking in men and risk of death from tobacco-related cancers. *J Natl Cancer Inst* 2000;92:333-337.

²³ Public Health Deeming Rule Comments, at 56.

²⁴ *Cigar Association of America et al. v. FDA, supra* at 16 (citing FDA reliance on "evidence establishing widespread misperceptions regarding the true health hazards of cigars and demonstrating that cigar smokers mistakenly believe that cigars are less addictive, more natural, and less harmful than cigarettes. . . This is true among both youth and adults.")

²⁵ Corey, et al., at Supplemental Table B.

III. DEFINITIONAL ISSUES (ANPRM Questions A1 and A2)

The ANPRM seeks public comments that would inform the FDA’s determination of the defining characteristics of premium cigars. However, any attempt to define a category of cigars, for the purpose of exempting that category from FDA regulation, is inherently problematic and subject to industry manipulation to exempt the broadest range of hazardous and addictive cigar products, to the detriment of public health. The Deeming Rule administrative record contains evidence of the long history of tobacco industry product manipulation to circumvent regulation and reduce the effectiveness of tobacco control policies.²⁶ For example, it is well known that manufacturers have modified their products to be classified as “cigars” rather than cigarettes to evade the prohibition of characterizing flavors in cigarettes and the use of misleading cigarette descriptors such as “light” and “low” under the Family Smoking Prevention and Tobacco Control Act.²⁷ Indeed, this manipulation has been the subject of recent FDA enforcement actions.²⁸ Manufacturers also added weight to filters to allow for reclassification of their cigarettes or “little cigars” as “large cigars” subject to lower federal excise taxes.²⁹

Attempts to draw clear-cut lines to differentiate between cigar products for the purpose of exempting some products from FDA oversight are vulnerable to evasion, thus amplifying the risk of industry manipulation. For example, in a study looking at the physical properties of large cigars and cigarillos, researchers found that weights of large cigar and cigarillo products varied greatly and weren’t necessarily consistent with the labeled product type³⁰ and some products called cigarillos weighed more than products called large cigars.³¹ In addition, nicotine content was not necessarily associated with the size of the cigar and determining which products might deliver more nicotine than others is not an intuitive process. Thus, although some cigarillo products weighed less than some large cigars, some of those cigarillos had the “greatest amount of free nicotine on a per-mass of tobacco basis.”³² The study indicated that “consumers smoking the same brand of cigar may unintentionally be exposed to varying doses of nicotine and potentially other smoke constituents.”³³ Thus, given the wide variability among cigars and the absence of consistent features defining categories of cigars, recent research reaffirms that efforts

²⁶ Public Health Deeming Rule Comments, at 16.

²⁷ *Id.* Delnevo, CD, et al., “Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation,” *Tobacco Control* 26(3):349-354, 2017.

²⁸ FDA News Release, “FDA takes action against four tobacco manufacturers for illegal sales of flavored cigarettes labeled as little cigars or cigars,” December 9, 2016.

²⁹ Delnevo, CD, et al., “Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation,” *Tobacco Control* 26(3):349-354, 2017. *See also*, Campaign for Tobacco-Free Kids, *Not Your Grandfather’s Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids*, March 13, 2013, at 15.

³⁰ Koszowski, B. et al., “Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States,” *Nicotine & Tobacco Research* 20(3):393-398, 2018.

³¹ *Id.* at 395.

³² *Id.* at 395, 397.

³³ *Id.* at 397.

by FDA to define a category of cigars to be exempt from regulation create real public health risks.

If, contrary to the evidence in the Deeming Rule record and in more recent studies, FDA determines to exempt a category of “premium cigars” from regulation, it must ensure that any differential regulatory treatment of that category will minimize the risk to public health and cannot be exploited by the industry. At a minimum, FDA should adopt all of the criteria set out in its proposed definition of “premium cigar” in setting out Option 2 in the proposed Deeming Rule.³⁴ FDA should reject any arguments to allow the category of “premium cigars” to include: (1) cigars that are not wrapped entirely in whole tobacco leaf, or (2) involve any machines in the production process, or (3) allow the use of homogenized tobacco leaf or reconstituted tobacco, or (4) weigh less than the minimum weight requirement set out in proposed Option 2, or (5) have any characterizing flavor other than tobacco.³⁵ Perhaps of greatest importance, FDA should set a minimum price per cigar of at least \$10 (as suggested by FDA for purposes of setting forth Option 2) and make it clear that this minimum price is after any discounts or coupons and will be indexed for inflation. Of all the criteria for defining “premium cigars,” a high minimum price is perhaps subject to the lowest risk of industry manipulation.

IV. CONCLUSION

By its own terms, and consistent with representations made on behalf of FDA to a federal court, this ANPRM is intended to address only the question whether data and other information that has become available since the final Deeming Rule was issued in May, 2016 is sufficient to justify a reconsideration of FDA’s Deeming Rule decision against exempting any category of cigars, including so-called “premium cigars,” from FDA regulation. The burden of producing such evidence rests with those supporting a “premium cigar” exemption. Far from supporting reconsideration of FDA’s Deeming Rule’s application of regulation to all cigars, the studies published since the final Deeming Rule confirm that FDA’s refusal to exempt any category of cigars is based on sound science.

Respectfully submitted,

³⁴ Proposed Rule Deeming All Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 79 Fed. Reg. 23142, 23150 (April 25, 2014).

³⁵ See generally, Public Health Deeming Rule Comments, at 16-17.

Action on Smoking and Health
American Academy of Family Physicians
American Academy of Pediatrics
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Physicians
American College of Preventive Medicine
American Dental Association
American Heart Association
American Lung Association
American Medical Association
American Medical Student Association
American Psychological Association
American Public Health Association
American School Health Association
American Society of Addiction Medicine
American Society of Clinical Oncology
Americans for Nonsmokers' Rights
Association of State and Territorial Health Officials
Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Community Anti-Drug Coalitions of America
Counter Tools
Eta Sigma Gamma - National Health Education Honorary
International Association for the Study of Lung Cancer
Mesothelioma Applied Research Foundation
National African American Tobacco Prevention Network
National Association of County & City Health Officials
National Association of Pediatric Nurse Practitioners
Oncology Nursing Society
Prevention Institute
Public Health Solutions
Society for Cardiovascular Angiography and Interventions
Society for Public Health Education
Students Against Destructive Decisions
The Society for State Leaders of Health and Physical Education
The Society of Thoracic Surgeons
The University of Texas MD Anderson Cancer Center
Trust for America's Health
Truth Initiative