FDA's proposed rule prohibiting characterizing flavors in cigars will reduce their appeal and will therefore reduce initiation rates, reduce tobacco-related deaths and diseases, and reduce health disparities; however, greater benefits will be realized if FDA prohibits flavors as additives and extends the scope of the rule to waterpipe

Docket No. FDA-2021-N-1309
for "Tobacco Product Standard for Characterizing Flavors in Cigars"

Lauren Kass Lempert, JD, MPH; Stanton A. Glantz, PhD; Gideon St.Helen, PhD; Andre Luiz Oliveira Da Silva, PhD; Valerie B. Yerger, ND[a]; Carol McGruder[a]; Phillip Gardiner, DrPH[a]; Benjamin Chaffee, DDS, MPH, PhD; Jing Cheng, MD, MS, PhD; Jennifer Fung, PhD; Claudia Guerra, MSW; Bonnie Halpern-Felsher, PhD;[b] Kristin Hoeft, PhD, MPH; Michael A. Matthay, MD; Wendy Max, PhD; Devin M. McCauley, PhD;[a] Vira Pravosud, PhD, MPH, MS; Chris Shaffer, MS, AHIP; Hai-Yen Sung, PhD; Maya Vijayaraghavan, MD, MAS; Yingning Wang, PhD; Pamela M. Ling, MD, MPH

UCSF TCORS

[a.] African American Tobacco Control Leadership Council
[b.] UCSF TCORS and Stanford University

August 1, 2022

We support the Food and Drug Administration's proposed rule prohibit characterizing flavors in cigars because it will reduce initiation rates of smoking cigars and will significantly reduce premature deaths and illnesses related to tobacco use. FDA should not delay finalizing the rule.

FDA's proposed rule is based on a substantial body of scientific evidence showing that flavors in cigars and other tobacco products play a key role in increasing the appeal of the products, promoting initiation among non-users, especially youth and young adults, and increasing the likelihood that youth and young adults who experiments with flavored cigars will progress to regular cigar smoking and other tobacco use. By reducing the appeal of cigars and decreasing the likelihood of experimentation, the proposed standard will improve public health by increasing the likelihood of cessation among existing cigar smokers and reducing tobacco-related diseases and death. Moreover, as the preamble to the proposed rule correctly states, certain populations including youth and young adults, racial minorities, those with low-income, and LGBTQ populations use cigars at disproportionately higher rates which contributes to health disparities. By removing flavors from cigars, FDA will take an important step towards reducing the appeal of these products and addressing tobacco-related deaths and health disparities.

1. **As a matter of health equity and social justice, FDA should immediately finalize and implement the proposed standard prohibiting flavors in cigars to reduce smoking-attributable deaths and disease and health disparities among African Americans, non-Hispanic Blacks, American Indians/Alaskan Natives, and other impacted populations**

In a previous public comment supporting FDA's proposed rule that would establish a public health standard prohibiting menthol as a characterizing flavor in cigarettes,[1] we detailed the disproportionate health harms to African Americans attributable to menthol smoking and how these harms are largely the result of decades of predatory marketing strategies targeting this community. These tactics include the tobacco industry's aggressive advertising, promotions, and price discounts promoting and integrating menthol into African American identity and culture,[2, 3] as well as supporting African American organizations and courting Black leaders to gain trust in the African American community.[4] FDA's proposed menthol standard would thus help address this social injustice and increase health equity, particular for the African American population.[5, 6]

The tobacco industry used similar marketing strategies to promote flavored filtered cigars and cigarillos by targeting specific racial and ethnic populations. As *Villanti et al.'s* June 2022 paper explains,[7] these inexpensive, mass-merchandised products are often marketed at retail outlets in neighborhoods with large numbers of African American residents, youth and young adults, and are heavily advertised online and on social media platforms. And like menthol cigarettes, flavored filtered cigar and cigarillo brands have been integrated into African American and urban culture to normalize and promote brand loyalty and product use. *Sterling et al.*[8] found that flavored little cigar and cigarillo users are more likely to be young adults, African American, Hispanic, and daily menthol cigarette users. Moreover, young people who initiate with menthol cigarettes or flavored cigars are more likely to continue smoking later.[9] For these reasons, the availability of flavored cigars as well as menthol cigarettes threatens to exacerbate the disproportionate rates of tobacco-caused morbidity and mortality among African American and other vulnerable populations.[10] Therefore, ***FDA should finalize the rule***

---

[1] Yerger VB, McGruder C, Gardiner P, et al. As a matter of health equity and social justice, FDA should immediately finalize and implement the proposed standard for menthol in cigarettes to reduce smoking-attributable deaths and health disparities among African Americans, Docket No. FDA-2021-N-1349 for "Tobacco Product Standard for Menthol in Cigarettes," June 24, 2022. Available: https://tobacco.ucsf.edu/matter-health-equity-and-social-justice-fda-should-immediately-finalize-and-implement-proposed-standard-menthol-cigarettes-reduce-smoking-attributable-deaths-and-health-disparities-among-african-americans

[2] Gardiner PS. The African Americanization of menthol cigarette use in the United States. Nicotine & Tobacco Research. 2004 Feb 1;6(Suppl_1):S55-65.

[3] Proctor RN, Proctor R. Golden holocaust: origins of the cigarette catastrophe and the case for abolition. Univ of California Press; 2011.

[4] Yerger VB, Malone RE. African American leadership groups: smoking with the enemy. Tobacco Control. 2002 Dec 1;11(4):336-45.

[5] Yerger V. What more evidence is needed? Remove menthol cigarettes from the marketplace—now. Tobacco Control. 2021 Sep 17.

[6] Delnevo CD,Ganz O,Goodwin RD.Banningmentholcigarettes:asocialjusticeissuelongoverdue.NicotineTob Res. 2020;22(10):1673-1675. doi:10.1093/ntr/ntaa152

[7] Villanti AC, Sterling K, Rose SW. US Food and Drug Administration Action on Menthol Cigarettes and Flavored Cigars—A Pivotal Moment for Health Equity. *JAMA Netw Open.* 2022;5(6):e2217150. doi:10.1001/jamanetworkopen.2022.17150

[8] Sterling K,Fryer C,Pagano I,Jones D,Fagan P.Associationbetweenmenthol-flavouredcigarettesmokingand flavoured little cigar and cigarillo use among African-American, Hispanic, and white young and middle-aged adult smokers. *Tob Control*. 2016;25(2)(suppl):ii21-ii31. doi:10.1136/tobaccocontrol-2016-053203

[9] VillantiAC,JohnsonAL,GlasserAM,etal.Associationofflavoredtobaccousewithtobaccoinitiationand subsequent use among US youth and adults, 2013-2015. *JAMA Netw Open*. 2019;2(10):e1913804. doi:10.1001/ jamanetworkopen.2019.13804

[10] Villanti AC, Sterling K, Rose SW. US Food and Drug Administration Action on Menthol Cigarettes and Flavored Cigars—A Pivotal Moment for Health Equity. *JAMA Netw Open.* 2022;5(6):e2217150. doi:10.1001/jamanetworkopen.2022.17150

prohibiting flavors in cigars to reduce health disparities and health inequities and promote social justice.

2. FDA should prohibit all flavor additives, compounds, constituents, and ingredients in cigars, and should not limit the proposed standard to prohibiting "characterizing flavors"

FDA's proposed standard would prohibit "characterizing flavors" in cigars, as well as in components or parts, including flavors that are separate from the cigar and intended to be added to cigars. FDA requested comments specifically addressing potential alternatives to prohibiting characterizing flavors (e.g., prohibiting all flavor additives, compounds, constituents, or ingredients).[11] ***FDA should prohibit all flavor additives, compounds, constituents, and ingredients in cigars, and not just characterizing flavors.***

Brian King, the new director of the Center for Tobacco Products, recognized that "policies based on characterizing flavor might not cover constituents added by the manufacturer that provide a cooling sensory experience (e.g., similar to menthol) that can increase appeal, but are not the characterizing flavor."[12] Indeed, many tobacco companies are now adding menthol analogs and constituents that provide a cooling sensation similar to menthol in addition to menthol, and studies have shown that they increase the appeal of the tobacco products, especially among young people.[13, 14, 15] Menthol is the dominant flavor chemical in both mint- and menthol-flavored e-cigarettes, so youth interchange mint and menthol products to achieve a "minty" flavor.[16]

Menthol is an important ingredient in many "non-menthol" cigars, even those that are not marketed with menthol as a characterizing flavor, and is added to increase addictiveness. Under the rule as proposed, tobacco companies could evade the intent of the rule and continue to add menthol to cigars as an ingredient, additive, or constituent to maximize their addictiveness if they simply stopped calling them "menthol cigars." Even low concentrations present in products that are not characterized as "menthol" are able to activate the cold receptor TRPM8.[17]

---

[11] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26437.

[12] King, BA. Flavors remain a major driver of youth e-cigarette use. Am J Public Health. Published online ahead of print May 26, 2022:e1-e2. DOI: https://doi.org/10.2105/AJPH.2022.306895.

[13] Davis DR, Morean ME, Bold KW, et al. Cooling e-cigarette flavors and the association with e-cigarette use among a sample of high school students. *PLoS One.* 2021;16(9):e0256844. https://doi.org/10.1371/journal.pone.0256844.

[14] Tackett AP, Barrington-Trimis JL, Leventhal AM. 'Flavour ban approved': new marketing strategies from tobacco-free nicotine pouch maker Zyn. *Tob Control* 2022;0:1–2. Epub ahead of print: 22 April 2022. doi:10.1136/ tobaccocontrol-2021-057222

[15] Leventhal AM, Tackett AP, Whitted L, et al. Ice flavours and non-menthol synthetic cooling agents in e-cigarette products: a review. *Tob Control* 2022;0:1–9. doi:10.1136/tobaccocontrol-2021-057073 Epub ahead of print: 28 April 2022. doi:10.1136/ tobaccocontrol-2021-057073.

[16] Omaiye, E. E., Luo, W., McWhirter, K. J., Pankow, J. F., & Talbot, P. (2021). Flavour chemicals, synthetic coolants and pulegone in popular mint-flavoured and menthol-flavoured e-cigarettes. *Tob Control.* Published Online First: 30 June 2021. doi: 10.1136/tobaccocontrol-2021-056582.

[17] Paschke M, Tkachenko A, Ackermann K, Hutzler C, Henkler F, Luch A. Activation of the cold-receptor TRPM8 by low levels of menthol in tobacco products. Toxicol Lett. 2017 Apr 5;271:50–7.

Manufacturers can evade flavor restrictions[18, 19] without removing mint/menthol and fruit ingredients just by using "concept flavor" names (e.g., "Lush Ice," "O.M.G" [Orange, mango and guava]) and associated packaging which contributes to the appeal of tobacco products.[20] The tobacco industry has a long and shameful history of deceiving the public about the addictiveness and other harmful health effects of smoking and evading FDA regulations, resulting in the landmark 2006 federal court judgment which found the major US tobacco companies had violated the Racketeer Influenced and Corrupt Organizations Act (RICO). Judge Kessler described in detail how the tobacco companies "have marketed and sold their lethal products with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted," and that they continue to engage in misconduct that "misleads consumers in order to maximize Defendants' revenues by recruiting new smokers (the majority of whom are under the age of 18), preventing current smokers from quitting, and thereby sustaining the industry."[21]

We urge FDA to ensure that the tobacco industry does not continue to deceive the public and evade the flavor prohibition in cigars by strengthening the rule to not only prohibit "characterizing flavors," but by prohibiting all flavor additives, compounds, constituents, and ingredients.

3. FDA's provision in the proposed rule that includes components, parts, and other flavorings that can be added to non-flavored cigars is essential for an effective rule and is necessary to decrease opportunities for evasion

FDA states that the proposed rule in 21 CFR section 1166.3 would establish a tobacco product standard that would not only prohibit the use of characterizing flavors in cigars, but would also extend to cover flavors that are separate from the cigar (e.g., liquid flavors), including menthol, intended or reasonable expected to be added to cigars.[22] We strongly support this essential provision.

This provision is justified by experience in the European Union,[23] the United Kingdom,[24] and Canada[25] where tobacco companies have made design changes and developed aftermarket products that allow smokers to add flavors to tobacco products. These aftermarket products allow companies to evade menthol and other flavor prohibitions and thereby limit the effectiveness of these rules by maintaining existing and attracting new menthol- and flavored- tobacco product customers. Especially

---

[18] Gaiha, Shivani Mathur, et al. "E-cigarette devices, brands, and flavors attract youth: Informing FDA's policies and priorities to close critical gaps." *Addictive Behaviors* 126 (2022): 107179.

[19] N. Hemmerich, K.M. Ribisl, S.M. Noar. A list of permissible electronic nicotine delivery systems ingredients would be more effective. *American Journal of Public Health,* 110 (6) (2020), pp. 774-775, 10.2105/AJPH.2020.305677.

[20] Erinoso O, Smith KC, Iacobelli M, Saraf S, Welding K, Cohen JE. Global review of tobacco product flavour policies. *Tob Control* 2021 Jul 1;30(4):373-9.

[21] US v Philip Morris USA Inc, 9 F. Supp. 2d 1, (D.D.C. 2006).

[22] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26437.

[23] Brink AL, Glahn AS, Kjaer NT. Tobacco companies' exploitation of loopholes in the EU ban on menthol cigarettes: a case study from Denmark. Tobacco Control. 2022 Mar 20; Available from: https://tobaccocontrol.bmj.com/content/early/2022/03/20/tobaccocontrol-2021-057213
Hiscock R, Silver K, Zatoński M, Gilmore AB. Tobacco industry tactics to circumvent and undermine the menthol cigarette ban in the UK. Tobacco Control. 2020 Dec 1;29(e1):e138–42.

[24] Hiscock, R., K. Silver, Mateusz Zatoń ski, et al. ''Tobacco Industry Tactics to Circumvent and Undermine the Menthol Cigarette Ban in the UK.'' Tobacco Control, 29:e138–e142, 2020. Available at http://dx.doi.org/10.1136/ tobaccocontrol-2020-055769.

[25] Chaiton, M.O., R. Schwartz, J.E. Cohen, et al. ''The Use of Flavour Cards and Other Additives After a Menthol Ban in Canada.'' Tobacco Control, 30:601–602, 2020. Available at *https://doi.org/ 10.1136/tobaccocontrol-2020-055698*

concerning, we know that youth use add-on e-cigarette flavor enhancers to evade flavor restrictions in e-cigarettes,[26, 27, 28] and they may migrate to similar flavor options if they were available in cigars. ***The FDA's rule as proposed would prohibit such work-arounds.***

4. FDA should model the proposed rule on Brazil's law that prohibits tobacco products that contain additives including menthol

The *Agência Nacional de Vigilância Sanitária* (ANVISA, Brazilian Health Regulatory Agency) adopted a resolution[29] (regulation) in March 2012 that applies to all tobacco products sold in Brazil, including cigars, whether made in Brazil or imported, that prohibits the importation or sale in Brazil of tobacco products that contain additives, including:

I. synthetic and natural substances in any form (pure substances, extracts, oils, distillates, balms, among others), with flavoring properties that can impart, intensify, modify or enhance the flavor of the product, including additives identified as flavoring agents…
II. processing aids for flavorings;
...
IX. ameliorants [defined as "a substance that reduces irritating aspects of the smoke of tobacco products]

"Additives" is defined in the resolution to include "any substance or compound that is not tobacco or water, used in the processing of tobacco leaf and reconstituted tobacco, in the manufacture and packaging of a tobacco product, including sugars, sweeteners, flavoring agents and (ameliorants)."

"Flavoring agents" is defined as "a natural or synthetic substance or mixture of substances that imparts, modifies, enhances or intensifies the flavor of tobacco products."

"Ameliorants" is defined as "a substance that reduces irritating aspects of the smoke of tobacco products."

"Tobacco product" is defined as "any product that is manufactured or derived from tobacco, containing in its composition tobacco leaf, even if it is only partially composed of tobacco."

Eight categories of additives (sugars, exclusively for the restitution of the sugar originally present in tobacco leaf prior to the curing process; adhesives; binders; combustion agents; processing aids that are not for flavorings; pigments or coloring agents used to whiten the paper or the filter and for other express purposes; glycerol and propylene glycol; and potassium sorbate) are exempted from

[26] Gaiha SM, Lempert LK, McKelvey K, Halpern-Felsher B. E-cigarette devices, brands, and flavors attract youth: Informing FDA's policies and priorities to close critical gaps. Addictive behaviors. 2022;126:107179.
[27] Cwalina SN, Leventhal AM, Barrington-Trimis JL. E-cigarette flavour enhancers: Flavoured pod attachments compatible with JUUL and other pod-based devices. Tob Control. 2020.
[28] Hemmerich N. Flavoured pod attachments score big as FDA fails to enforce premarket review. Tob Control. 2020.
[29] Agencia Nacional de Vigilancia Sanitaria, Collegiate Directorate. Resolution – RDC No. 14, of March 15, 2012. Available: https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0014_15_03_2012.pdf

the rule. However, because menthol is both a flavoring agent and an ameliorant, it squarely conforms with the rule's definition of a prohibited additive and is not permitted in tobacco products in Brazil.

FDA should adopt language similar to that in Brazil's rule and prohibit all flavors, including menthol, as additives in all cigars.

5. The proposed product standard prohibiting flavors in cigars should also cover waterpipe in addition to cigars

FDA's proposed rule would prohibit characterizing flavors in cigars, but would not extend to waterpipe, pipe tobacco, and other tobacco products. FDA requested comments regarding whether the standard should also cover waterpipe and/or pipe tobacco. FDA said it was focusing the rule on characterizing flavors in cigars because "this action would help to prevent youth and young adults' use of combusted tobacco products."[30] Because waterpipe is popular with youth and young adults but is not a safer alternative to cigarettes or cigars, extending the rule to cover waterpipe would also help to protect the public health. We urge FDA to extend the product standard to include waterpipe.

Waterpipes are not safer alternatives to combustible cigarettes. Several studies have measured tobacco-related toxicants in waterpipe smoke, including polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs) such as formaldehyde, acetone, and acrolein, and carcinogenic tobacco-specific nitrosamines (TSNAs).[31] Waterpipe smoking machine studies indicated that the amount of waterpipe tobacco used in a single smoking session produced 100-fold more tar, 4-fold more nicotine, 11-fold more CO, and 2- to 5-fold more polycyclic aromatic hydrocarbons than did a single cigarette.[32]

Tobacco used in waterpipe is often a sweetened flavored tobacco mixture and contains nicotine at various concentrations on the label, such as 0.05% or 0.5% nicotine. Waterpipe tobacco in the US is usually composed of a moist fruit preparation containing varying amounts of tobacco, which explains the varying nicotine concentrations. The nicotine level advertised on the label does not predict nicotine exposure even when users' smoking topography is standardized.[33] This is because the nicotine on the labels may not be accurate. Also, manufacturers can easily increase the amount of tobacco in the fruit preparation.

The health risks associated with waterpipe use are determined to a great extent by the use patterns and intensity of use. Although the prevalence and/or frequency of waterpipe use in the U.S. may be lower than that of combustible cigarettes, a single waterpipe session typically lasts for 45 minutes and may produce 50 to 100 times the smoke volume inhaled from a single cigarette.[34] An

---

[30] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26435.
[31] Schubert J, Heinke V, Bewersdorff J, Luch A, Schulz TG. Waterpipe smoking: the role of humectants in the release of toxic carbonyls. Arch Toxicol. 2012;86(8):1309-16.
[32] Shihadeh A, Saleh R. Polycyclic aromatic hydrocarbons, carbon monoxide, "tar", and nicotine in the mainstream smoke aerosol of the narghile water pipe. Food Chem Toxicol 2005;43:655–61.
[33] Vansickel AR, Shihadeh A, Eissenberg T. Waterpipe tobacco products: nicotine labelling versus nicotine delivery. Tob Control 2011:tc. 2010.042416.
[34] Haddad L, El-Shahawy O, Ghadban R, et al. Waterpipe Smoking and Regulation in the United States: A Comprehensive Review of the Literature. Int J Environ Res Public Health 2015;12(6):6115-6135. doi:10.3390/ijerph120606115.

hour-long session of smoking waterpipes gives users a dose of nicotine similar to smoking two to three cigarettes, and delivers qualitatively the same toxicants, albeit at different concentrations, to the body.[35, 36, 37]

To date, UCSF has conducted three comprehensive studies of systemic intake of tobacco-related toxicants from waterpipe use. In the first study, involving a single use of waterpipe in a hospital research ward, we measured plasma nicotine levels that were comparable to levels attained after smoking cigarettes; carbon monoxide levels were much higher than in cigarette smokers; and we measured significant increases in urine NNAL, a breakdown product of NNK (a nicotine-derived nitrosamine and known pulmonary carcinogen), as well as breakdown products of PAHs.[38]

We then conducted a crossover study to compare nicotine intake and carcinogen exposure from waterpipe and cigarette smoking. This study was also conducted in a hospital research ward. Compared to cigarette smoking, we reported lower nicotine intake, greater carbon monoxide exposure, and a different pattern of carcinogen exposure, with greater exposure to benzene and high molecular weight PAHs, and less exposure to tobacco-specific nitrosamines, 1,3-butadiene and acrolein, acrylonitrile, propylene oxide, ethylene oxide, and low molecular weight PAHs following waterpipe smoking.[39] This study showed that exposure to tobacco smoke toxicants in waterpipe smoke is similar qualitatively but quantitatively delivers higher levels of several toxicants than cigarette smoke. Importantly, exposure to benzene, a chemical known to cause leukemia in humans, and high molecular weight PAHs, which are known to be more potent carcinogens than the lighter weight PAHs, were higher while smoking waterpipe than tobacco cigarettes.

The third study entailed assessing nicotine intake and exposure to tobacco-specific nitrosamines and volatile organic compounds from waterpipe smoking in a natural setting (i.e., hookah bars or lounges) as opposed to a hospital research ward. In the natural setting, waterpipe users shared waterpipes with multiple users. Again, this study showed substantial nicotine intake comparable to at least one cigarette as well as significant exposure to NNK (measured using urine NNAL) and breakdown products of carcinogenic VOCs such as benzene, 1,3-butadiene, acrylonitrile, and ethylene oxide.[40]

---

[35] Jacob P 3rd, Abu Raddaha AH, Dempsey D, Havel C, Peng M, Yu L, Benowitz NL. Nicotine, carbon monoxide, and carcinogen exposure after a single use of a water pipe. Cancer Epidemiol Biomarkers Prev. 2011 Nov;20(11):2345-53. doi: 10.1158/1055-9965.EPI-11-0545. Epub 2011 Sep 9.

[36] Jacob P 3rd, Abu Raddaha AH, Dempsey D, Havel C, Peng M, Yu L, Benowitz NL. Comparison of nicotine and carcinogen exposure with water pipe and cigarette smoking. Cancer Epidemiol Biomarkers Prev. 2013 May;22(5):765-72. doi: 10.1158/1055-9965.EPI-12-1422. Epub 2013 Mar 5.

[37] Everts S. What's Hookah, And Is It Healthier Than Smoking A Cigarette? Chemical & Engineering News, Vol. 93, Issue 25, p. 41, June 22, 2015.

[38] Jacob P, Raddaha AHA, Dempsey D, Havel C, Peng M, Yu L, et al. Nicotine, carbon monoxide, and carcinogen exposure after a single use of a water pipe. Cancer Epidemiology Biomarkers & Prevention. 2011;20(11):2345-53.

[39] Jacob P, Raddaha AHA, Dempsey D, Havel C, Peng M, Yu L, et al. Comparison of Nicotine and Carcinogen Exposure with Water pipe and Cigarette Smoking. Cancer Epidemiology Biomarkers & Prevention. 2013;22(5):765-72.

[40] St.Helen G, Benowitz NL, Dains KM, Havel C, Peng M, Jacob P, 3rd. Nicotine and carcinogen exposure after water pipe smoking in hookah bars. Cancer Epidemiol Biomarkers Prev. 2014;23(6):1055-66.

Carbon monoxide (CO) is a toxicant that is a risk for all users,[9] with some studies showing extremely high CO levels for users.[41] Case reports have even indicated CO poisoning among young adult waterpipe users.[42, 43, 44]

A study published in March 2016 assessing the effects of waterpipe smoking on the human lung in young, light-use waterpipe smokers found that young, light-use waterpipe-only smokers have a variety of abnormalities in multiple lung-related biologic and clinical parameters including more cough and sputum, lower lung diffusing capacity, abnormal epithelial lining fluid metabolome profile, increased proportions of small airway epithelial (SAE) secretory and intermediate cells, reduced proportions of SAE ciliated and basal cells, markedly abnormal SAE and alveolar macrophage transcriptomes, and elevated levels of apoptotic endothelial cell microparticles.[45] These results suggest that even limited waterpipe use has broad consequences on human lung biology and health.

The charcoal used to heat the tobacco-fruit preparation is a significant source of toxicants in the waterpipe smoke that users inhale. Charcoal is produced by incomplete combustion of wood. As in incomplete combustion of other organic materials, polycyclic aromatic hydrocarbons (PAHs) are produced. It is well known that burning charcoal produces large amounts of CO. Burning charcoal produces benzene,[46] a carcinogen associated with increased incidence of leukemia. Charcoal emissions were the primary source of CO and carcinogenic PAHs; 90% of CO and 75-92% of 4- and 5-ring PAHs (the heavy molecular PAHs) originated from the charcoal.[47]

Waterpipe smoking presents health risks that in some ways are higher than cigarette smoking. One session of waterpipe use can lead to inhalation of 40 to 80 liters of smoke versus approximately 1 liter of smoke from a cigarette.[48] Many of the toxicants found in cigarette smoke are found in waterpipe smoke, which includes polycyclic aromatic hydrocarbons, volatile aldehydes, carbon monoxide, and heavy metals. Given the higher volume of smoke inhalation, a waterpipe user can be exposed to greater levels of these toxicants than from smoking a cigarette.[49]

Waterpipe smoking has increased over the past decade in the United States, most notably among adolescents and young adults.[50] A February 2022 analysis of Population Assessment of

---

[41] Barnett TE, Curbow BA, Weitz JR, et al. (2009) Water pipe tobacco smoking among middle and high school students. AJPH, 99, 2014-2019. doi:10.2105/AJPH.2008.151225.
[42] Ashurst JV, Urquhart M., Cook MD (2012). Carbon monoxide poisoning secondary to hookah smoking. Journal American Osteopathic Association, 112,686–688.
[43] Cavus UY, Rehber ZH, Ozeke O (2010). Carbon monoxide poisoning associated with Narghile use. Emergency Medicine Journal, 27, 406. doi:10.1136/emj.2009.077214
[44] Lim BL, Lim GH, Seow E (2010). Case of carbon monoxide poisoning after smoking shisha. International Journal of Emergency Medicine, 11, 121–122. doi:10.1007/s12245-009-0097-8
[45] Strulovici-Barel Y, Shaykhiev R, Salit J, et al. Pulmonary Abnormalities in Young, Light-use Waterpipe (Hookah) Smokers. AJRCCM Articles in Press. Published on 23-March-2016 as 10.1164/rccm.201512-2470OC.
[46] Olsson M; Petersson G. Benzene emitted from glowing charcoal. Science of the Total Environment 2003;, 303: 215-220.
[47] Monzer B, Sepetdjian E, Saliba N, Shihadeh A. Charcoal emissions as a source of CO and carcinogenic PAH in mainstream narghile waterpipe smoke. Food Chem Toxicol. 2008;46(9):2991-5.
[48] Pepper JK, Eissenberg T. Waterpipes and electronic cigarettes: increasing prevalence and expanding science. Chem Res Toxicol. 2014 Aug 18;27(8):1336-43.
[49] Shihadeh AL, Eissenberg TE. Significance of smoking machine toxicant yields to blood-level exposure in water pipe tobacco smokers. Cancer Epidemiol Biomarkers Prev. 2011 Nov;20(11):2457-60; Pepper JK, Eissenberg T. Waterpipes and electronic cigarettes: increasing prevalence and expanding science. Chem Res Toxicol. 2014 Aug 18;27(8):1336-43.
[50] Soule EK, Lipato T, Eissenberg T. Waterpipe tobacco smoking: A new smoking epidemic among the young? Curr Pulmonol Rep. 2015 Dec 1;4(4):163-172.

Tobacco and Health (PATH) data found a high prevalence of waterpipe tobacco initiation and progression among adolescents and young adults over time, with minority racial/ethnic groups (e.g., Hispanic, non-Hispanic Black) at greater risk for both initiation and progression.[51] Young adults who engage in waterpipe smoking are most often dual- or poly-users with other tobacco or nicotine products. Among young-adult waterpipe smokers in a 2017 FDA/NIH PATH study, only 29% were exclusive users of waterpipe.[52] The high prevalence of dual-use suggests that waterpipe smoking would be viewed as an acceptable alternative to cigars for at least some cigar smokers.

Finally, presenting waterpipe as a "safer" alternative to conventional cigarettes or to cigars could increase youth use, something harmful in its own right, and that may have additional consequences because waterpipe use is predictive of future conventional cigarette use. Waterpipe use among never cigarette smoking youth is associated with about a doubling (OR, 1.92; 95% CI, 1.17-3.17) of the odds of subsequent cigarette initiation in PATH.[53] To the extent that smokers switch to waterpipe, they could increase their levels of toxicant exposure.

For these reasons, the proposed product standard prohibiting flavors in cigars should also cover waterpipe in addition to cigars.

Conclusion

We urge FDA to finalize the proposed rule prohibiting flavors in cigars for the following reasons:

(1) By prohibiting flavors in cigars, FDA will help to make cigars less appealing which will reduce initiation rates of smoking cigars, thereby significantly reducing premature deaths and illnesses related to tobacco use.
(2) The proposed standard would reduce health disparities and inequities and promote social justice.
(3) In addition to prohibiting "characterizing flavors" in cigars, FDA should prohibit all flavor additives, compounds, constituents, and ingredients in cigars to ensure that the tobacco industry does not deceive the public and evade the flavor prohibition.
(4) FDA should extend the proposed product standard prohibiting flavors in cigars to also cover waterpipe in addition to cigars to minimize migration from flavored cigars to flavored waterpipe, which is not a safe alternative.

[51] Gautam, Prem et al. "Prevalence and Predictors of Waterpipe Smoking Initiation and Progression Among Adolescents and Young Adults in Waves 1-4 (2013-18) of the Population Assessment of Tobacco and Health (PATH) Study." Nicotine & tobacco research (2022).
[52] Salloum RG, Thrasher JF, Getz KR, Barnett TE, Asfar T, Maziak W. Patterns of Waterpipe Tobacco Smoking Among U.S. Young Adults, 2013-2014. Am J Prev Med. 2017 Apr;52(4):507-512.

[53] Watkins SL, Glantz SA, Chaffee BW. Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015. JAMA Pediatr. 2018 Feb 1;172(2):181-187. doi: 10.1001/jamapediatrics.2017.4173.