PUBLIC HEALTH
LAW CENTER
at Mitchell Hamline School of Law

August 2, 2022

Commissioner Robert M. Califf M.D.
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Tobacco Product Standard for Characterizing Flavors in Cigars

Docket No. FDA-2021-N-1309

Dear Commissioner Califf:

The Public Health Law Center is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the need for a product standard prohibiting characterizing flavors in cigars. The Public Health Law Center (the Center) is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For over twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity.

The Center, with many partner organizations, filed a citizen petition in 2013 requesting that the FDA begin regulating cigars and other then unregulated products and that the agency take additional regulatory steps, one of which was a request to prohibit flavors.[1] The FDA partially granted that petition in 2014 when it first proposed its rule deeming all tobacco products to be subject to its jurisdiction. At that time, the FDA attempted to prohibit flavors in cigars through the enforcement of premarket review, but this provision was removed while the rule was reviewed by the Office of Information and Regulatory Affairs. While we are disappointed that it has taken almost ten years for the agency to begin a rulemaking process to implement a product standard to address flavors in cigars, we

[1] TOBACCO CONTROL LEGAL CONSORTIUM, *Citizen Petition*, Docket FDA-2013-P-1127 (Sept. 3, 2013), https://www.regulations.gov/document/FDA-2013-P-1127-0001.

P: 651.290.7506 F: 651.290.7515
W: www.PublicHealthLawCenter.org
875 Summit Avenue, St. Paul,
Minnesota 55105

congratulate the FDA for taking this step and we fully supports a product standard that will protect public health.

This action by the agency is the only the first step in a multi-step process that is likely to end with the government defending such action against multiple lawsuits. This comment will offer some additional sources of scientific information, not referenced by the FDA, as well as some potential changes to the language and structure of the FDA's proposed rule. We also offer some suggestions for actions that the FDA can take outside of this rulemaking that will further improve the public health benefits of the product standard. Perhaps, most importantly, this comment begins with a discussion of one of the most important aspects of this rule: the amount of time that it takes to move from this proposal to the day when flavored cigars are no longer sitting on store shelves all over the country.

I. The decision to establish a product standard is based solely on whether the standard will protect public health and to provide the most protection.

In proposing a product standard, the FDA has initiated a process with only two possible outcomes: a final rule implementing the proposed standard or a notice of a termination of the development of the standard. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act, the Act, or TCA) requires the FDA to either finalize a rule or explain why it is not doing so after it has read and considered the public comments.[2] Unfortunately, the statute does not establish a timeframe for this step, so this is left to the agency's discretion. What is clear is that after considering the comments, the FDA is required to decide to finalize the rule or not.

It is also clear from the statute that if the FDA determines that the proposed standard would protect public health, the standard must be finalized. The FDA is obligated to accept comments that discuss the technical achievability of the proposed standard and consider any countervailing effects of the standard. At the same time, the decision to finalize the standard is ultimately based on whether the product standard will advance public health. If the proposed standard will protect the public health, then the standard must be finalized.[3]

A comprehensive reading of the statute shows that the FDA can propose a standard after the agency has considered the public health impacts. 21 U.S.C. § 387g(a)(3)(B)(i). The proposal is published in the Federal Register (21 U.S.C. §

[2] 21 U.S.C. § 387g(d)(1).
[3] *Id.* ("[T]he Secretary shall . . . if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard . . . .").

387g(c)) and the agency accepts comments. 21 U.S.C. § 387g(d)(1) describes the next step in the process, which requires the FDA to decide either to finalize or terminate the proposal. The agency must consider comments submitted under 21 U.S.C. § 387g(b), which relates to technical achievability and countervailing effects, as well as 21 U.S.C. § 387g(c), which relates to the protection of public health, the potential to advantage foreign-grown tobacco over domestically grown tobacco, and any information the Secretary of Agriculture deems relevant to the standard. However, it is absolutely critical that, if the FDA determines that the standard "would be appropriate for the protection of public health," [4] the agency must finalize the standard.[5] The FDA is required to analyze issues that are not directly health-related, such as technical achievability and countervailing effects, but because the decision on whether to finalize the standard is based on the appropriateness of the protection of public health, the FDA's focus must be on the health effects of the issues that are not directly health-related.

As a health-focused agency and an expert on the health consequences of the products it regulates, the FDA – when proposing a product standard, the FDA must focus its own analysis on the three prongs of the public health standard. When it accepts comments on its proposal, it must solicit information on the abovementioned issues that are not directly related to health, but as it considers those comments, it is only the *health* consequences of those issues that the FDA must examine. For example, if a commenter raises an issue about the technical feasibility of a proposed standard and concludes that because of technical limitations, achieving the standard will be difficult and costly to the regulated industry, then in analyzing that comment, if the information is accurate, the FDA cannot adjust the standard to accommodate the difficulty if that means that the standard is less protective of health. The FDA can only make changes to the proposed standard if those changes make the proposed standard more health protective, not less. Furthermore, if the weight of the evidence relevant to the public health standard establishes that the rule will protect public health, even if costly or challenging, the FDA is *required* to finalize the rule.

II. Delay in the implementation of a final rule can be measured in additional lives lost and so the FDA must finalize this rule quickly with a short implementation period.

The evidence base demonstrating the need for the rule is clear and the FDA has reviewed the evidence thoroughly over a period of years. As with most actions that the agency can take to regulate tobacco products, the public health benefits are well-

[4] 21 U.S.C. § 387g(d)(1)(A).
[5] *Id.* ("the Secretary shall").

documented. If action saves lives, inaction costs lives, and so it is absolutely incumbent on the FDA to act as quickly as possible to finalize life-saving rules.

The purpose of the public comment period is to allow the agency to gather information it may not possess and to hear perspectives on the regulatory issue that it may not have heard. Because of the amount of time that has been devoted to this issue and the number of opportunities for formal and informal engagement with the FDA, it is incredibly unlikely that any comment that the agency receives will provide any new information or perspective that the FDA has not already analyzed thoroughly. The volume of information that is already known makes it all but impossible that any new information would so significantly change the FDA's analysis as to require a delay for additional analysis.

The agency has already analyzed the potential impacts of the standard and has addressed all relevant substantive issues in its proposal. It should be very simple for the agency to draft a final rule even if it chooses to modify the proposed standard. The analysis under the Public Health Standard should not change significantly from the proposal which means that the analysis in the final rule should look essentially the same. Addressing issues raised in comments that are already substantively addressed in the proposal should also take little time for the FDA to draft. The final version of this product standard should be written and published shortly after the close of the comment period.

Similarly, there is no reason the FDA cannot establish a short implementation period for the final rule. The only two relevant issues that could impact the timeline for implementation are the statutory requirements and the logistics of implementing and enforcing a rule.

The TCA has specific and clear standards for the process of implementing a product standard. The statute sets a default implementation date of not more than one year "unless the Secretary determines that an earlier date is necessary for the protection of the public health."[6] It is clear from this provision that when establishing a product standard, Congress intended to provide the FDA discretion to shorten the period of time for implementation when it would create a public health benefit. The TCA envisions some standards where the need would not be so great as to warrant an implementation period of less than one year.[7] However, when there is a need and no need could be greater than saving lives - Congress gave the FDA the ability to act more quickly. There could be no better time for the FDA to seize that opportunity.

---

[6] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 907(d)(2), 123 Stat. 1776, 1802 (2009).

[7] *See id.* § 907(a)(4)(B)(ii) ("provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product").

In fact, Congress gave the FDA a very clear model to work from. The TCA established the very first tobacco product standard by prohibiting all flavors in cigarettes except tobacco and menthol. This standard was implemented just three months after the TCA became law, at a time when the FDA's Center for Tobacco Products had few staff and the Center was working on meeting numerous other congressional deadlines. Given the Center's size in 2022, the robust enforcement infrastructure, and the agency's years of experience enforcing a prohibition on flavors in cigarettes, there is no reason the FDA could not establish a similar three-month, or shorter, implementation period for this standard. Because Congress did not establish a one-year implementation period for the existing product standard for flavors in cigarettes, it seems likely that this is exactly the type of standard that was intended to have a shorter implementation period.

It is also worth noting that tobacco product manufacturers have been on notice for several years that such a standard was a possibility. Any loss of revenue due to inflexible manufacturing and distribution mechanisms is a result of failing to adapt to a changing regulatory environment which is not a concern for the FDA. Because this standard would prohibit the addition of something to a product that is not inherent to the product, it is hard to imagine that the standard would be difficult to implement at the manufacturing level. There should be no reason that manufacturers could not simply stop adding flavor constituents on the day that a final rule is published or shortly thereafter and the inventory of non-compliant products would run out quickly. This is a standard easy for manufacturers to implement and will save a tremendous number of lives. It is difficult to imagine a situation more suited to the FDA using its discretion to shorten the implementation period for a product standard.

III. While the FDA has failed to act, research on the effects of flavors in cigars on public health has continued to accumulate.

This proposed rule provides an extensive review of the harms of flavored cigars and the reasons for banning them. The following information serves to support FDA's decision to ban flavored cigars for health equity purposes and provides further evidence of the importance of that action.

The Center applauds the FDA for its recognition of health equity as an integral part of the consideration of what is best for the population as a whole. The Center completely agrees that "advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which result from denied opportunity and access to economic, political, and social participation."[8] Banning

[8] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396, 26,401 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).

flavored cigars is a necessary step for the advancement of health equity. Therefore, this comment centers around the importance of health equity.

A. The presence of flavors facilitates initiation.

Flavored tobacco products, including if not especially menthol, are important to attracting new consumers and maintaining current tobacco product users. As noted in our 2021 Supplement to our 2013 citizen petition requesting action on menthol in cigarettes and recognized in the proposed rule, the tobacco industry has known that flavored tobacco products, including cigars and little cigars, are "good starter products" for new consumers, and especially youth. FDA states in the proposed rule that flavors enhance the addictiveness of tobacco products like cigars, making initiation as well as continued use more likely.[9] FDA is correct to raise these concerns in its proposed rule, and to further establish its objective to curtail regular use of cigars and little cigars by reducing the appeal that drives initiation.

FDA correctly notes that flavored cigars became more popular following the passage of the TCA and the subsequent prohibition on the sale of most characterizing flavors in cigarettes.[10] This is true for youth and adults alike, and as FDA reiterates, data from the National Youth Tobacco Survey (NYTS) in 2020 estimates approximately 960,000 middle and high school students smoke cigars.[11] Flavors are a leading, if not the sole, reason for youth use of any tobacco product, including cigars. The most important potential outcome of prohibiting the sale of flavors in cigars is the precipitous decline in youth cigar consumption.

We encourage the finalization of this rule in tandem with the proposed rule prohibiting the sale of menthol-flavored cigarettes, as these two rules complement each other's objectives. Research demonstrates that cigar consumption is associated with cigarette consumption, meaning that persons who smoke cigars are more likely to also smoke cigarettes.[12] Given the role that flavors play in encouraging and sustaining tobacco product use, the importance of removing all flavors from all tobacco products - and namely cigarettes and cigars, as the two proposed rules would do - cannot be understated. For persons who are inclined to initiate tobacco use with flavors, especially youth, closing off the substitution appeal for flavored cigars is an important support to the health equity objectives of the prohibition on sales for menthol-flavored cigarettes.

---

[9] *Id.* at 26,405.
[10] *Id.* at 26,403.
[11] *Id.* at 26,414.
[12] Erin L. Mead et al., *An Ecological Momentary Assessment of Cigarette and Cigar Dual Use Among African American Young Adults*, 20 NICOTINE & TOBACCO RSCH. (SUPP. 1) S12 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6093372/.

1. Youth are particularly susceptible to initiation of tobacco products via flavored cigars.

The evidence is clear and reaffirms the fact that flavored cigars are a vehicle of tobacco product use initiation among youth and that flavors play an outsized role in youth and young adult tobacco use.[13] The proposed rule highlights the disparity of high flavored cigar use among youth and young adults, discussing rates of flavored cigar usage among youth and the heightened appeal of flavored products.[14] FDA notes in the proposed rule that "an analysis of harmonized data from five large national surveys found a consistent peak in cigar initiation among individuals aged 17-19 years. The consistency of this age of initiation across all five studies increases the confidence in this finding and suggests cigar initiation extends into young adulthood."[15] A 2020 study on PATH data reached a similar conclusion—that initiation for cigar use is more likely to occur prior to age 17, for young men generally and young Black men particularly.[16] Additionally, the proposed rule references the "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019" Morbidity and Mortality Weekly Report article.[17] One finding of that study, while not directly cited in the proposed rule, is that 69.6% of middle and high school students who currently used tobacco products reported using at least one flavored tobacco product.[18] We add to the record the updated numbers from the 2021 version of this study. In only two years, that same percentage increased to 79.1%.[19] The enormous impact of flavored tobacco on youth clearly suggests that a flavored cigar ban would decrease harm to youth.

---

[13] PUB. HEALTH L. CTR., *Supplement to Citizen Petition: Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke* (Jan. 15, 2021), https://www.publichealthlawcenter.org/sites/default/files/resources/Supplement-to-Menthol-Citizen-Petition.pdf (citing Brown & Williamson Tobacco Corp., *Kool Isn't Getting the Starters*, TRUTH TOBACCO INDUS. DOCUMENTS 621079918-621079921 (Feb. 17, 1987), https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=mnbd0132).

[14] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26,403.

[15] *Id.* at 26,400 (citing Howard Fishbein et al., *Harmonizing Cigar Survey Data Across Tobacco Centers of Regulatory Science, Center for Tobacco Products, and Population Assessment of Tobacco and Health Studies: The Cigar Collaborative Research Group*, 23 NICOTINE & TOBACCO RSCH. 212 (2019), https://pubmed.ncbi.nlm.nih.gov/31665435/).

[16] Baojiang Chen et al., *Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars Among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017*, 15 PLOS ONE e0243372 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7725294/.

[17] Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 1 (2019), https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm?s_cid=ss6812a1_w.

[18] *Id.*

[19] Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1 (2022), https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w.

In the Center's 2018 comment to the FDA's Advance Notice of Proposed Rulemaking related to flavors in tobacco products, we showed that one of the key drivers of tobacco use in the United States is the availability of flavored tobacco products.[20] According to recent PATH data, for ever-users of all tobacco products, initiation with a flavored product was more likely in every age group, including an astonishing 81% of youth, 86% of young adults, and 55% of adults.[21] FDA is correct in laying out the benefits to youth and young adults of prohibiting flavors in cigars, noting in the proposed rule that "[c]igars are more commonly used among youth and young adults relative to other combusted tobacco products, including cigarettes."[22]

Flavors contribute to youth misconceptions about the harm of consuming tobacco products like little cigars, while also increasing perceptions of pleasure and enjoyment from use, the combination of which contributes to uptake and sustained use. A 2020 study confirms what older research demonstrated with respect to the role that flavors, including in flavored cigars, have in altering youth perceptions as to the risk and harms for consuming cigars, instead of and in addition to cigarettes.[23] It is not enough to have warning labels as to the health risks of the product when there are also colorful and enticing descriptors for the same product.[24] Encouragingly, FDA has likewise reached these conclusions as it notes in the proposed rule: "Characterizing flavors in tobacco products increase the appeal of those tobacco products to youth and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will progress to regular cigar smoking."[25] The proposed ban would drastically reduce initiation, preventing tens of thousands of young people from becoming regular users each year.[26]

---

[20] PUB. HEALTH L. CTR., *Regulation of Flavors in Tobacco Products* (July 19, 2018), https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-flavors-comment-fda-2018.pdf.

[21] Andrea C. Villanti et al., *Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013–2014)*, 53 AM. J. PREVENTIVE MED. 139 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28318902.

[22] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396, 26,406 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).

[23] Rose S. Bono et al., *Behavioral Economic Assessment of Abuse Liability for Black & Mild Cigar Flavors Among Young Adults*, 30 EXPERIMENTAL & CLINICAL PYSCHOPHARMACOLOGY 113 (2022), https://pubmed.ncbi.nlm.nih.gov/33001692/.

[24] Clare Meernik et al., *The Effect of Cigarillo Packaging Elements on Young Adult Perceptions of Product Flavor, Taste, Smell, and Appeal*, 13 PLOS ONE e0196236 (2018), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0196236.

[25] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26,397.

[26] Brian L. Rostron et al., *Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US*, 16 INT'L J. ENV'T RSCH. & PUB. HEALTH 3234 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6765886/.

2. Due to purposeful targeting by the tobacco industry, Black and African American people initiate and use flavored cigars at higher rates than other racial and ethnic groups.

While young people as a whole are particularly susceptible to the harms of flavored cigars, there exist disparities within subgroups. Among college students, Black, Asian, and Hispanic students are significantly more likely to use flavored cigars.[27] Additionally, Black students smoke cigars at higher rates than cigarettes[28] and have a higher risk of initiating use.[29] Among college students, younger, female, and racial/ethnic minority cigar users had significantly greater odds of using flavored cigars than other subgroups.[30] Among dual users of cigars and cigarettes, those who cited using cigars because they were cheaper than cigarettes and because cigars felt like smoking regular cigarettes had greater odds of using flavored cigars compared to their peers.[31] These usage disparities indicate that a flavored cigar ban will be especially beneficial in these communities, reducing health disparities.

B. The presence of flavors in cigars suppresses cessation.

In 2011, TPSAC concluded that flavored tobacco products, including cigars and cigarettes, make cessation more difficult and impede quit attempts.[32] As we noted in the supplement to our 2013 citizen petition regarding menthol in cigarettes, this is especially true for menthol,[33] but is applicable to all flavors in cigars and little cigars. The FDA recognizes in its proposed rule that cigar use is disproportionately burdening non-White communities - and particularly the Black community - and for youth especially the presence of flavors is important for initiation. Cessation for tobacco products is similarly negatively impacted within these same vulnerable populations, owing in part to flavors, which mask the harshness of inhaling smoke.

The FDA further notes that the sale of flavored cigars increased following the prohibition on the sale of flavored cigarettes (except menthol flavored cigarettes) in

---

[27] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26,404.
[28] *Id.*
[29] *Id.* at 26,414; Chen et al., *supra* note 16.
[30] Josephine T. Hinds et al., *Flavored Cigars Appeal to Younger, Female, and Racial/Ethnic Minority College Students*, 20 NICOTINE & TOBACCO RSCH. 347 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5896537/.
[31] *Id.*
[32] TOBACCO PRODUCTS SCI. ADVISORY COMM., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS (2011), https://wayback.archive-it.org/7993/20170405201731/https:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.
[33] PUB. HEALTH L. CTR., *supra* note 13, at 13.

2009.[34] This was a foreseeable result of focusing on prohibiting the sale of most flavored cigarettes in isolation from other tobacco products. This lesson is important when considering that the prohibition on the sale of menthol cigarettes is currently being considered in tandem with this proposed rule prohibiting flavored cigars. To be optimally effective in aiding smokers to quit, removing substitutes which may maintain smoking and nicotine dependency is crucial.

A main reason for the lower cessation rates among flavored cigar smokers is the nicotine dependency that flavored cigars promote. As the FDA states in the proposed rule, flavors enhance the addictiveness of tobacco products like cigars, making cessation more difficult.[35]

The FDA identifies the insidious role that flavors play in sustaining tobacco product use, facilitating nicotine dependency. As flavors are particularly appealing for youth initiation, they can contribute to young people becoming addicted to nicotine and dependent on tobacco products to satiate that addiction - setting up years of potential health risks resulting from regular use. Noted in the proposed rule: "[C]onsiderable research shows that exposure to nicotine in adolescence causes long-term changes in the brain, with implications for nicotine dependence, attention, and impulsivity, as well as other areas of cognitive function and substance use."[36] The risks for forming nicotine dependency through cigar consumption are profound, and reducing the appeal of those tobacco products by prohibiting the sale of flavored cigars will likely lead to significant public health gains for generations.

Flavors like menthol are especially concerning with respect to their facilitating nicotine dependency. Recent studies show that menthol specifically facilitates deeper addiction and dependency in both youth and adult smokers. Research published in 2022 reaffirms what older studies have found: menthol is more appealing than the flavor of tobacco, especially among youth, which contributes to smoking intensity and risks for nicotine dependency.[37] This outcome is partially driven by the way in which menthol affects nicotinic receptors in the brain. At the biological, animal studies show that menthol increases dependence by interacting with nicotine to produce additional nicotine-specific receptors in the brain. This increases the sensitivity and prevents desensitization of nicotine specific receptors, and increases dopamine release due to greater dopamine neuron excitability.

---

[34] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396, 26,403 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).
[35] *Id.* at 26,424.
[36] *Id.* at 26,407.
[37] Amy M. Cohn et al., *Affirming the Abuse Liability and Addiction Potential of Menthol: Differences in Subjective Appeal to Smoking Menthol Versus Non-Menthol Cigarettes Across African American and White Young Adult Smokers*, 24 NICOTINE & TOBACCO RSCH. 20 (2022), https://pubmed.ncbi.nlm.nih.gov/34405884/.

Additionally, because menthol has a distinct and recognizable odor, research in mice shows that menthol can increase relapse and drive nicotine-seeking behaviors. Research into tobacco industry documents shows that the industry has long been studying these physiological impacts and has used this knowledge to manipulate menthol in cigarettes to promote addiction.

C. Prohibiting flavors in cigars benefits users and nonusers.

The FDA estimates that approximately 60,000 18-year-olds who currently use cigars would no longer do so without flavors.[38] For the general population of cigar users, FDA's estimation that 41.9% of current users would reduce if not cease their consumption of cigars, and lead to 400 to 1,100 fewer deaths annually.[39] Research that the FDA relies upon further suggests a reduction in current cigar prevalence among 18-year-olds by 37.1%.[40] Related to the decrease in current users and lower likelihood for initiation in the absence of flavors, we note that reductions in any tobacco use has a positive impact on non-users who are thereby at lower risk for exposure to secondhand smoke. Secondhand smoke is connected to some of the same health risks that tobacco users face when using tobacco products, raising nonuser's risk for cancer and heart disease. Reductions in consumption of cigars leads to less exposure events for nonusers. This impact may be most felt within the Black community, where cigar use and secondhand smoke exposure are disproportionately high.[41] Furthermore, a flavored cigar ban would promote cessation in an equitable manner. A study on smokers of flavored cigars and menthol cigarettes found that Black smokers are less likely to switch to non-flavored products after a ban.[42]

The FDA estimates that implementing a prohibition on the sale of flavored cigars could yield an incredible cost savings to the national economy. The agency estimates that the sum of monetized benefits over 40 years could amount to between $3.9 and $12.4 billion dollars. While FDA action relies solely on the benefit to public health, not monetary benefits, these values still present a compelling argument for quick and efficacious enactment for the prohibition.

---

[38] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26,429.
[39] *Id.* at 26,431.
[40] Rostron et al., *supra* note 26.
[41] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26,423.
[42] Yong Yang et al., *How Smokers of Menthol Cigarettes and Flavored Cigars Might Respond to FDA's Proposed Bans*, NICOTINE & TOBACCO RSCH. (2022), https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntac078/6556048.

D. The FDA can learn lessons from the jurisdictions that have led on prohibiting flavored cigars.

We strongly advocate for a comprehensive flavored cigar ban. Health equity is a major reason for the necessity of a comprehensive ban. A study on the availability and advertising of flavored tobacco products in California jurisdictions before and after flavored tobacco sales restrictions found that non-comprehensive policies were inequitable.[43] Policies with partial exemptions were less effective at decreasing the availability of products and addressing health disparities.

Bans on flavored tobacco products have proven to be effective. One example of this success is shown in a study of flavored tobacco sales restrictions in Alameda and San Francisco Counties in California.[44] Within these counties, there were some cities that enacted flavored tobacco sales restrictions (Category 1 cities) and some that did not (Category 2 cities). Availability of flavored tobacco products dropped by 90.6% in Category 1 cities, but only 13.6% in Category 2 cities.[45] There was also a significant difference in flavored tobacco advertising between Category 1 and Category 2 cities.[46] Studies like these showcase the vast impact that flavored tobacco product bans can have and support the importance of this proposed rule to ban flavored cigars.

Additionally, past flavor bans give insight into how to structure the final rule. The tobacco industry has responded to past flavor bans by skirting regulation. For example, manufacturers have re-labeled products as non-flavored, while leaving the flavor chemicals intact.[47] To avoid this issue the final rule should prohibit all flavors as additives. See section IV of this comment for further discussion of this recommendation.

E. Examining the scientific evidence base through the lens of health equity demands that the FDA prohibit flavors in cigars.

The expansive scientific evidence listed in the proposed rule paints an exceptionally clear picture: flavored cigars must be banned. The material listed in this comment adds to that evidence, leaving no room for doubt. A flavored cigar ban would save

---

[43] Louisa M. Holmes et al., *Flavored Tobacco Sales Restrictions Reduce Tobacco Product Availability and Retailer Advertising*, 19 INT'L J. ENV'T RSCH. & PUB. HEALTH 3455 (2022), https://www.mdpi.com/1660-4601/19/6/3455/htm.

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] Shannon M. Farley et al., *Flavour Chemicals in a Sample of Non-Cigarette Tobacco Products Without Explicit Flavour Names Sold in New York City in 2015*, 27 TOBACCO CONTROL 170 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5870443/.

countless tobacco-related harms to smokers and non-smokers alike. These benefits would be especially pronounced in marginalized communities, reducing persistent disparities. The Center reiterates our appreciation of the FDA's recognition of health equity as inherent in the decision of what is "appropriate for the protection of the public health" and urges the FDA to ban flavored cigars to advance health equity.

IV. In order to maximize the benefits to public health, the FDA must strengthen the proposed rule.

While the FDA's proposed rule will create tremendous public health benefits and promote health equity, the rule can still be strengthened to increase the benefits to public health. Some of these improvements require changes to the proposed rule and others can be done entirely outside the rulemaking process.

A. The FDA must entirely prohibit the addition of flavors to cigars.

The FDA has proposed a rule that would ban all characterizing flavors, (including menthol) in cigars and their components and parts. This is a bold and courageous action that is, "appropriate for the protection of public health." In announcing this proposed rule, the FDA cited data from 2019 and 2020 National Youth Tobacco Survey (NYTS), showing that each year more and more young adults tried flavored cigars. Those children tended to be non-Hispanic Black by a more than two to one margin. Finally, the FDA estimated 9,000 premature deaths occurred as the result of the use of flavored tobacco.

The FDA's action is supported by the same legal and scientific framework that underpin the proposed prohibition on menthol-concerns for health equity and attempting to break the vicious cycle of initiation, dependency, and cessation. However, this proposed rule can be strengthened to provide even greater benefits.

The rule would restrict flavors in only cigars, leaving other flavored combustible tobacco products on the market. There is no health-based reasoning to exclude waterpipe and pipe tobacco from the proposed rule.

In addition to expanding the proposed rule to include waterpipe and pipe tobacco, the FDA should prohibit the addition of flavor additives entirely. The overwhelming body of scientific evidence and historic tobacco company documents show that tobacco companies add flavors to cigars to increase their appeal, addictiveness, and to make cessation difficult. It is irrelevant whether the flavor is deemed a characterizing flavor or not, the addition of flavors to combustible tobacco products harms users and non-users alike. The FDA should ban the addition of all flavors in cigars, waterpipe and pipe tobacco because it is appropriate for the protection of public health.

P: 651.290.7506 F: 651.290.7515
W: www.PublicHealthLawCenter.org
875 Summit Avenue, St. Paul,
Minnesota 55105

A. In order to maximize the public health benefits of the rule, the FDA must stringently enforce the new regulation.

While the proposed rule spends little time discussing how the new rule will be enforced, the FDA must make certain that the rule is enforced with fidelity in order to provide the most protection to the public. The tobacco industry has perennially raised issues of illicit trade as a barrier to action. However, the FDA has enforcement tools that can mitigate and entirely prevent such activities from jeopardizing the benefits of the rule, if they even represent a real threat to public health.

1. Illicit trade concerns are less significant than what the tobacco industry claims.

Illicit trade – the manufacture, distribution, and sale of prohibited products – does not undermine the public health benefits of the proposed rule and is less significant than industry claims. Moreover, the proposed rule will reduce the illegal selling of tobacco products to minors and youth. Even if illicit trade and illegal sales to minors occurs because of a flavored cigar ban, it should be easy to identify because it would require the manufacture, distribution, promotion, and sale of products that would not otherwise be legally sold.

The National Research Council and the Institute of Medicine (now known as the National Academies of Sciences, Engineering and Medicine) concluded in their 2015 report that "the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest."[48] The Tobacco Control Act prohibited the use of characterizing flavors, other than menthol, in cigarettes. Although there is limited literature on the market response, no substantial market in illicit flavored cigarettes appears to have developed as a result.

2. The most important illicit market is that which provides cigars to consumers too young to buy them legally.

The most significant consequence of the proposed rule is likely to be a substantial reduction in the illicit sale of combusted tobacco products to customers below the minimum legal sales age. The tobacco industry will argue that FDA should not impose any rule eliminating flavors in cigars because, as it claims when any tobacco control measure is proposed, it would cause illicit sales. However, that argument ignores the fact that illegal sales to people under the minimum legal sales age has existed for decades. Yet one could not credibly argue that the ban on sales to youth

[48] NAT'L RSCH. COUNCIL & INST. MED., UNDERSTANDING THE U.S. ILLICIT TOBACCO MARKET 9 (National Academies Press ed., 2015).

should be repealed because it has led to some illegal sales. One of the central purposes of the proposed rule is to curtail use by and sales to youth, and thus eliminate illegal sales to youth by making tobacco products less appealing to young people. In this context, it is ironic that the tobacco industry would put forth the argument that the rule would "create" illicit markets. Given that virtually all smokers start in their youth, today's tobacco epidemic is in large measure the product of an existing illicit market that makes combusted tobacco products available to consumers too young to legally sell to. The rule has been proposed because of the recognition that this illicit market will continue to exist so long as products that are addictive and attractive to youth are allowed to be sold.

Moreover, those who argue most vociferously against a flavor ban because of concerns about illicit markets are the very companies whose conduct has been found to have created and sustained the illicit marketing of tobacco products to youth and who continue to derive their customer base from that market.[49]

1. Enforcement measures must remain focused on manufacturers, importers, distributors, and retailers.

For illicit *trade* to exist in the United Sates, there must first be either illicit manufacturing or smuggling. Track-and-Trace authority allows the federal government to prevent both illicit manufacturing and smuggling in collaboration with other agencies. Track-and-Trace is an effective enforcement policy that will reduce the risk of illicit trade and is important to ensure the success of the proposed rule. Key elements to combat illicit trade and non-compliance include: frequent and unannounced inspection of manufacturers, retailer education, and inspection of products labeled for export. In other words, to identify illicit products and keep them off the market, the FDA should use its existing authority under the Tobacco Control Act to track the transportation of tobacco products at every level of the supply chain.

Specifically, Section 920 of the Tobacco Control Act already directs FDA to implement a Track-and-Trace system.[50] Such a system would permit the FDA and other law enforcement authorities to identify the source and distribution history of product packages and greatly increase the effectiveness of law enforcement. These systems have been most effective when they have included encrypted cigarette stamps.

Under a Track-and-Trace system, each tobacco product produced or sold in the United States would bear a unique, counterfeit-resistant identifying code that allows

[49] *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 561–691 (D.D.C. 2006), aff'd in relevant part, 595 F.3d 1095 (D.C. Cir. 2009).
[50] 21 U.S.C. § 387.

its origin to be identified and linked to a computer database of required records that would permit the product to be tracked and traced. Such a system would enable the FDA to track goods from manufacture or importation to the point of retail sale and provide it with the ability to trace back those goods to their point of origin. This kind of system would be of great value in enforcing compliance with the rule, in addition to deterring smuggling and trafficking and preventing illegal diversion. To accomplish these goals, a national track and trace system should, at minimum, have the features outlined with much input and consideration by the World Health Organization's Framework Convention on Tobacco Control's (FCTC).[51]

In developing a policy for effective enforcement of the proposed rule, FDA must coordinate its activities with those of other federal agencies with experience in these areas. Measures the FDA can implement pursuant to the Tobacco Control Act, such as implementation of an effective Track-and-Trace system, can provide substantial assistance to other federal agencies in the performance of their functions, particularly in the identification of products on which taxes or import duties have not been paid. Effective coordination between the FDA and other federal enforcement agencies is essential. The FDA should also coordinate its enforcement efforts with those of state law enforcement agencies and those of indigenous Tribal governments.

Moreover, other federal agencies already exercise authority that is highly relevant to the task FDA will face. The Bureaus of Immigration and Customs Enforcement ("ICE") and Customs and Border Protection ("CBP"), agencies of the Department of Homeland Security, have been responsible for identifying imported tobacco products and ensuring that appropriate taxes and import duties are paid and the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF"), has been responsible for administration of the PACT Act. Similarly, for domestic products, the Alcohol and Tobacco Tax Bureau in the Department of the Treasury ("TTB") has been responsible for monitoring the shipment of domestically manufactured tobacco products and ensuring that taxes are paid. It is important that any track and trace system implemented by FDA to be under the direct management and control of the federal government. In addition, such a system should be designed to allow states and local jurisdictions shared access to data systems storing shipping and receiving information to and from local jurisdictions to ensure that required taxes have been paid and to assist with enforcement.

---

[51] World Health Org., *Framework Convention on Tobacco Control, Conference of the Parties, Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products, fourth session*, Geneva, Switzerland (2010) (analysis of the available technology for unique markings in view of the global track-and-trace regime proposed).

FDA should reject efforts by the tobacco industry to participate in the development of such a system or to use the industry-sponsored systems. In sum, the threat of an illicit market does not outweigh public health benefit.

4. The FDA should establish a "prohibited product list" or "permitted product list" with existing information to root out hidden flavors in commercial tobacco products because it is appropriate for the protection of public health.

The Tobacco Control Act grants the FDA wide ranging authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public's health. Section 905(i)(1) of the FD&C Act requires that all tobacco product manufacturers "shall, at the time of registration . . . . file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution." What this means in practice is that all commercial tobacco product manufacturers are required to file form 3741A, *Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishment,*[52] or the electronic equivalent, every year, for every product they put into the stream of commerce. This document—filed under penalty of perjury—on page 7, section 7, requires manufacturers to list any flavor present, including menthol. The FDA could use this list to easily identify products that are currently marketed as having a characterizing flavor. Similarly, the FDA can use information gathered under Section 904(a) to determine which currently marketed cigarettes contain added flavor constituents.

The time has come for the FDA to operationalize the data it routinely collects for the protection of public health. Here, it can do so by creating a "prohibited product list" or "permitted product list" with the information that manufacturers are required to report. In so doing, the FDA will be able to easily identify compliant and non-compliant products, making enforcement of this product standard exceptionally simple.

5. **The FDA should take immediate action to remove flavored "components or parts" from the market because they lack marketing authorization and will be used to make an end run around the flavor prohibition.**

---

[52] U.S. DEP'T HEALTH & HUM. SERVS., FDA, *Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishment*, Form 3741a, https://www.fda.gov/media/99863/download.

The proposed rule would also prohibit all flavors in cigar "components and parts."[53] A product is a component or part if it: (1) alters or affects the performance, composition, constituencies, or characteristics of a cigar; or (2) can be used by humans to consume a cigar.[54] Components or parts include products such as filters, papers, flavor cards, drops, oils, or other additives. All components and parts are subject to FDA regulation and require marketing authorization. Under this rule, any flavored cigar components and parts would *not* be compliant with the proposed product standard, and the FDA would have authority to remove them from the market.

This complete ban of flavor components or parts from the marketplace is the right course of action because the tobacco industry has a long and sordid history of exploiting regulatory loopholes. For instance, the tobacco industry began to heavily market flavored cigars after the passage of the TCA in 2009, thereby undercutting the public health gains made by the TCA's ban on flavored cigarettes. More recently, the industry took advantage of defects in the European Union's menthol ban—the exemption of menthol accessories if they were sold outside the package—to introduce separately sold component products manufactured and designed to reintroduce menthol into banned commercial tobacco products.[55] By 2017, Imperial Brands had launched menthol flavor tips, and by 2020, menthol "Flavor Infusion" cards.[129] By mid-2021, Imperial reported selling 900,000 packs of flavor cards per week.[130] British American Tobacco and smaller tobacco brands followed the same business strategy, adding more flavored accessories to the market.[131] Therefore, because it is completely foreseeable that the industry will try to defang the flavor prohibition on flavored cigars via the sale of accessories or components and parts, the FDA should ensure that enforcement of this rule includes enforcement action against manufacturers of components and parts designed to evade the product standard.

B. There is no legal authority or scientific justification for the FDA to create a waiver process to exempt products from the proposed standard.

The FDA has asked whether it should set up a waiver process for any product that a manufacturer wishes to receive an exemption for. This is a bad idea because it is not rooted in the law nor would it benefit public health.

First, there is no provision in the TCA that provides for waivers from product standards. Under section 907 of the FD&C Act, the FDA has the authority to establish

---

[53] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396, 26,397 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).
[54] 21 C.F.R. § 1140.3.
[55]

tobacco product standards regarding the construction, components, ingredients, additives, constituents, and properties of tobacco products.[56] There is nothing in this section that allows the FDA to create a waiver process. Hence, a creating a waiver process is outside of FDA's authority. Had Congress envisioned such a system, it would have specified so. Because it did not, it is clear that Congress intended a product standard to cover an entire class of products, a hallmark of a delegation of rulemaking authority, not to create an individualized application process, a hallmark of an adjudicatory authority. These two types of authorities are defined and governed differently under the Administrative Procedure Act. There is no question that Section 907 does not create any authority for some sort of adjudicatory waiver system. The creation of such a system would be squarely outside of the FDA's authority.

Moreover, in order to establish a *new* tobacco product standard, the FDA must find that the standard is, "appropriate for the protection of the public health."[57] Thus, even if there were legal for the FDA to create a waiver process, the FDA has not made the prerequisite showing that such a waiver would be appropriate for the protection of public health.

B. There are actions that the FDA can take outside of this rulemaking that will further increase the public health benefits of this proposed rule.

The FDA has the authority and tools to take steps to prevent cigar smoking in young people. The proposed flavor ban is a crucial step in that process. As the rule making process continues, the FDA should focus on how to prevent smoking or promote cessation among marginalized populations to advance public health. Public health is not a one size fits all approach. The history of racism and marginalization in the United States requires the FDA to pursue culturally specific interventions that prevent initiation and promote cessation of smoking in vulnerable populations. The FDA must take a leadership role in coordinating with other government and non-government entities that advance smoke-free policies. Finally, by working to promote other product standards for menthol cigarettes and e-cigarettes, the FDA has options to advance smoke free measures in addition to the rule making process for flavored cigars. These actions, discussed below, do not require a finalized rule, and can be implemented immediately.

A. Cessation Programs should emphasize cultural competence for better results.

[56] 21 U.S.C. § 387g.
[57] *Id.* § 387g(a)(3)(B)(i).

Public health policy should lead with a health equity lens to support populations most at risk of harm from flavored cigars. In the United States, studies show that young people and people from communities of color are more likely to smoke cigars.[58] Cigars are a tobacco product that is still sold in flavors, and the industry uses that to directly entice children and young people. About half of the students surveyed in the 2020 NYTS survey noted that flavors in cigars were a leading reason for smoking cigars.[59] Knowing this, the FDA has a responsibility to implement a cigar flavor ban and promote other cessation and smoking prevention strategies to protect vulnerable populations.

The FDA can do work outside of the rule by collaborating with organizations like the Center for Black Health and Equity, African American Tobacco Control Leadership Council, Action on Smoking and Health, Truth Initiative, and the Campaign for Tobacco Free Kids among others. These entities are engaging communities of color and young people to advance smoking cessation and tobacco control policies. The FDA should support their efforts by being present at their activities and amplifying their work to promote public health.

The African American Tobacco Control Leadership Council (AATCLC) supports policy changes across the country to ban the sale of flavored cigars, cigarillos, and blunt wrappers.[60] AATCLC's goal is to support jurisdictions that implement policies that focus on making it harder for young people to obtain nicotine products like cigars. It works on increasing the pricing of cigars and changing the packaging to be less enticing to minors. AATCLC advocates for a federal sales tax on all tobacco products that would fund dedicated initiatives to support marginalized communities that smoking has disproportionately harmed.[61]

The AATCLC has programs that address specific needs of young Black Americans to prevent their uptake of cigars. Research on culturally specific programming has shown that it can increase the quit rates for demographics if the material and counseling addresses culturally specific issues.[62] The FDA can support efforts by AATCLC and others by learning from these groups and incorporating those resources into tools the FDA uses to promote smoking cessation and prevention.

---

[58] Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Students — United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1881 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a1.htm?s_cid=mm6950a1_w.
[59] *Id.*
[60] Finishing the Fight!, AFRICAN AM. TOBACCO CONTROL LEADERSHIP COUNCIL, https://www.savingblacklives.org/finishingthefight (last visited July 28, 2022).
[61] *Our Priorities*, AFRICAN AM. TOBACCO CONTROL LEADERSHIP COUNCIL, https://www.savingblacklives.org/quantumleap (last visited July 28, 2022).
[62] Monica Webb Hopper et al., *Effects of a Culturally Specific Tobacco Cessation Intervention Among African American Quitline Enrollees: A Randomized Control Trial*, 18 BMC PUB. HEALTH 123 (2018), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-5015-z.

Studies are beginning to look at the effects of culturally specific cessation and intervention programs to determine their effectiveness.[63] Early findings suggest that culturally tailored programming can have an additional positive effect on preventing smoking in adolescents from minority groups and support cessation in African American adults.

The AATCLC wants to partner with organizations and government entities, and the FDA should collaborate with AATCLC and other similar organizations to promote policies that reduce the attractiveness of products like flavored cigars. The FDA should collaborate with such community organizations to show that the government is invested in addressing public health disparities related to cigars.

The Campaign for Tobacco Free Kids is also in the fight to ban the sale of flavored cigars. Like how the industry specifically marketed menthol cigarettes to African Americans, the industry markets flavored cigars to children and young people. Flavors mask the harshness of tobacco smoke and make it easier for young people to continue smoking.[64] The Campaign has programs that seek youth engagement at their schools and provide resources for young leaders to advocate that their peers do not take up smoking. Other government organizations like the National Cancer Institute support two evidenced based school programs to prevent young people from smoking.[65] The FDA should expend its efforts to further promote these programs and effectively message the harms of smoking flavored cigars among young people.

AATCLC and the Campaign for Tobacco Free Kids are two examples of the work that organizations around the country do to promote smoking cessation and control the sale of flavored cigars. These organizations are focused on interventions that are culturally appropriate for the demographics they work with. Organizations and local and state governments are implementing policies to limit advertisements and limit the age at which people can buy cigars and other flavored tobacco products. The

---

[63] Grace Kong et al., *A Review of Culturally Targeted/Tailored Tobacco Prevention and Cessation Interventions for Minority Adolescents*, 14 NICOTINE & TOBACCO RSCH. 1394 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3509015/; Webb et. al., *supra* note 52; Alicia K. Matthews et al., *Development of a Culturally Targeted Smoking Cessation Intervention for African American Smokers*, 34 J. CMTY. HEALTH 480 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3712791/.

[64] *U.S. State and Local Issues: Ending the Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 11, 2022), https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products.

[65] *A Smoking Prevention Interactive Experience (ASPIRE)*, NAT'L CANCER INST. (Jan. 31, 2022) https://ebccp.cancercontrol.cancer.gov/programDetails.do?programId=2440327; Not-On-Tobacco Program (N-O-T), NAT'L CANCER INST. (June 25, 2020) https://ebccp.cancercontrol.cancer.gov/programDetails.do?programId=269048.

FDA should continue to be involved in supporting enforcement of policies that limit the sale of flavored cigars to young people.

The 2020 Surgeon General's Report notes the importance of community work to implement population wide policies. The FDA should be the leading government agency to advance smoke free measures across the country. The FDA should become a more vocal proponent of local and state efforts to advance public health related to cigars.[66] This work can be done in advance of the final rule to ban flavored cigars.

B. The FDA must implement other product standards to close all potential loopholes.

The next few months will have an outsized focus on the rules to ban menthols and flavored cigars. As this is happening, the FDA should continue efforts to advance regulations for other tobacco products. The concurrent release of the menthol rule for cigarettes is an example of how the FDA can advance new regulations at the same time. The menthol rule and the flavored cigar rule complement each other well and address smoking issues in marginalized communities. Removing menthol from cigarettes and flavors from cigars will decrease initiation and increase cessation.[67] This is a public health benefit worth pursuing.

The FDA must also advance product standards related to e-cigarettes. E-cigarettes have increased in popularity and have some health risks similar to conventional cigarettes.[68] In a limited manner, the FDA has prevented some e-cigarettes from entering the market, but the industry continues to find ways around the FDA's premarket review process and target young people in selling e-cigarettes.[69] The FDA took a first step in this arena by denying the market order for JUUL. Similar to that effort to decrease youth access to nicotine, the FDA announced that it will seek to lower the amount of nicotine in tobacco products. Following through on these product standards will have a significant impact on the addictiveness of tobacco products by decreasing the main addictive ingredient.

C. Conclusion

---

[66] U.S. DEP'T HEALTH & HUM. SERVS., SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.

[67] Chen et al., *supra* note 16; Yang et al., *supra* note 42.

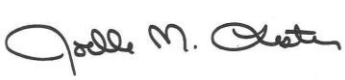
[68] *U.S. State and Local Issues: Ending the Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 11, 2022), https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products.

[69] *Action Needed on E-Cigarettes*, TRUTH INITIATIVE (Nov. 13, 2020), https://truthinitiative.org/research-resources/emerging-tobacco-products/action-needed-e-cigarettes.

While we congratulate the FDA for finally issuing this proposed rule, it has taken far too long to reach this step. The public health impact of the presence of flavors in cigars is well studied. There was already more than enough information to support the of flavors when the FDA asserted jurisdiction over cigars in 2016. The amount of time spent contemplating action and gathering information and the resources spent continuing to study this issue is wasteful. To salvage those resources and the reputation of the agency, this rule must be finalized as soon as possible.

When finalized, this rule will save many lives. The benefits depend on the FDA finishing this work and not diluting the policy due to the influence of a corrupt industry that has preyed on communities that were already marginalized. The entire public health and medical communities are united in their support of this policy, as are some of the largest organizations representing the communities most in need of this policy. The time is now. Finish this work and finalize this rule with the sense of urgency that this policy deserves. Lives are at stake and those lives matter.

Respectfully,



Joelle Lester
Director

Desmond Jenson
Lead Senior Staff Attorney for Federal Regulation

P: 651.290.7506 F: 651.290.7515
W: www.PublicHealthLawCenter.org

875 Summit Avenue, St. Paul,
Minnesota 55105