FDA should not allow any extensions of time to submit public comments about the proposed rule on characterizing flavors in cigars

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

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The Food and Drug Administration's proposed rule to prohibit characterizing flavors in cigars will reduce youth and young adult initiation rates of smoking cigars and significantly reduce premature deaths and illnesses related to tobacco use. Youth and young adults are especially attracted to the flavors in cigars, increasing the likelihood that they will initiate and progress to regular cigar smoking, and perhaps continue smoking other tobacco products concurrently with cigars. Moreover, the proposed rule correctly states that 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.

We generally support FDA's proposed rule which is based on good science. ***Because of the tremendous health impacts that would accrue from the enactment of this proposed standard, we urge FDA to deny any requests for extensions of time to submit public comments.***

As FDA correctly stated, any additional delays "would only increase the numbers of youth and young adults who experiment with and become regular smokers after experimenting with flavored cigars, would delay cessation by current smokers, and would exacerbate tobacco-related health disparities."[1]

1. Every month delay in implementing the proposed flavor standard would result in an additional 44,000 new cigar smokers

Based on data from the 2019 National Survey on Drug Use and Health,[2] FDA determined that every day 1,210 youth (aged 12-17) and 3,163 young adults (aged 18-25) smoke their first

[1] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26438.

[2] Substance Abuse and Mental Health Services Administration. ''Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–

cigar.[3] And Wave 5 PATH data[4] show that for 60.4% of youth and 63.2% of young adults, this first cigar is flavored.[5] This means that 731 youth and 1,999 young adults smoke a first cigar that is flavored each day, and each month, 12,925 youth and 59,970 young adults (81,895 youth and young adults combined) smoke a first flavored cigar.

FDA accurately reports that many studies indicate that "experimentation with cigars is associated with progression to regular use, the majority of youth and young adults who initiate cigar use do so with flavored cigars, and initiating with flavored cigars (compared to non-flavored cigars) is associated with an increased risk of current and ongoing tobacco use, as compared to experimentation with non-flavored cigars. To the extent that youth and young adult cigar users using a flavored cigar on their first use would not otherwise initiate with non-flavored cigars or other tobacco products, the proposed standard would prevent future tobacco-related disease and death among these youth and young adults."[6] FDA concluded that prohibiting characterizing flavors in cigars "would reduce the likelihood that youth and young adults would initiate cigar use and also mean fewer youth and young adults progressing to regular cigar use."[7]

If cigar smokers behave similarly to cigarette smokers, 54% of youth and young adults would not start smoking cigars.[8] ***Thus, every month delay in implementing the ban would result in an additional 44,000 new cigar smokers.***

2. FDA must not grant any extensions of time to submit public comments and must not delay in implementing the proposed flavor standard for cigars because each month of delay would cause at least an additional 774 premature deaths in future years

FDA's own statistical analysis estimated that 774 deaths (equal to 15% of the 5,200 annual deaths from exclusive cigar smoking) would be averted annually by implementing the prohibition of flavors in cigars.[9] Based on FDA's analysis, ***each month of delay would cause an additional 65 deaths, and the 60-day (two-month) extension requested by several tobacco industry entities would lead to 130 avoidable, premature deaths.***

07–01–001, NSDUH Series H–55).'' Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020. Available at https:// nsduhweb.rti.org/respweb/ homepage.cfm

[3] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26406.

[4] FDA, ''Memorandum of Summary of Internal Analyses of Flavored Cigars Using Wave 5 of the Population Assessment of Tobacco and Health (PATH) Study.'' Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2021.

[5] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26404.

[6] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26425.

[7] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26426.

[8] Harrell MB, Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist?. Tobacco regulatory science. 2017 Apr 1;3(2):168-73.

[9] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26430-26431.

To protect public health and avoid preventable premature deaths, FDA must not delay a single additional day.

3. FDA must not delay the public comment process or implementation period of the proposed standard because in addition to lives lost, a 60-day delay would eventually cost $1.17-$1.43 billion in costs

In its Summary of Cost and Benefits,[10] FDA estimated that the annualized benefits from the proposed rule including reduced smoking-attributable mortality that is the result of cigar use among adult cigar smokers, reduced mortality from secondhand smoke among non-users, reduced smoking attributable mortality among youth who are deterred from initiating, medical cost savings, productivity loss savings, improved quality of life, and environmental impacts would amount to $8.575 billion per year (discounted at 3%) or $7.024 billion per year (discounted at 7%). This averages to $715 million per month (3%) or $585 million per month (7%), so every month delay in implementing the rule would eventually cost approximately $585-$715 million. ***Therefore, if FDA granted the requests to extend the time to submit public comments an additional 60 days (two months), in addition to promoting poor health outcomes and thousands of premature deaths, FDA would incur an additional $1.17-$1.43 billion in costs.***

4. The tobacco industry has had more than enough time to prepare for the proposed menthol standard

In the preamble to the proposed rule, the FDA lays out in detail the background and relevant regulatory history of the proposed standard that would prohibit characterizing flavors in cigars.[11] The industry has known since long before the Tobacco Control Act was enacted in June 2009 that FDA was considering prohibiting characterizing flavors in tobacco products and has strenuously worked to oppose this outcome, including contesting FDA's 2018 Advanced Notice of Proposed Rulemaking on flavors in tobacco products, which included flavored cigars.

Tobacco industry entities and other interested parties have had ample notice and time to prepare comments in response to the proposed rule and have been researching and lobbying against any flavor restrictions for at least 13 years.

5. Conclusion

We urge FDA to deny these requests and to close the comment period on July 5, 2022.

[10] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26438-26439.
[11] US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26399-26402.