Tobacco Product Standard for Characterizing Flavors in Cigars

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This letter is on behalf of the Board of Directors for the Society for Research on Nicotine and Tobacco (SRNT), in response to the invitation for public comment on a Tobacco Product Standard for Characterizing Flavors in Cigars from the US Food and Drug Administration (FDA), May 4, 2022. SRNT is the largest scientific organization dedicated to interdisciplinary nicotine and tobacco research from molecular to societal levels and has an international membership of 1,060 members worldwide. The work of many of our members have contributed to the scientific evidence on flavored cigars and our members’ work is heavily cited in the evidence underpinning the proposed rule. Importantly, we distinguish commercial tobacco throughout this comment from ceremonial tobacco—plants which are used by many indigenous populations for ceremonial and cultural purposes (1). For this comment, we will use the term “tobacco” to describe “commercial tobacco.” SRNT strongly supports swift implementation of a final rule prohibiting the sale, distribution and manufacture of flavored cigars in the US. We offer the following points for consideration in finalizing the rule.

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D. The new characterizing flavors standard should be applied to all flavors (except tobacco) and all cigars, with no exceptions for “adult-appealing” flavors or “premium” cigars.

E. We support the inclusion of all ‘components’ and ‘parts’ that could add characterizing flavors to cigars, including, but not limited to, blunt wraps, drops, capsules, filter tips, roll-your-own tobacco, and flavor cards.

F. The characterizing flavor policy will likely have few to no countervailing effects, including but not limited to: transition to unflavored combusted tobacco smoking, illicit trade, and cannabis co-use.

G. SRNT strongly supports that nothing in the final rule should preempt states/localities from applying more comprehensive restrictions on flavored tobacco products.

Consistent with the above key points, SRNT makes the following recommendations for implementation and expansion of the rule:

1. The FDA should establish a tobacco product standard addressing flavors in all combusted tobacco products intended to be smoked, including hookah/waterpipe, pipe tobacco, and other combusted tobacco.

2. The FDA should extend the characterizing flavor standard to non-combusted tobacco such as e-cigarettes, smokeless/spit/ chew tobacco, and other emerging smokeless products.

3. To minimize potential countervailing effects and enhance the effectiveness of the characterizing flavors standard, we recommend that the standard be combined with the following:
   (a) Enhanced market surveillance and restrictions on marketing.
   (b) A retailer and public education campaign and promotion of cessation services.
   (c) An infrastructure to rapidly monitor, test, and enforce penalties on illegal trade, in order to minimize the effects of an illicit market.

4. The FDA should minimize sell-off dates.

5. No further extensions of the comment period.
The science on flavored cigars is clear and supports the FDA’s conclusions that a ban on characterizing flavors is critical for protecting public health and reducing tobacco-related disparities.

A. Characterizing flavors in cigars increase initiation and use, discourage users to quit, and increase harm from tobacco. Evidence from local and state policies support the effectiveness of the characterizing flavor standard on reducing use.

The evidence on flavored cigars is clear and supports the FDA’s conclusions that a ban on characterizing flavors in cigars is of paramount importance for protecting public health (2). In 2009, flavored cigarettes (with the exception of menthol) were banned in the US because of their appeal to and disproportionate use by youth <18 years. We support FDA’s proposed rules extending the flavor prohibition to mentholated cigarettes and to all non-tobacco characterizing flavors, including menthol, in cigars. We address menthol cigarettes in greater detail in separate comments and reiterate our support for finalizing the menthol cigarette and flavored cigar rules together to maximize the rules’ public health and health equity impact. We also support finalization of the flavored cigar rule standing alone and focus these comments on the sound scientific basis for prohibiting flavored cigars.

Our case is founded on scientific evidence. First, flavored cigars are important in smoking initiation and progression to regular use among young people. Cigars are also one of the most popular combusted tobacco products used among youth, young adults, and adults (3). The addition of flavors to tobacco products like cigars increases initiation and use by enhancing their appeal, making them easier to smoke, and increasing their addictiveness. Research has established that flavored tobacco products, including flavored cigars, are associated with initiation and use among youth. Indeed, data from the longitudinal, nationally representative Population Assessment of Tobacco and Health (PATH) Study show that 65% of youth who report ever cigar use initiated with a flavored cigar (4), and data from the 2019 National Youth Tobacco Survey (NYTS) show that more than half of youth who currently smoke cigars report smoking flavored cigars (5). Longitudinal cohort data from the PATH study confirm these findings, with one study using four waves of data showing that initiation with menthol/mint cigars is associated with subsequent cigar use among young people (6). A systematic review found
consistent evidence that flavors are a key reason for use of cigars and other tobacco products (7).

Second, flavors make it harder to quit smoking. In a cross sectional analysis of the 2014-15 nationally representative Tobacco Use Supplement to the Current Population Survey, use of flavored cigars and other flavored tobacco products was associated with greater tobacco dependence (8), which impedes cessation. Intentions to quit are lower among youth who smoke flavored cigars than youth who smoke unflavored cigars (9).

Third, cigar smoking is extremely hazardous, increasing the risk of cancer, coronary heart disease, lung disease, and many other illnesses (10). In one study using 2013-14 PATH data (11), cigar smokers who smoked only cigars (not cigarettes or other products) daily had levels of toxicant biomarkers comparable to every day cigarette smokers and dual product (cigarette-cigar) smokers. Characterizing flavors encourage heavier, more regular use of cigars, thereby increasing cigar smokers’ exposure to toxicants. Cigar smokers report that flavored cigars are easier and more palatable for smoking (12), which is supported by the tobacco industry’s own research (13). The prevalence of cigar use is higher among youth who report that flavored tobacco is easier to use than non-flavored tobacco (4). Moreover, a systematic review found consistent evidence that flavors are associated with multiple tobacco product use (7), which increases the health risks.

Overall, the evidence is consistent and more than sufficient to show a relationship between characterizing flavors in cigars and smoking initiation, progression to regular use, nicotine dependence, and harm. Thus, prohibiting characterizing flavors in cigars is expected to protect and improve public health by reducing youth initiation, progression to regular use, nicotine dependence, and harm.

Over 320 municipalities across 10 states have implemented restrictions on flavored cigar sales, and the evidence to date clearly shows the effectiveness of these policies on reducing availability and use. A recent systematic review found moderate-high quality evidence that flavored tobacco restrictions (including flavored cigars) lead to reductions in product availability, and moderate evidence that restrictions are associated with reduced sales and reduced tobacco use (14). Other recent research provides further support for the effectiveness of local and state flavor restrictions. Following flavored tobacco restrictions in California, store audits indicated that restrictions were associated with reduced availability and advertising of flavored tobacco products (15). Similarly, another study found lower perceived availability among youth in California cities with a local flavored tobacco restriction (16). Local flavor ordinances in Minnesota likewise found lower rates of increase in youth tobacco use in cities with flavored tobacco restrictions compared to those without (17).

Opponents of flavor restrictions have used a study by Friedman (18) to support their unfounded claim that a ban on flavored tobacco product sales would increase youth cigarette use. However, this study had serious methodological flaws that diminish its conclusions and relevance to this product standard. In this study, Friedman (18) examined changes in smoking
rates among high school students in San Francisco before and after a ban on all flavored tobacco using data from the 2011-2019 Youth Risk Behavior Surveillance System (YRBSS), finding that youth cigarette use increased after the ban. However, the study used a single post-policy data point (19, 20) that was collected prior to enforcement of the flavored tobacco sales restriction (21). Therefore, the study was, in reality, unable to evaluate the impact of the policy on youth combustible use using that data source. Moreover, the study failed to examine electronic cigarette use and other products that are likely to have confounded the analysis (19, 20, 22). A more rigorous study of Oakland, in which survey data were collected after enforcement of the flavored tobacco ban, found that, in fact, youth vaping and cigarette use declined (21).

**B. Flavored cigars disproportionately impact minoritized communities, especially non-Hispanic African-American/Black individuals. The product standard will improve tobacco-related health equity.**

A ban on characterizing flavors in cigars would have a significant beneficial impact on minoritized communities, especially Non-Hispanic (NH) African-American/Black individuals. Because enforcement efforts would focus on manufacturers, producers, and retailers, and not on individual consumers, it is unlikely to unfairly target these communities, and, in fact, will be of great health benefit to these communities. Our position is supported by three bodies of scientific evidence:

First, cigar use is more prevalent among individuals from racially/ethnically minoritized backgrounds and socioeconomically disadvantaged groups (23, 24). One study using the nationally representative National Survey on Drug Use and Health found that, while cigar use declined among NH White and Hispanic/Latinx individuals from 2002-2016, prevalence did not change among NH African-American/Black individuals and other NH racially minoritized groups, and in fact increased among NH African-American/Black women (25). African-American/Black youth are more likely to initiate tobacco with cigars than NH White youth (26), and the prevalence of current cigar use is highest among Native Hawaiian/Other Pacific Islander youth, followed by American Indian/Alaskan Native (AI/AN) youth, and African-American/Black youth (27). Cigar smoking patterns also appear to be more advanced in racially/ethnically minoritized groups. Compared to NH White adults, NH African-American/Black adults are more likely to smoke cigars daily and to be established cigar smokers, and Hispanic/Latinx adults are more likely to smoke cigars within 30 minutes of waking (23). The evidence to date has also shown a higher prevalence of cigar smoking among sexual minority individuals, particularly among women (28-30). Characterizing flavors are a significant reason for these disparities. Multiple studies have found that racially/ethnically minoritized individuals are more likely to prefer and choose flavored cigars and other flavored tobacco (4, 31-33). The prevalence of flavored cigar
smoking is also higher among those with lower levels of education and wealth and who identify as an individual from a sexual minority group (33), further leading to disparities for these groups.

Second, current evidence suggests disparities in the marketing of flavored cigars, as described in tobacco industry reports that highlight the targeting of specific populations, such as women, low-income individuals, and African-American/Black individuals (13). For example, the Al Capone brand of flavored cigarillos has sponsored rap battles to promote its products among African-American/Black young people, similar to the 2004 Kool Mixx cigarette campaign (34)—a campaign for which R.J. Reynolds Tobacco Co. entered into a settlement agreement with three State Attorneys General for alleged violations of the Master Settlement Agreement (MSA). However, restrictions on cigarette brand music sponsorship, such as those in the MSA and FDA’s regulations, do not exist for cigars (35). Several expert reviews have causally linked marketing exposure with tobacco use (36-39). Cigars are also more available in minoritized communities. In one study of Washington, D.C. retailers, cigars were more available and cheaper, and external advertising of cigars was greater, in neighborhoods with African-American/Black residents and young adults (40). Nearly all of the retailers selling cigars sold flavored cigars (40). A study in Los Angeles found similar patterns of excess advertising for cigars (including flavored cigars) in African-American/Black, Hispanic/Latinx, and Korean American communities (41). Differential availability and advertising exposure of flavored cigars are likely to increase tobacco use disparities.

Third, evidence from local and state policies also support the significant, positive impact that the characterizing flavor standard will have on health equity. For example, as a result of California’s local flavored ordinances, African-American/Black residents were covered by flavored tobacco sales restrictions at a rate higher than the state’s general population (42). Given the evidence that state and local flavor policies are associated with decreased product availability and use, this enhanced coverage is likely to help combat decades of targeted marketing to these communities, and reduce the significant disparity seen in cigar use by racial/ethnic minoritized groups. Similarly, uniform coverage nationwide under the proposed standard is also likely to close the disparity rates in product use among communities of color and other population groups that currently bear a disproportionate burden of the flavored tobacco problem.

C. The standard should be applied to all retailers, with no exemptions.

The characterizing flavor standard should be applied to all retailers, including online vendors, on-demand delivery, and cigar-only or adult-only shops. Exempting any retailer types would lead to loopholes that could undermine the effectiveness of the rule and increase disparities.
The evidence clearly shows that the tobacco industry has previously used loopholes to circumvent and reduce the effectiveness of regulation. For example, from 2018-2020 Oakland, CA, banned flavored tobacco products, while exempting 8% of retailers. Researchers collected cigar wrappers during that time period, and found that more than half of the sample was flavored, suggesting that the partial ban had limited effectiveness (43).

Moreover, flavored cigars were more likely to be found in African-American/Black neighborhoods than NH White neighborhoods after the partial ban (43), suggesting the significance of retailer exemptions for tobacco-related health equity. An analysis of retailer-based exemptions to flavored tobacco sales restrictions in the US found that exemptions for liquor stores and tobacco “adult only” retailers would likely lead to greater availability of flavored tobacco products in urban areas where racial/ethnic minoritized groups reside (44). In locales like Duluth, MN, for example, exemptions for “adult-only” smoke shops led to convenience stores renovating their spaces to open smoke shops in order to circumvent the sales restriction (45, 46). Furthermore, online and on-demand delivery of tobacco products are particularly difficult for local and state governments to regulate (47), and provide easy access to underage youth (48, 49). FDA is best positioned to prevent retailer exemptions from becoming massive loopholes that minimize the intended benefits of the rule. Thus, FDA should ensure the product standard applies to all retailers.

D. The new characterizing flavors standard should be applied to all flavors (except tobacco) and all cigars, with no exceptions for “adult-appealing” flavors or “premium” cigars.

We agree with FDA’s proposal that the product’s characterizing flavor should be determined by the presence and amount of various artificial or natural flavor additives, compounds, constituents, or ingredients; multisensory experience; explicit or implicit flavor representations on the packaging, labeling, or advertising; and any other means to represent a flavor other than tobacco. These factors cover the range of ways both manufacturers intend to convey to consumers, and consumers comprehend, products to be flavored. Together, they also clearly build on challenges experienced enforcing flavor sales restrictions at the state and local level and avoid loopholes that have been exploited by the tobacco industry elsewhere.

Cigars with ambiguous flavor descriptors such as ‘Jazz’ (also referred to as ‘concept’ flavors) are enormously popular in the US and have increased in popularity, especially for cigarillos (50, 51). After a sales restriction on flavored cigars in Providence, Rhode Island, explicit-named flavor sales declined by 93%, but ‘concept’ flavored cigar sales increased by 74% (52). After Canada banned flavored small cigars (except menthol) in 2009, manufacturers relabeled the packages from flavor descriptors to color descriptors (such as blue), potentially to convey the impression of flavors without violating the law (53). In New York City, tobacco products that were relabeled with ambiguous descriptors on their packaging still had significant
levels of flavor chemicals after the 2009 flavor ban (54). In a study of cigar advertising near schools, ads with ambiguous flavors were more likely to feature implicit health claims and sensory descriptors (55). These studies illustrate the importance of not just regulating the levels of flavor chemicals in tobacco products or explicit flavor names on product packaging, labeling, and advertising, but also other ways that flavor representations can be implied (e.g., use of blue or green packaging with the descriptor “ice” or “mellow”) or made explicit (e.g., consistent consumer reviews that an ambiguously labeled product has a distinct tropical fruit flavor).

We also support the rule applying to all products meeting the definition of a cigar – with no exceptions for “premium” cigars. The FDA’s current definition of “premium” cigars includes that they cannot have a characterizing flavor other than tobacco. This standard should continue to be applied. Historically, the tobacco industry has used exempted products as a loophole for flavor bans (56). For example, when flavors other than menthol were banned from cigarettes in the US, Kretek International reformulated their Djarum clove cigarettes into Djarum clove cigars in order to circumvent the ban, and sales of the cigars increased by more than 1400% from 2009 to 2012 (57). Avoiding these potential loopholes in the final flavor standard is important for the rule to have its intended effect and will more fully protect public health.

E. We support the inclusion of all ‘components’ and ‘parts’ that could add characterizing flavors to cigars, including, but not limited to, blunt wraps, drops, capsules, filter tips, roll-your-own tobacco, and flavor cards.

The ban on menthol flavoring in other countries illustrates the importance of a wide definition of components and parts that could add flavoring to cigars, thereby circumventing the flavor ban. In Canada, flavor cards and menthol drops—which add menthol flavor to products—became available after the 2017 ban on menthol. The percentage of pre-ban daily menthol smokers using additives increased from 4% pre-ban to 15% post-ban (58). Roll-your-own filter tips were also developed to provide menthol flavoring in order to circumvent menthol cigarette regulation (59). Moreover, regulations that are not fully inclusive of all flavor additive products can cause confusion, leading to low retailer compliance. For example, in a study of California localities that have banned flavored tobacco, Andersen-Rodgers, et al. (42) found that retailer compliance with prohibited flavored cigarillos/cigar wraps appeared deficient, with over half of retailers selling cigarillos or cigar wraps with explicit flavor names or ambiguous names. Retailers noted uncertainty about which products can be sold, which reduced compliance. The tobacco industry is extremely adept at undermining flavor bans, and so we encourage the FDA to make their definition of flavor-adding accessories as inclusive as possible.
F. The characterizing flavor policy will likely have few to no countervailing effects, including but not limited to: transition to unflavored combusted tobacco smoking, illicit trade, and cannabis co-use.

A product standard banning characterizing flavors in cigars is unlikely to produce countervailing effects that would outweigh the overall benefits of the ban, such as: (a) smokers transitioning to unflavored combusted tobacco use, (b) illicit trade, or (c) increased cannabis use or co-use.

After the 2017 ban on menthol in most tobacco products in Canada, sales data (60) and cohort (61) studies found that menthol smoking decreased and cessation increased among menthol smokers, with little substitution with unflavored combusted tobacco product use. A study examined changes in menthol and nonflavored cigarette sales in Massachusetts compared with sales in states without a flavor ban following Massachusetts’s statewide comprehensive flavor ban on all tobacco products in June 2020 (62). The study found that the flavor ban in Massachusetts was associated with a statistically significant decrease in state-level menthol cigarette sales. Although the study reported a small increase in nonflavored cigarettes, the analysis showed a significant decrease in overall cigarette sales in Massachusetts, demonstrating a net positive benefit in reducing cigarette sales and that substitution of nonflavored cigarettes did not fully offset reduced menthol cigarette sales. Another study confirmed the impact of the policy on reduced availability and use of flavored tobacco by youth (63). Gammon, et al. (64) examined sales in San Francisco before and after a comprehensive ban on all flavors (including menthol) in all tobacco products in all retailers, and compared it to San Jose and San Diego (which had no bans). Sales of all tobacco products (including flavored and non-flavored) tobacco products decreased at a greater rate in San Francisco (by 25%) from the period before to the period after implementation of the flavored tobacco policy compared with San Jose (8% decline) and San Diego (17% decline), suggesting that there was not a one-to-one substitution of the flavored to the unflavored products.

As noted by Schroth, et al. (65), the Tobacco Control Act gives the FDA authority to protect against the threat of illicit markets, such as the implementation of a track-and-trace program. If all characterizing flavors in cigars were banned in the US, producers would have to find new illicit sources. Schroth, et al. (65)’s analysis of the illicit market following a menthol cigarette ban applies to flavored cigars as well: “Illicit domestic production is likely to pose substantial financial and legal risks to the producers. Reliance on international sources is likely to increase the costs of evading US customs and other law enforcement authorities.” In other words, the significant financial and legal burden of domestic production and international importation will likely make a robust illicit marketplace prohibitive. Indeed, one study with cigarette smokers suggests that they would be unlikely to purchase illicit tobacco products that were too costly, poor quality, or inconvenient to buy (66). Following the 2015 ban on menthol cigarette sales in Nova Scotia, the
number of illicit cigarettes did not surge (67). Overall, illicit trade in flavored cigars is unlikely to be significant.

Because co-use of cigars and cannabis (including blunts) is popular in the US, especially among African-American/Black individuals, youth, and young adults (68-71), there may be concerns about the impact of a flavored cigar ban on cannabis use. The currently available research suggests that a ban on characterizing flavors in cigars would not have a negative impact on cannabis use. In one unpublished study that is currently under review, Glasser, et al. (72) found that young adult cigarillo smokers who live in an area where flavored cigarillos are banned were less likely to use cannabis in the past 30 days than those who live in an area without a ban. Thus, current evidence suggests that increased cannabis use or co-use with tobacco will not substantially occur.

G. SRNT strongly supports that nothing in the final rule should preempt states/localities from applying more comprehensive restrictions on flavored tobacco products.

Preemption would impede states and localities from enacting more stringent regulations to meet the needs of their communities, but the Tobacco Control Act expressly allows states and localities to implement their own sales and distribution policies on flavored tobacco products, including cigars. State and local policies can also inform federal tobacco control efforts. Indeed, the FDA’s analysis for the proposed rule has relied on evaluation studies from US localities that have already implemented flavored tobacco policies. Thus, the FDA’s implementing regulations should avoid restricting state/local authority to more stringently regulate the sale and distribution of flavored tobacco products.
Consistent with the above key points, SRNT makes the following **recommendations** for implementation and expansion of the rule:

1. The FDA should establish a tobacco product standard addressing flavors in all combusted tobacco products intended to be smoked, including hookah/waterpipe, pipe tobacco, and other combusted tobacco.

   While cigarettes and cigars are currently the two most popular combusted tobacco products in the US, the FDA should extend product standards to other combustibles including hookah (waterpipe), pipe tobacco, and all combusted tobacco. These other combusted products are toxic when used as intended, and could become substitutes if they continue to be sold with flavors, similar to how use of menthol cigarettes, cigars, and pipes increased after the 2009 ban on flavored cigarettes (73). The tobacco industry is adept at shifting product lines and marketing to respond to changes in the policy environment. For example, when clove was banned as a cigarette flavoring, Kretek International developed clove “cigars,” with sales increasing 1400% from 2009 to 2012 (57).

   After cigars and cigarettes, hookah may be the next most important product for flavor restriction or elimination to protect youth. Hookah use is prevalent among high school youth (7.8% past year use) and young adults (12.3% past year use) (74). Hookah tobacco smokers inhale high amounts of toxicants that cause tobacco-related diseases, including respiratory diseases, cardiovascular disease, and cancer (75). Toxicant content per hookah session is at least comparable to that of a cigarette, and for many toxicants is several magnitudes of order higher (75, 76). The introduction of flavored hookah tobacco is considered a major reason for the global resurgence of hookah smoking due to its attractiveness to youth and young adults, mass marketing, and improved variety and availability (77). A clinical study found that smoking flavored hookah was associated with lower harm perception compared with non-flavored hookah (78). Hookah use can also lead to nicotine addiction, and studies have found that initial exposure to hookah during adolescence is associated with cigarette smoking in the future (79). Hookah smoking can also contribute to disparities in tobacco use. A study of PATH data found that Hispanic/Latinx and African-American/Black people were approximately two times more likely to initiate and progress from hookah use to cigarettes than NH White people among both adolescents and young adults (80).
2. The FDA should extend the characterizing flavor standard to smokeless tobacco, such as snuff, spit, and chew.

Having a comprehensive flavor standard apply to smokeless tobacco (including chewing tobacco, snuff, and dip) is necessary to address the negative impacts of characterizing flavors in all tobacco products on public health. According to 2021 NYTS data, 70% of youth who currently used smokeless tobacco used flavored product (3). An analysis of tobacco industry documents found that characterizing flavors were used to attract young and inexperienced individuals to smokeless tobacco by evoking a perception of mildness, masking the strong tobacco taste and unpleasant mouth feel, and modifying nicotine delivery by affecting the product’s pH (81). Smokeless tobacco is highly addictive, increases the risk of subsequent cigarette smoking, contains carcinogenic chemicals, and poses reproductive and developmental risks (82). The expansion of the characterizing flavor ban to these products may have a significant positive impact on health by reducing appeal to young people and decreasing initiation of tobacco use.

Local comprehensive flavored tobacco sales restrictions that include smokeless/spit/chew tobacco have been implemented successfully in local jurisdictions, including California (64, 83), and New York (84, 85), with high levels of compliance among retailers, and led to reduced smokeless tobacco sales. Gammon, et al. (64) evaluated the impact of San Francisco’s comprehensive restriction on all flavored tobacco sales (including all flavors, all products, and all retailers) on changes in tobacco sales, including smokeless tobacco, in San Francisco and in two comparison California cities without any sales restriction (San Diego and San Jose). Total sales of smokeless tobacco decreased by 37% and sales of flavored smokeless tobacco decreased by 97% in San Francisco from the period before to the period after implementation of the flavored tobacco policy compared with San Jose (total: 10% decline, flavored: 3% decline) and San Diego (total: 4% decline, flavored: 3% increase). In New York City, sales of flavored smokeless tobacco products declined by nearly 98% following implementation of the policy (85).

Collectively, these findings indicate that a flavor ban that includes smokeless products will likely prevent many youth from becoming addicted to tobacco compared with more limited flavor restrictions on cigars and menthol cigarettes alone.
3. To minimize potential countervailing effects and enhance the effectiveness of the characterizing flavors standard, we recommend that the standard be combined with the following:

(a) Enhanced market surveillance and restrictions on marketing

(b) A retailer and public education campaign and promotion of cessation services

(c) An infrastructure to rapidly monitor, test, and enforce penalties on illegal trade, in order to minimize the effects of an illicit market.

A robust market surveillance system with marketing restrictions will help to ensure that the final rule has the intended effect and will more fully protect public health. Evidence from other countries as well as US localities shows that the industry uses product innovation and marketing tactics to circumvent flavored restriction policies. As described in Sections D and E above, the industry has responded to flavor bans with innovations in products and accessories to add flavors and to change packaging and labeling to convey flavors. Consequently, the FDA’s implementation of the flavored cigar ban should ensure that post-policy surveillance is in place to monitor tobacco industry behavior and consumer perceptions of substitutes, including but not limited to: repackaging, label changes, descriptor changes, accessories to add flavors, advertisements, and product reformulation. The FDA should be prepared to quickly intervene and enforce against industry tactics.

FDA should ensure that all retailers receive education on the new regulation and conduct enforcement with fines and penalties for violations including no-tobacco-sales orders of sufficient magnitude and regularity to ensure that retailers who are violating the policy are addressed as quickly as possible. Retailer education as well as compliance monitoring and enforcement will be critical for effective implementation. Local and state policies can enhance federal tobacco control efforts by providing additional monitoring and enforcement efforts in areas of greatest need. Additionally, we urge the FDA to use all other tools at its disposal to support quitting among flavored cigar smokers so as to maximize the product standard’s likely benefit of increased cessation. This includes actions through FDA’s public education programs, partnerships, and authority to authorize drugs such as cessation medications and smoking cessation products. We encourage FDA to ensure that they pair the implementation of the rule with effective cessation messaging, free access to NRT, and cessation medication, and tailored cessation programming to different communities most affected by a flavored cigar ban. Furthermore, we urge the FDA to ensure that all partners across and beyond the Federal government and the FDA are primed and ready to support and engage flavored cigar smokers to quit when the ban is implemented (86).
As discussed in Section F, the evidence shows that a post-ban illicit market is unlikely to be significant. However, several interventions have been recommended by the National Research Council to decrease the illicit market, such as enhanced track-and-trace systems and enforcement efforts (87). Investment in these measures and coordination with enforcement agencies are key to the success of the product standard.

4. The FDA should minimize sell-off dates

Every day, new people are experimenting with and becoming addicted to cigars, especially youth, young adults, African-American/Black individuals, and other minoritized groups. As we have already described, flavorings in cigars play an enormous role in initiation, use, and addiction. An estimated 5.6 million young people alive today will die prematurely from tobacco (88). The longer the FDA waits to implement and enforce the rule, the more lives will be lost.

The proposed effective date is one year after the final rule has been issued, and we advise that no additional time should be granted. A year is more than sufficient for public and retailer education, retailers to sell-off their supplies, enforcement agencies to conduct warning visits, and coordination of the key players (89). We argue that too long of a grace period risks the loss of momentum and public interest, increasing the difficulty of implementation and enforcement, and continued public health risks from flavored cigar use. Additionally, the experience from the United Kingdom with its menthol ban is that the tobacco industry used the grace period to prolong and increase menthol sales, rather than to prepare for the menthol ban (59). Therefore, in the interests of public health, we recommend the minimization of sell-off dates.

5. No further extensions of the comment period

All interested parties have had years to comment on a flavored cigar product standard, including a prior comment period on an Advanced Notice of Proposed Rulemaking for flavored tobacco products in 2018. The FDA has already extended the comment period to 90 days. No additional extension to the comment period should be granted beyond August 2, 2022.

Overall, the science of characterizing flavors in cigars and other tobacco products is clear. A ban on flavored cigars is both appropriate for the protection of public health and is long overdue given the strength and consistency of the evidence-base contributed to by many of our members over many years. **SRNT strongly supports FDA in swiftly issuing and enforcing a final rule banning flavored cigars.** This policy will save lives and reduce the disproportionate burden of tobacco on our underserved and minoritized communities.

We thank you for consideration of our comments and recommendations.
References Cited:


2. FDA. Scientific assessment of the impact of flavors in cigar products. Silver Spring, MD: HHS, FDA, Center for Tobacco Products; 2022.


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