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**Docket Nos. FDA-2021-N-1309 and 2021-N-1349**

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COMMENTS

of

**WASHINGTON LEGAL FOUNDATION**

to the

**FOOD AND DRUG ADMINISTRATION**

Concerning

**TOBACCO PRODUCT STANDARD FOR CHARACTERIZING  
FLAVORS IN CIGARS and TOBACCO PRODUCT  
STANDARD FOR MENTHOL IN CIGARETTES**

IN RESPONSE TO THE PROPOSED RULES PUBLISHED AT  
87 FED. REG. 26,396 and 87 FED. REG. 26,454 ON MAY 4, 2022

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July 6, 2022

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July 6, 2022

**Submitted via regulations.gov**

Dr. Robert Califf  
Commissioner of Food and Drugs  
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**Re: Comment On Proposed Rules Banning Flavored Cigars  
And Menthol Cigarettes**

Dr. Califf:

Washington Legal Foundation submits this comment responding to the Food and Drug Administration's Proposed Rules about flavor guidelines for tobacco products. Banning menthol cigarettes and flavored cigars will not significantly decrease smoking rates among adults and children. Rather, alternative and illegal products will meet current demands. This means that those who prefer menthol cigarettes and flavored cigars will see their health deteriorate as they turn to less safe options. As a result, the FDA should withdraw the Proposed Rules and maintain the status quo.

**I. WLF's Interests**

WLF is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, WLF's Litigation Division submits amicus briefs on matters related to the FDA's regulation of tobacco products.<sup>1</sup> Similarly, WLF's Legal Studies Division publishes papers by outside experts analyzing the FDA's approach to modified risk tobacco products.<sup>2</sup>

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<sup>1</sup> See, e.g., *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

<sup>2</sup> See Azim Chowdhury & Adam M. Susser, *Implementing the Continuum of Risks: Modified Risk Tobacco Products*, WLF LEGAL OPINION LETTER (Oct. 19, 2018); Joel Kurtzberg et al., *FDA's First Amendment Blindspot Widens with Overzealous Interpretation of Modified-Risk Tobacco Regulation*, WLF LEGAL OPINION LETTER (July 16, 2020).

This comment focuses on three areas where the FDA’s analysis is flawed. First, the regulations will spur creative workarounds by menthol cigarette and flavored cigar smokers. Second, the illegal market for restricted tobacco products will flourish. Finally, the bans will have a disproportionate effect on historically marginalized groups. In total, the negative outcomes following these bans will far outweigh the positives.

## **II. The FDA’s Approach Will Mainly Inconvenience—Not Reduce—Consumption.**

Flavor and menthol bans will inspire most smokers to try different tobacco products, not quit. When the European Union banned menthol cigarettes, 40% continued smoking non-menthol varieties and 13% acquired menthol cigarettes from “other sources.”<sup>3</sup> Only 8% ceased smoking.<sup>4</sup> The Proposed Rules don’t explain why the reaction to the bans on this side of the Atlantic will be different. And for good reason.

Past flavor bans in America haven’t reduced tobacco consumption. After Massachusetts banned menthol cigarettes in 2020, nearly \$140 million in sales migrated to neighboring states.<sup>5</sup> Cigarette sales across New England increased despite predictions that they would decrease.<sup>6</sup> A nationwide ban will yield similar results. Many countries in Asia and South America still have thriving markets for flavored cigarettes and cigars. Without the threat of prosecution for possession, Americans will freely obtain cigars and cigarettes from other countries and bring them into the U.S.

The FDA also exaggerates the role flavors play in youth initiation. When asked why they smoked e-cigarettes, “75 percent of young people cited reasons

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<sup>3</sup> David Janazzo, *EU Menthol Cigarette Ban Survey*, Found. for a Smoke-Free World (Jan. 28, 2021), <https://bit.ly/3tCOQWM>.

<sup>4</sup> Janazzo, *supra* note 3.

<sup>5</sup> Guy Bentley, *Maine Should Learn from Massachusetts’ Failed Flavored Tobacco Ban*, Reason Found. (June 7, 2021), <https://bit.ly/3xW75J1>.

<sup>6</sup> Karl Abramson, *Massachusetts’ Flavor Ban Fiasco Is Costing the State Millions in Tax Revenue*, Ams. for Tax Reform (May 4, 2021), <https://bit.ly/3QC7Puq>.

other than flavors.”<sup>7</sup> Similarly, after Canada banned menthol cigarettes, most adolescent smokers switched to unflavored varieties.<sup>8</sup> These statistics show that flavors are a supplement to—not a prerequisite for—adolescent smoking. Eliminating flavored products while leaving available similar alternatives will barely dent youth smoking rates.

Further, if adults continue smoking, so will adolescents. Adolescent initiation is strongly correlated with parental smoking.<sup>9</sup> Because “ensuring other products are on the market to serve as less harmful alternatives to menthol cigarettes or flavored cigars isn’t part of the FDA’s mandate[s],”<sup>10</sup> adults will struggle to curtail their smoking habits. This means that young adults will continue mirroring adults’ habits, and neither group will benefit from the bans.

### **III. Underground Sales of Tobacco Will Increase While Tax Revenue Decreases.**

Obtaining menthol cigarettes from other countries will not be the only way to circumvent the bans. Illegal distributors will easily satisfy the demand for flavored cigars and cigarettes. The current FDA proposals penalize black-market sellers and manufacturers with small fines. This minor slap on the wrist will not discourage participation in an illegal market. Rather, those who face jail time if caught selling illegal drugs will begin selling illegal flavored cigars and cigarettes. When that does not satisfy the demand, new vendors will enter the market. In short, purchasing illegal products will be far easier than quitting smoking.

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<sup>7</sup> Bentley, *supra* note 5.

<sup>8</sup> *Flavoured and Menthol Tobacco*, Tobacco Tactics (May 27, 2022), <https://bit.ly/3N0yBJE>.

<sup>9</sup> See Joana Alves et al., *The Role of Parental Smoking on Adolescent Smoking and Its Social Patterning: A Cross-Sectional Survey in Six European Cities*, 39 J. of Pub. Health 339, 341-42 (2017); Mike Vuolo & Jeremy Staff, *Parent and Child Cigarette Use: A Longitudinal, Multigenerational Study*, 132 Pediatrics e568, e573-74 (2013), <https://bit.ly/3nqwdBL>.

<sup>10</sup> Celine Castronuovo, *Menthol Ban Opens Door for FDA to Flex Power Over Big Tobacco*, Bloomberg Law (May 11, 2022), <https://bit.ly/3N6GhdK>.

Further, when the illegal tobacco market grows, states suffer from a decrease in tax revenue. For example, after Massachusetts' ban, tax revenue decreased by \$50 million in six months.<sup>11</sup> To make matters worse, Massachusetts had used that revenue to fund tobacco prevention programs.<sup>12</sup> So when sales shifted to other states, it was "stuck with the costs associated with tobacco consumption, but without the revenue from taxing tobacco."<sup>13</sup>

Under the Proposed Rules, this will happen nationwide. States will experience a combined revenue loss of \$4.7 billion.<sup>14</sup> Moreover, because of underground sales, the decrease in tax revenue will not come with a proportional decrease in smoking rates. Instead, states will be left without sufficient funds to mitigate the harms caused by the illegal market. Additionally, roughly 500,000 Americans will lose their jobs<sup>15</sup> to illegal manufacturers and distributors.

History also shows that the FDA will not properly monitor underground sales. For instance, three years have passed since the FDA first proposed regulating flavored e-cigarettes.<sup>16</sup> Yet the FDA is only now reviewing many top manufacturers' products.<sup>17</sup> If the FDA cannot timely monitor legal sales, it will fail to regulate the harder-to-trace illegal sales.

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<sup>11</sup> Ulrik Boesen, *Massachusetts Flavored Tobacco Ban Has Severe Impact on Tax Revenue*, Tax Found. (Jan. 19, 2021), <https://bit.ly/3xwIzgg>.

<sup>12</sup> Abramson, *supra* note 6.

<sup>13</sup> Ulrik Boesen, *Federal Menthol Cigarette Ban May Cost Governments \$6.6 Billion*, Tax Found. (Mar. 2, 2022), <https://bit.ly/3mSXcFE>.

<sup>14</sup> Boesen, *supra* note 13.

<sup>15</sup> Andrew Cheyne et al., *The Debate on Regulating Menthol Cigarettes: Closing a Dangerous Loophole vs Freedom of Choice*, 104 Am. J. of Pub. Health e54, e58 (2014), <https://bit.ly/3uafW7C>.

<sup>16</sup> U.S. Food & Drug Admin., *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry* (2020).

<sup>17</sup> See Dennis Thompson, *Flavored Vapes Still in Stores Despite Federal Ban*, WebMD (Dec. 28, 2021), <https://wb.md/3xwmLRR>; see, e.g., Press Release, FDA, FDA Denies Authorization to Market JUUL Products (June 23, 2022).

This increase in illegal sales will also have a disproportionate effect on youth smoking because “criminal markets . . . ignore minimum age laws.”<sup>18</sup> Minimum age laws normally deter youth tobacco use. Because illegal sellers won’t “ask the young smoker to present identification . . . at the door of a vehicle,”<sup>19</sup> tobacco products will become much more accessible to youth.

#### **IV. The Effects Of The FDA’s Regulations Will Be Felt Mainly By Marginalized People.**

The Proposed Rules show that the current administration’s commitment to serving marginalized groups has been inconsistent. In one breath, President Biden ordered agencies to rework rules that disproportionately burdened people of color.<sup>20</sup> In the next, the FDA proposed criminalizing the distribution of tobacco products favored by marginalized groups. Either the left hand didn’t know what the right was doing, or the FDA ignored the downstream effects of its Proposed Rules.

The downstream effects will be numerous. Menthol smokers who switch to unflavored or handmade cigarettes will not see improved health. Like in the EU, those who decrease their consumption of menthol cigarettes will continue or increase their consumption of nonmenthol cigarettes.<sup>21</sup> The impacts on those who switch to illegal flavored products will be even more extreme. Given the small chance of enforcement against illegal sales, there will be little motivation for sellers of illicit products to comply with FDA requirements. Unregulated cigars and cigarettes will then carry unknown health risks. As the FDA acknowledges, LGBT, Black, Hispanic, and female smokers prefer flavored tobacco. As a result, they will bear a disproportionate amount of those risks.

Migration to popular flavored alternatives will also hurt marginalized groups. Although often perceived as safer than cigars and cigarettes, waterpipe (hookah) smoking is at least as damaging. “[D]epending on which chemicals are used for comparison, carcinogen exposures from a single hookah session

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<sup>18</sup> Castronuovo, *supra* note 10.

<sup>19</sup> Cheyne et al., *supra* note 15, at e58.

<sup>20</sup> Exec. Order No. 13985, 86 Fed. Reg. 7009 (Jan. 20, 2021).

<sup>21</sup> Janazzo, *supra* note 3.

have been estimated to be equivalent to smoking 10 to 50 cigarettes.”<sup>22</sup> The average smoker smokes 14 cigarettes a day,<sup>23</sup> so shifting to hookah will cause many to see increased carcinogen exposure.

Another alternative, adding menthol capsules or filters to unflavored cigarettes,<sup>24</sup> will also become more harmful than smoking manufactured menthol cigarettes. At-home “mentholization” accessories currently don’t adversely affect filtration.<sup>25</sup> However, the FDA will struggle to monitor the accessory market when it expands to serve growing demand. If trends in the U.S. mirror those in the EU, 13% of the 18.5 million American menthol smokers will begin mentholizing their own cigarettes after the ban. The FDA will not realistically be able to monitor unflavored tobacco products, illegal tobacco sales, and an accessory market serving 2.4 million Americans all at once. Accessories will likely fall through the cracks, and those who mentholize their own cigarettes will bear the consequences.

Further, smokers who switch to roll-your-own cigarettes and cigars will smoke more daily. Despite public opinion to the contrary, handmade cigarettes are “just as dangerous as ready-made ones.”<sup>26</sup> Because the perceived harm of tobacco products is correlated with cessation rates,<sup>27</sup> those who transition to

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<sup>22</sup> Yin Xiong et al., *Hookah Smoke Mediates Cancer-Associated Epigenomic and Transcriptomic Signatures in Human Respiratory Epithelial Cells*, 2 JTO Clinical and Rsch. Reps. 100181 (2021).

<sup>23</sup> Press Release, CDC, Smoking is Down, But Almost 38 Million Adults Still Smoke (Jan. 18, 2018).

<sup>24</sup> See generally Janazzo, *supra* note 3.

<sup>25</sup> Chrysanthi Dolka et al., *Menthol Addition to Cigarettes Using Breakable Capsules in the Filter*, 26 Chem. Res. Toxicology 1430, 1439 (2013).

<sup>26</sup> Jess Kirby, *Roll-Your-Own Cigarettes: How Dangerous Are They?*, Cancer Rsch. UK (July 7, 2009), <https://bit.ly/3OIJ8R2>.

<sup>27</sup> See generally Olusegun Owotomo et al., *Perceptions of the Harm and Addictiveness of Conventional Cigarette Smoking Among Adolescent E-Cigarette Users*, 62 J. Adolesc. Health 87 (2017); Thi Phuong Thao Tran et al., *Association Between Perceived Harm of Tobacco and Intention to Quit: A Cross-Sectional Analysis of the Vietnam Global Adult Tobacco Survey*, 22 BMC Pub. Health 909 (2022).

handmade cigars and cigarettes will find quitting even more difficult. Nor will the cost of handmade flavored cigars and menthol cigarettes deter tobacco use. Online retailers currently sell menthol cigarette capsules for 4¢ each, and cheap liquors and extracts can flavor cigars cost-effectively. With easy, inexpensive alternatives at their disposal, smokers will not opt to quit.

Because marginalized groups will largely switch to more harmful alternatives instead of quitting, it's unclear who these bans will serve. At best, the Proposed Rules disregard the negative externalities they will cause. At worst, they suggest that some "Americans have no agency in . . . their cigarette consumption and inevitably need protection from the state."<sup>28</sup> No matter what, for underserved communities, these bans will be "the absolute wrong move at the absolute wrong time in our history."<sup>29</sup>

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Across the board, the FDA's prohibitions will exacerbate many smoking-related dangers. Adult cessation rates will be nominal and adolescents will keep experimenting with smoking. The continued demand for flavored tobacco products will also push sales into the unregulated illegal market. Finally, switching to more harmful and illegal products will widen existing health disparities nationwide. Because of these long-term effects, WLF urges the FDA to reconsider the Proposed Rules.

Respectfully submitted,

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<sup>28</sup> Alys Watson Brown, *Banning Menthol Cigs Is the Wrong Way to Go About Curbing Smoking*, Ctr. Square (May 31, 2022), <https://bit.ly/3NYS6DL>.

<sup>29</sup> Helen Redmond, *Why a Menthol Cigarette Ban Cannot Be the Answer*, Filter Mag, (June 9, 2021), <https://bit.ly/3zGkoPa>.