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Dockets Management Staff (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

**Re:** Docket No. FDA-2021-N-1349 for "Tobacco Product Standard for Menthol in Cigarettes" and Docket No. FDA-2021-N-1309 "Tobacco Product Standard for Characterizing Flavors in Cigars"

# To Whom It May Concern:

The R Street Institute (R Street) respectfully submits comments on the proposed tobacco product standards for menthol in cigarettes and characterizing flavors in cigars. R Street is a nonprofit, nonpartisan public policy organization focused on advancing limited, effective government in a variety of areas, including Integrated Harm Reduction and Criminal Justice and Civil Liberties. A foundational component of our work is a belief that health policy grounded in harm reduction has the potential to drastically reduce the negative consequences associated with various harmful behaviors while significantly relieving the burden of cost to the healthcare system. Additionally, overcriminalizing risky behavior creates racial disparities and misuses the resources in our justice and carceral system. Our overall strategy stems from a simple insight that is well supported by decades of research and experience: abstinence-only approaches do not work at a population-level for any type of risky behavior. Policies that try to restrict behaviors, such as smoking, via prohibition and criminalization, are followed by various unintended negative consequences, as is detailed in these comments.

To understand the potential impacts of a national menthol ban, it is important to look at the lessons learned by our northern neighbors as menthol cigarettes have been banned in Canada since late 2017. A 2016-2018 study evaluating the impact of that ban found that "59.1% of pre-ban menthol smokers switched to non-menthol cigarettes; 21.5% quit smoking and 19.5% still smoked menthols, primarily purchased from First Nations reserves." The vast majority—78.6 percent—of menthol smokers

<sup>&</sup>lt;sup>1</sup> Wilson, David P. Wilson et al., "The cost-effectiveness of harm reduction," *International Journal of Drug Policy* 26 (2015), pp. S5-S11. http://optimamodel.com/pubs/Wilson%202015%20Harm%20Reduction.pdf.

<sup>&</sup>lt;sup>2</sup> Janet Chung-Hall et al., "Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: longitudinal findings from the Canadian arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys," *Tobacco Control* 31:4 (2021), pp. 556-563.

https://tobaccocontrol.bmj.com/content/early/2021/03/31/tobaccocontrol-2020-056259.

continued to smoke.<sup>3</sup> The study estimates that, in the United States, where there are about 19 million menthol smokers, a ban could spur over 900,000 people to quit, including over 200,000 Black Americans. These findings are on the conservative end of the analysis completed by the Food & Drug Administration (FDA) in support of the proposed rule. That in and of itself would be a success by any public health metric utilized in the assessment of population health, but only if we are able to isolate that outcome without stimulating an illicit market and overcriminalizing a portion of the 78 percent that continue to smoke. From a public health perspective, the less people that are using deadly combustible tobacco products, the better. However, even with noble intentions in health policy, there are a number of blind spots policymakers would be wise to consider in pursuit of a menthol ban, including: illicit markets, overcriminalization, and inconsistent tobacco messaging.

#### I. Illicit Markets

Previously, the FDA asked the National Research Council (NRC) and the Institute of Medicine (IOM) to assess the international illicit tobacco market, including variations by country; the effects of various policy mechanisms on the market; and the applicability of international experiences to the United States. According to the report:

The worldwide illicit tobacco trade comprises four main schemes: bootlegging, large-scale smuggling, illicit whites, and illegal production . . . large-scale international smuggling, counterfeit cigarettes, and "illicit whites"—cigarettes legally produced under unique brand names or no brand name—which are prevalent in many other countries, are largely absent from the U.S. market.<sup>4</sup>

Illicit cigarette sales in the United States range from 1.24 to 2.91 billion packs of cigarettes annually and account for between 8.5 percent and 21 percent of the total tobacco market; however, the market is driven primarily by bootlegging between low-tax and high-tax jurisdictions. Bootlegging is "the legal purchase of cigarettes in one jurisdiction and their consumption or resale in another, without the payment of applicable taxes or duties in the jurisdictions where they are resold. For example, when a flavor ban on tobacco products was enacted in Massachusetts in June 2020, evidence showed a decrease in the sale of tobacco products but failed to analyze cross-border sales. While Massachusetts experienced a decrease in flavored tobacco sales, New Hampshire and Rhode Island saw increases at nearly equivalent rates, suggesting that consumer purchasing behavior simply crossed state lines. While a federal ban might stem cross-state sales, it would not address bootlegging from sovereign nations, such as federal Indian reservations or Mexico, and may give rise to new types of illicit trade. There is cause for concern of the

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> National Research Council, *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*, (National Academies Press, 2015). <a href="https://doi.org/10.17226/19016">https://doi.org/10.17226/19016</a>.

<sup>&</sup>lt;sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> Samuel Asare et al., "Association of Cigarette Sales With Comprehensive Menthol Flavor Ban in Massachusetts," *JAMA Internal Medicine* 182:2 (2022), pp. 231-234. https://www.reginfo.gov/public/do/eoDownloadDocument?pubId=&eodoc=true&documentID=133892.

<sup>&</sup>lt;sup>8</sup> Ulrik Boesen, "Massachusetts Flavored Tobacco Ban: No Impact on New England Sales, Tax Foundation, Feb. 3, 2022. <a href="https://taxfoundation.org/massachusetts-flavored-tobacco-ban-sales-jama-study">https://taxfoundation.org/massachusetts-flavored-tobacco-ban-sales-jama-study</a>.

latter due to a recent report by *Milenio*, a Mexican newspaper, that details the ramping up of both production and sale of illegal cigarettes in Mexico through a group called the Tobacco Cartel.<sup>9</sup>

Further, the Canadian experience suggests that the vast majority of menthol smokers will switch to non-menthol cigarettes, obtain menthol cigarettes from illicit markets and/or mentholate their own tobacco products. Though research on menthol cigarettes has been limited to consumer surveys and short-term laboratory studies, the NRC and IOM's report states that "most smokers would consider legal alternatives, including switching to a non-mentholated cigarette or quitting. Some may choose some kind of self-mentholation technology if the option is available. Though illicit menthol cigarettes be unavailable, heavy menthol users may turn to self-mentholation practices if regulated substitutes, such as menthol or mint-flavored electronic nicotine delivery systems, are also banned. The concept of roll-your-own (RYO cigarettes) is not foreign to American consumers as they represent about 6.7 percent of smokers. When an individual is holding a RYO on the street, there is no visible difference between cannabis and tobacco. Consumers can purchase products to add menthol to non-menthol cigarettes, such as flavor sprays or menthol liquids and there are products on the market, such as mentholated filter tips or menthol-infused rolling paper. Policymakers would be wise to consider the consequences of alcohol prohibition in the United States, when, despite it being illegal, people continued to drink. Worse still, they drank despite the supply of alcohol becoming less safe.

The E-cigarette or Vaping Use-Associated Lung Injury (EVALI) outbreak of 2020 is a contemporary and adjacent example. EVALI cases started appearing in mid-2019, and by February 2020, the Centers for Disease Control and Prevention (CDC) recorded 2,807 cases of EVALI across all 50 U.S. states and two territories, including 68 deaths in 29 states and the District of Columbia. In November 2019, the CDC activated the Emergency Operations Center to investigate the outbreak and eventually diagnosed the root cause as vitamin E acetate in counterfeit tetrahydrocannabinol vape cartridges. This is a prime example of the unintended consequences that arise from policies rooted in prohibition, specifically the illegality of recreational cannabis, and magnifies the devastating impacts of such policies in terms of scope, severity, and speed for which illicit markets proliferate and wreak havoc. In an analysis conducted on state marijuana policies and EVALI, the authors concluded that "recreational marijuana laws predicted lower 2019 EVALI incidences." In fact, the differences were stark in the sense that "EVALI incidence was

<sup>&</sup>lt;sup>9</sup> Peter Appleby, "Jalisco Cartel Cashing in on Mexico's Illegal Cigarette Market," Insight Crime, June 8, 2022. https://insightcrime.org/news/jalisco-cartel-cashing-in-on-mexicos-illegal-cigarette-market

<sup>&</sup>lt;sup>10</sup> Ibid.

<sup>&</sup>lt;sup>11</sup> Ibid.

<sup>&</sup>lt;sup>12</sup> David Young et al., "Prevalence and attributes of roll-your-own smokers in the International Tobacco Control (ITC) Four Country Survey," *Tobacco Control* 15 (2006), pp.iii76-iii82. https://pubmed.ncbi.nlm.nih.gov/16754951.

<sup>&</sup>lt;sup>13</sup> Mark Thornton, "Alcohol Prohibition Was a Failure," CATO Institute, 1991. <a href="https://www.cato.org/policy-analysis/alcohol-prohibition-was-failure">https://www.cato.org/policy-analysis/alcohol-prohibition-was-failure</a>.

<sup>&</sup>lt;sup>14</sup> Lily Rothman, "The History of Poisoned Alcohol Includes an Unlikely Culprit: The U.S. Government," *TIME*, Jan. 14, 2015, https://time.com/3665643/deadly-drinking.

<sup>&</sup>lt;sup>15</sup> "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping Products," Centers for Disease Control and Prevention, Aug. 3, 2021. <a href="https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html#overview">https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html#overview</a>

<sup>&</sup>lt;sup>16</sup> Abigail S. Friedman and Meghan E. Morean, "State marijuana policies and vaping associated lung injuries in the US", *Drug and Alcohol Dependence* 228 (Nov. 1, 2021). <a href="https://doi.org/10.1016/j.drugalcdep.2021.109086">https://doi.org/10.1016/j.drugalcdep.2021.109086</a>.

42% lower in recreational marijuana states."<sup>17</sup> In this case, the prohibition of supply without intention to address demand resulted in needless deaths. This is not limited to vapes or cannabis but is also prevalent in the opioid crisis where the proliferation of ultra-potent fentanyl has made the nation's drug supply more dangerous. This phenomenon is widely cited in the academic literature, and is known as "the iron law of prohibition," where the interruption or suppression of illicit drug supply yields more compact substitutes.<sup>18</sup>

Regardless of the substance prohibited, the calculation of harms in Black and Brown communities associated with overcriminalization is immeasurable. Adding flavored tobacco to that list will only exacerbate inequalities regardless of whether the FDA proposes exclusive supply-side enforcement mechanisms.

#### II. Overcriminalization

In an FDA news release, the agency articulated that enforcement of the menthol ban would focus exclusively on manufacturers, distributors, wholesalers, importers and retailers, rather than on individual consumer possession or consumption.<sup>19</sup> Although this market-oriented enforcement approach sounds reasonable, the reality is that all 50 states treat unlicensed distribution and sale of banned tobacco products as a crime. In 44 of these states, the crime is classified as a felony. In 37 states, the crime is subject to mandatory minimum sentences and mere possession is treated as a crime. A coalition letter by the Law Enforcement Action Partnership, in conjunction with 20 organizations, including R Street, details the criminal justice ramifications of prohibition and calls attention to the unintended consequences of overcriminalization for "a product used by 18 million adults, particularly a product preferred by Black and Brown citizens," especially given "the web of criminal laws that compound the impact of any single arrest, prosecution, or conviction."<sup>20</sup> The letter states that menthol cigarette-related arrests have the very real possibility of not only prosecution, but intensified consequences that include multiplied prison terms under repeat offender statutes, immediate parole revocation, voter disenfranchisement, and possible deportation even for persons with legally issued visas. The ACLU joined in opposition when the ban was announced in 2020, writing that "our experience with alcohol, opioid, and cannabis prohibition teaches us that this is a policy disaster waiting to happen, with Black and other communities of color bearing the brunt."21

<sup>&</sup>lt;sup>17</sup> Ibid.

<sup>&</sup>lt;sup>18</sup> Leo Beletsky and Corey S. Davis, "Today's fentanyl crisis: Prohibition's Iron Law, revisited," *International Journal of Drug Policy* 46 (2017), pp. 156-159. https://doi.org/10.1016/j.drugpo.2017.05.050.

<sup>&</sup>lt;sup>19</sup> "FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers," U.S. Food and Drug Administration, April 29, 2021. <a href="https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers">https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers</a>.

<sup>&</sup>lt;sup>20</sup> "Coalition Concerns with Blanket Prohibition on Menthol and Other Flavored Tobacco within H.R. 2339, Reversing the Youth Tobacco Epidemic Act," ACLU, Feb. 27, 2020. <a href="https://www.aclu.org/letter/coalition-letter-criminal-justice-concerns-hr-2339-reversing-youth-tobacco-epidemic-act">https://www.aclu.org/letter/coalition-letter-criminal-justice-concerns-hr-2339-reversing-youth-tobacco-epidemic-act</a>.

<sup>21</sup> Ibid.

This concern is not unfounded. Public comments submitted by Mark J. Dannels, Sheriff of Cochise County in Arizona, echo these statements.<sup>22</sup> Sheriff Dannels writes that "this proposal is essentially an unfunded mandate for law enforcement—where it will shift responsibility for enforcement of the product to state, local, and federal law enforcement, but without the resources needed to deal with it."<sup>23</sup> The fact of the matter is that regardless of the FDAs guidance on enforcement, menthol cigarettes will be an illegal tobacco product that law enforcement officers will be required to police. Indeed, Sheriff Dannels goes on to say that

[When] confronted by an influx of illegal product, law enforcement would now become the menthol cigarette police, investigating and interdicting illicit domestic manufacturing, illegal smuggling at the borders . . . and at the ports, illicit distribution within and across state lines, and, ultimately, illicit sales in our communities.<sup>24</sup>

Unfortunately, there is not a recognized data set that details justifications for probable cause stops and seizures, particularly for Black and Brown communities. In the absence of that information, the FDA and the American public have only anecdotal evidence of overcriminalization concerns from which to operate.

In our collective memory are the events that unfolded in 2014 surrounding the killing of Eric Garner on Staten Island, largely precipitated by the selling of illegal tobacco. An article by the *New York Times* indicated that "plainclothes officers inside knew Mr. Garner well, mostly for selling untaxed cigarettes not far from the nearby Staten Island Ferry Terminal."<sup>25</sup> Taxes on cigarettes in New York are the highest in the United States, stimulating demand for an illicit market of cheaper cigarettes often sold individually, known as "loosies," for which Mr. Garner was initially apprehended. Since tobacco taxation is regressive, individuals with a lower socioeconomic status bear the brunt of such policies. It is perhaps unsurprising that the area of Bay Street and the park saw frequent sales of cheap cigarettes sold "individually at \$1 or less, rather than a whole pack for 10 times that," as it was "a poor and working-class area whose population swell[ed] each day with those bound for the welfare office across the street." Illicit markets do not consist exclusively of large distribution networks, but also include everyday Americans struggling to make ends meet that also happen to be addicted to cigarettes. In the absence of accessible reduced-risk products, their options are further narrowed.

Regulations that have the potential to increase the number of engagements between law enforcement and Black and Brown communities, especially during an era of acute issues involving race and policing, are at odds with improving the health and welfare of those same individuals. While every case may not resemble Eric Garner, it is not hard to imagine a situation in which a number of these additional interactions have poor results. Take for example, the violent arrests of six unarmed Black teenagers and

<sup>&</sup>lt;sup>22</sup> Mark J. Dannels, "Comment from Cochise County Sheriff's Office," U.S. Food & Drug Administration, 2022. https://www.regulations.gov/comment/FDA-2021-N-1349-47140.

<sup>&</sup>lt;sup>23</sup> Ibid.

<sup>&</sup>lt;sup>24</sup> Ibid.

<sup>&</sup>lt;sup>25</sup> Al Baker, et al., "Beyond the Chokehold: The Path to Eric Garner's Death," *The New York Times*, June 14, 2015. https://www.nytimes.com/2015/06/14/nyregion/eric-garner-police-chokehold-staten-island.html.

<sup>&</sup>lt;sup>26</sup> Ulrik Boesen, "Analysis of Federal Proposal to Increase Tobacco and Nicotine Products Taxes," Tax Foundation, Aug. 31, 2021. <a href="https://taxfoundation.org/federal-tobacco-tax-proposal">https://taxfoundation.org/federal-tobacco-tax-proposal</a>.

<sup>27</sup> Ibid.

tasing of one in Ocean City, Maryland, in June 2021. Police reported that the apprehension of one of the teenagers was to check ID because he was vaping and looked underage. One of the glaring omissions of the proposed rule is the lack of contributions or engagement from law enforcement and criminal justice professionals. In Sheriff Dannels' public comments, he states that the "FDA has taken none of the time needed to engage with the law enforcement community on this issue, despite us raising these concerns in the past," and was especially disappointed that there were no visible efforts "on the agency's part to bring law enforcement to the table to evaluate or even discuss the concerns we have raised." Dannels concludes as we do, that regulation, not full prohibition, is a better answer to keep both law enforcement and communities safe.

## **III.** Mixed Messages on Tobacco

In December 2021, the FDA quietly authorized the marketing and sale of two lower-nicotine combustible cigarettes, one of which was a menthol product.<sup>30</sup> By receiving the FDA's modified risk tobacco product (MRTP) designation, it represented "the first combusted cigarettes to be authorized and the second tobacco products overall to receive "exposure modification" orders, which allows them to be marketed as having a reduced level of, or presenting a reduced exposure to, a substance;" the products contain 95 percent less nicotine than traditional cigarettes. The public health rationale for lower-nicotine combustible cigarettes is that by reducing nicotine to non-addictive levels, people will find it easier to quit smoking. However, it is the combustion of tobacco that is most detrimental to health, not the nicotine concentration.<sup>31</sup> Essentially, the FDA is prohibiting a class of cigarettes from the market, yet approving the marketing and promotion of another class of cigarettes, including menthol. If the FDA ban aims to rectify health disparities among Black and Brown communities, one cannot help but wonder why the agency continues approving combustible flavored tobacco products – regardless of the nicotine content they contain.

Scientific researchers have found that multi-dimensional factors contribute to racial disparities in smoking cessation, and why Black Americans distrust the U.S. medical system. The authors reason that mistrust is "primarily a consequence of the medical community's historical bias toward addressing white Americans' health needs, often at the expense of Black Americans' health and well-being."<sup>32</sup> The authors set forth a number of novel interventions to address racial cessation disparities, including: mobile health apps, innovative pharmaceutical smoking cessation therapies, and culturally tailored modes of cognitive behavioral therapy.<sup>33</sup> What is most intriguing is the authors did not call for a flavored tobacco product ban to address disparities. It is unclear what the FDA has done to reduce racial smoking disparities aside from

<sup>&</sup>lt;sup>28</sup> Steve Thompson and Ovetta Wiggins, "Ocean City boardwalk: Violent arrests of unarmed young men raise questions about policing," *The Washington Post*, June 25, 2021. <a href="https://www.washingtonpost.com/dc-md-va/2021/06/25/ocean-city-maryland-police-vape-arrests">https://www.washingtonpost.com/dc-md-va/2021/06/25/ocean-city-maryland-police-vape-arrests</a>.
<sup>29</sup> Ibid.

<sup>&</sup>lt;sup>30</sup> "FDA Authorizes Marketing of Tobacco Products that Help Reduce Exposure to and Consumption of Nicotine for Smokers Who Use Them," U.S. Food and Drug Administration, Dec. 31, 2021. <a href="https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-tobacco-products-help-reduce-exposure-and-consumption-nicotine-smokers-who.">https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-tobacco-products-help-reduce-exposure-and-consumption-nicotine-smokers-who.</a>

<sup>&</sup>lt;sup>31</sup> "Tobacco," The United Kingdom National Health Service, last accessed June 22, 2022. https://www.nhsinform.scot/healthy-living/stopping-smoking/reasons-to-stop/tobacco.

<sup>&</sup>lt;sup>32</sup> Bryan H. Heckman, et al., "How to Reduce Racial Disparities in Smoking Deaths," *Scientific American*, Aug. 26, 2021. <a href="https://www.scientificamerican.com/article/how-to-reduce-racial-disparities-in-smoking-deaths">https://www.scientificamerican.com/article/how-to-reduce-racial-disparities-in-smoking-deaths</a>
<sup>33</sup> Ibid.

featuring Brown and Black individuals on downloadable posters and proposing these standards. To effectively address health disparities, culturally-competent educational collateral is needed that is targeted specifically for Black and Brown communities and addresses the multi-dimensional factors of smoking. It bears repeating: prohibition is *not* harm reduction.

## IV. The Role of Tobacco Harm Reduction in Advancing Public Health

Smoking cessation is undeniably the most beneficial for improving health outcomes and the best way for smokers to drastically reduce their risks. Unfortunately, this goal remains largely unattainable for a majority of smokers, with only about 5 percent to 8 percent achieving long term abstinence (6-12 months).<sup>34</sup> Currently available nicotine replacement therapies are aimed at replacing nicotine from cigarettes to reduce the motivation to smoke withdrawal symptoms. For those smokers who have no intention of quitting or who are unable to quit, these therapies have proven to be less effective in attaining long-term quitting rates than e-cigarettes.<sup>35</sup>

There is a continuum of risk across different products containing nicotine.<sup>36</sup> While there is need for long-term epidemiological studies, the risk cliff—i.e. the difference in harm due to use of combustible tobacco products and non-combustible nicotine products—is steep, with combustible tobacco products being the most harmful to health while vape and oral tobacco products being closer to nicotine replacement therapies in their risk profile.<sup>37</sup> By using an evidence-based approach, tobacco harm reduction has a far greater likelihood of advancing public health goals than absolutist approaches that leave behind three-quarters of existing menthol users through exclusive promotion of prohibition and abstinence.

Adopting a tobacco harm reduction approach that meets adult smokers where they are is a step towards achieving improved health outcomes in an equitable manner. Health equity is said to be achieved when individuals can attain their full health potential regardless of their social circumstances.<sup>38</sup> Tobacco control measures aimed at combustible tobacco products such as price increases, comprehensive bans on advertising or promotions, product warning labels, increased access to cessation therapies and education, have proven successful in bringing down smoking rates. Data from studies indicate the "Healthy People 2020" goal of reducing smoking prevalence to less than 12 percent has been achieved or exceeded for

<sup>&</sup>lt;sup>34</sup> MeLisa R. Creamer et al., "Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018." *MMWR Morbidity Mortality Weekly Report* 68 (2019), pp.1013-1019. https://www.cdc.gov/mmwr/volumes/68/wr/mm6845a2.htm.

<sup>&</sup>lt;sup>35</sup> Peter Hajek et al., "A randomized trial of e-cigarettes versus nicotine-replacement therapy," *New England Journal of Medicine* 380:7 (2019), pp. 629-637. <a href="https://www.nejm.org/doi/full/10.1056/nejmoa1808779">https://www.nejm.org/doi/full/10.1056/nejmoa1808779</a>.

<sup>&</sup>lt;sup>36</sup> David B. Abrams et al., "Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine use to Rapidly Save Lives," *Annual Review of Public Health* 39 (2018), pp.193-213. https://pubmed.ncbi.nlm.nih.gov/29323611.

<sup>&</sup>lt;sup>37</sup> Ibid; Tobacco Advisory Group, "Nicotine without smoke: Tobacco harm reduction," Royal College of Physicians, April 28, 2016. <a href="https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction">https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction</a>; David J. Nutt et al., "Estimating the harms of nicotine-containing products using the MCDA approach," *European Addiction Research* 20:5 (2014), pp. 218-225. <a href="https://pubmed.ncbi.nlm.nih.gov/24714502">https://pubmed.ncbi.nlm.nih.gov/24714502</a>; National Academies of Sciences Engineering and Medicine, *Public Health Consequences of E-cigarettes*, (The National Academies Press, 2018).

<sup>&</sup>lt;sup>38</sup> M. Whitehead and G. Dahlgren, *Leveling Up (Part 1): A Discussion Paper on Concepts and Principles for Tackling Social Inequities in Health*, (World Health Organization, 2006). https://apps.who.int/iris/handle/10665/107790.

some population groups; for example, those with higher education and incomes.<sup>39</sup> The challenges faced by the remaining 14 percent (31 million) adult smokers, to transition from a smoking habit which is costing them their lives, is compounded by their social circumstances.<sup>40</sup> The highest smoking rates are seen in marginalized or vulnerable populations based on education and income level, race, mental health diagnoses, sexual orientation, occupation and geographic location.<sup>41</sup> By promoting a quit-or-die philosophy, bans do not consider the multidimensional and intersectional factors that drive individual smoking habits, and prioritize short-term gains over long-term sustainability. To be successful in achieving long-term declines in national smoking prevalence across all populations, addressing social determinants of health through a tailored tobacco harm reduction strategy is key in eliminating smoking disparities.

### V. Policy Recommendations

Should the proposed rule represent a foregone conclusion, the R Street Institute recommends a number of harm reduction policy interventions to interrupt health disparities while mitigating potentially negative unintended consequences. Policymakers would be wise to consider the following:

- 1. Provide a longer runway for menthol ban implementation to allow the FDA to designate—through established regulatory processes—reduced-risk menthol- and mint-flavored tobacco product alternatives than traditional menthol-flavored combustible tobacco.
- 2. Develop and amplify a public education campaign that clarifies the relative risks of tobacco versus nicotine, in addition to culturally-competent harm reduction education, geared towards communities disproportionately affected by tobacco.
- 3. Publicize an inventory of PMTA- and MRTP-designated products categorized along a risk continuum dependent on harms posed.
- 4. Convene multi-stakeholder engagement sessions, including: federal and state-level criminal justice stakeholders, industry and consumers, to help regulate new technologies and educate on the market-oriented enforcement approach. Findings should be used to harmonize approaches to individual enforcement of banned tobacco products.
- 5. Implement continued enforcement oversight of T-21 laws prevalent in all 50 states to ensure that the purchase of tobacco products is only for those aged 21 years of age and older.

The R Street Institute deeply appreciates the opportunity to comment on the proposed standards. We want to reiterate that the less people are smoking, the better. We believe, however, that harm reduction is a

https://pophealthmetrics.biomedcentral.com/articles/10.1186/1478-7954-12-5.

<sup>&</sup>lt;sup>39</sup> "Topics & Objectives," Office of Disease Prevention and Health Promotion, last accessed June 29, 2022. <a href="https://www.healthypeople.gov/2020/topics-objectives">https://www.healthypeople.gov/2020/topics-objectives</a>; Ahmed Jamal et al., "Current cigarette smoking among adults—United States, 2016," *Morbidity and Mortality Weekly Report* 67:2 (2018), pp. 53-59. <a href="https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a1.htm">https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a1.htm</a>.

<sup>&</sup>lt;sup>40</sup> "Healthy People 2022: Who's Leading the Leading Health Indicators" Office of Disease Prevention and Health Promotion, last accessed June 29, 2022.

https://www.healthypeople.gov/sites/default/files/HP2020LHIWebinarTobacco508.pdf.

<sup>&</sup>lt;sup>41</sup> "The Health Consequences of Smoking—50 Years of Progress," U.S. Dept of Health and Human Services and Centers for Disease Control and Prevention 2014. <a href="https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf">https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf</a>; Laura Dwyer-Lindgren et al., "Cigarette smoking prevalence in U.S. counties: 1996- 2012," *Population Health Metrics* 12:5 (2014), pp. 1-13.

more effective way to address smoking disparities than prohibition and the negative consequences that arise from regulating human behaviors.

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