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August 2, 2022

Dockets Management Staff  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

Re: Docket No. FDA-2021-N-1349

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), and more than 40 million volunteers and supporters, we appreciate the opportunity to provide comments on the proposed product standard for menthol in cigarettes.

AHA strongly supports the Food and Drug Administration's (FDA) proposal to prohibit menthol as a characterizing flavor in cigarettes. For decades, AHA has worked to combat the tremendous toll of tobacco use. Tobacco use is a leading preventable cause of death, disease, and disability in the U.S., and smoking is a major risk factor for cardiovascular disease, including stroke. More than 16 million Americans are living with a disease caused by smoking, and it is responsible for over 480,000 deaths in the U.S. each year.<sup>1</sup> Tobacco use is also the leading cause of premature death (before the age of 70) from cardiovascular disease.<sup>2</sup>

AHA would like to see an end to all tobacco and nicotine addiction in the U.S. We are particularly concerned about combustible products, like cigarettes, because they pose the highest risk to users and those exposed to secondhand smoke. Removing menthol cigarettes from the market would help minimize the use of combustible products and help us reach the tobacco endgame, which AHA defines as reducing the use of tobacco products to less than 5% in the U.S. by 2035, prioritizing less than 5% prevalence of combustible tobacco use by 2030 while continuing to ensure that other products do not addict the next generation of youth and adolescents. This ambitious, lifesaving goal is likely only achievable through the implementation of equity-focused public policies, such as this proposed rule.

The evidence supporting the proposed rule is clear. As we discuss below, menthol makes cigarettes easier to smoke and more appealing to new users, such as youth and young adults. Menthol increases the likelihood that new users who experiment with cigarettes will progress to regular use. And menthol increases the likelihood and degree of addiction and makes it harder to quit. Menthol cigarettes also contribute to tobacco-related health disparities and the resulting disparities in health outcomes. This is particularly concerning for Black smokers and youth who have been explicitly targeted in marketing and advertising by the tobacco industry. Removing menthol cigarettes from the market would have enormous benefits for public health, including reduced initiation, increased cessation, and lower rates of tobacco-related death and disease. The rule would also lower health care costs and advance health equity.

Simply put, there is no question that prohibiting menthol cigarettes is “appropriate for the protection of public health.” We urge the FDA to move forward without delay.

### **Impact of Menthol Cigarettes on Tobacco Use**

#### ***FDA Review of the Scientific Evidence***

According to the Federal Register notice, “over the past several years FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes.”<sup>3</sup> The first of these reviews was mandated by Congress in the Family Smoking Prevention and Tobacco Control Act. Congress was so concerned by the “unique issues surrounding menthol cigarettes,” the high prevalence of use by Black smokers, the targeting of Black Americans by the tobacco industry, and the potential for “unique health risks to those who smoke [menthol cigarettes],” that Congress ordered the FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) to immediately begin its review as the Committee’s first order of business.<sup>4</sup> The TPSAC report, which was released in 2011, concluded that “removal of menthol cigarettes from the marketplace would benefit the public health in the United States.”<sup>5</sup> At the time, menthol cigarettes represented one quarter of all cigarette sales in the U.S. and were smoked by nearly 7 in 10 Black smokers. Unfortunately, menthol cigarette sales and prevalence have only increased since that time.

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<sup>1</sup> U.S. Department of Health & Human Services. Smoking Cessation by the Numbers. Smoking Cessation: A Report of the Surgeon General. 2020.

<sup>2</sup> Roy A, et al. Tobacco and Cardiovascular Disease: A Summary of Evidence (in) Cardiovascular, Respiratory, and Related Disorders. 3<sup>rd</sup> edition. Washington, DC: The International Bank for Reconstruction and Development. The World Bank; 2017.

<sup>3</sup> 87 FR at 26458.

<sup>4</sup> Family Smoking Prevention and Tobacco Control Act Report 111-58 Part 1.

<sup>5</sup> Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011.

In 2020, menthol cigarettes made up 37% of domestic cigarette sales in the U.S.<sup>6</sup> and 85% of Black smokers now smoke menthol cigarettes.<sup>7</sup>

In 2013, the TPSAC report was followed by a separate internal review conducted by FDA scientists. Like the TPSAC report, the FDA found that menthol increases initiation and progression to regular smoking and enhances the addictiveness and dependence of tobacco.<sup>8,9</sup> Similar to TPSAC, the FDA report concluded that menthol cigarettes likely pose a greater public health risk than non-menthol versions.<sup>10</sup>

More recently, the FDA conducted two additional reviews of menthol cigarettes. The first, “Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021,” examined peer-reviewed literature on menthol cigarettes’ impact on regular use, dependence, and cessation. The second, “Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes,” looked at the impact a menthol ban may have on a variety of outcomes such as tobacco use behavior, tobacco sales, illicit sales, user modification of products, and more. Both reports were released in conjunction with this proposed rule and add to the substantial evidence base.

In addition, the FDA received voluminous public feedback in response to two advanced notices of proposed rulemaking on the potential regulation of menthol (2013) and the potential regulation of all flavored tobacco products, including menthol (2018), as well as a citizen petition (2013) and citizen petition supplement (2021). The citizen petition, the supplement, and many of the public comments also provided data and information that can inform a menthol cigarette product standard.

The FDA has ample evidence to support a ban of menthol cigarettes. We include a small sample of that evidence below.

### ***Menthol Appeals to New Users and Increases Initiation***

Flavored tobacco products are highly attractive to youth and have led to increased initiation among children and adolescents. Menthol cigarettes are no exception; menthol cigarettes are very popular with youth.

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<sup>6</sup> Annette Choi and Cristina Rivero. Politico Pro DataPoint. Sources: FDA, Federal Trade Commission, POLITICO reporting. April 29, 2022.

<sup>7</sup> Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014. *Tobacco control*. 2016;25(Suppl 2):ii14-ii20.

<sup>8</sup> Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes. 2013.

<sup>9</sup> TPSAC Report.

<sup>10</sup> FDA Preliminary Scientific Evaluation.

Studies show that menthol makes cigarettes easier to smoke. Menthol provides a cooling effect in the back of the throat, reduces the harshness of cigarette smoke, and suppresses coughing.<sup>11</sup> Youth and young adults “who initiate smoking with menthol cigarettes are more likely to report having a pleasant first smoking experience”<sup>12</sup> and fewer experience nausea.<sup>13</sup> This makes menthol cigarettes a “starter product” for youth or other inexperienced users to initiate tobacco use.

Menthol also masks the taste of tobacco, making cigarettes taste better. According to discussion groups conducted by Creative Research Group (CRG) for British American Tobacco in 1982, “There is no question that menthol has a significant masking effect on both the taste of the tobacco and the harshness of the smoking experience. Some menthol smokers seek as much masking effect as possible, attempting to eradicate the tobacco taste altogether.”<sup>14</sup> Participants in those focus groups shared feedback such as: “As far as I am concerned, I want the menthol to completely cover up the taste of the tobacco. I don't like the taste of tobacco” or “If the menthol was gone, I wouldn't be able to stand the cigarette!”<sup>15</sup> indicating that some smokers do not find non-mentholated cigarettes appealing.

Menthol cigarettes increased in popularity after the FDA implemented the flavored cigarette ban. In 2019, approximately half of youth (46.7%) and young adult (51%) cigarette smokers smoked menthol cigarettes; that number declines for older smokers to 39%.<sup>16</sup> According to the FDA's 2013 scientific evaluation of menthol, younger populations have the highest rate of smoking menthol cigarettes. In fact, the FDA found that menthol is *substantially more popular among newer smokers* than the general population.<sup>17</sup> Youth and young adults are also more likely to try a menthol cigarette as their first cigarette.<sup>18</sup>

Menthol's popularity among youth and young adults is clear – and the result of intentional targeting by the tobacco industry. As the 2012 Surgeon General's Report on Preventing Tobacco Use Among Youth and Young Adults concluded, the tobacco industry designed their products to appeal to youth, including the use of menthol and other youth-appealing flavors,

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<sup>11</sup> FDA Preliminary Scientific Evaluation.

<sup>12</sup> 87 FR at 26464. Cohn, A. and J. D'Silva. Menthol Smoking and Subjective Response to the First Cigarette Smoked. *Tobacco Regulatory Science*, 5(6):554–566, 2019.

<sup>13</sup> 87 FR at 26470. D'Silva, J. et al. Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers. *Nicotine & Tobacco Research*, 20(9):1062–1068, 2018.

<sup>14</sup> Yerger, Valerie B. Menthol's potential effects on nicotine dependence: a tobacco industry perspective. *Tobacco control* vol. 20 Suppl 2, Suppl\_2 (2011): ii29-36. doi:10.1136/tc.2010.041970

<sup>15</sup> Ibid.

<sup>16</sup> 87 FR at 26462.

<sup>17</sup> FDA Preliminary Scientific Evaluation.

<sup>18</sup> 87 FR 26464.

to remain profitable over the long-term.<sup>19</sup> For example, one industry document calls menthol a good starter product “because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy,” while another document notes that “the base of our business is the high school student.”<sup>20</sup> The industry has also exploited positive misperceptions about menthol cigarettes. According to a Truth Initiative survey, 41% incorrectly believe that there are health benefits associated with menthol compared with non-menthol cigarettes; and 61% believe that menthol makes it easier to quit smoking.<sup>21</sup> These perceptions, combined with the appealing flavor and advertising that uses youthful imagery,<sup>22</sup> help tobacco companies recruit young “replacement smokers” to replace older smokers who die of a tobacco-related disease. Unfortunately, these efforts appear to be working, as a recent study found that menthol cigarettes alone were responsible for 10.1 million extra smokers (or approximately 265,000 new smokers each year) between 1980 and 2018.<sup>23</sup> During this same time period, menthol cigarettes also resulted in 378,000 premature deaths and 3 million life years lost.<sup>24</sup>

### ***Menthol Increases Progression to Regular Smoking***

Menthol increases the likelihood that new users who experiment with cigarettes will progress to regular use and nicotine dependence.

Studies show that menthol facilitates repeated use. As the FDA found in its most recent scientific review, “[t]he sensory effects of menthol make cigarettes more palatable by masking the harsh taste of tobacco and reducing aversive responses associated with initial smoking experiences (e.g., throat irritation, coughing) that can deter new and inexperienced users from repeated experimentation.”<sup>25</sup> The report continues to note that “[r]epeated exposure to nicotine, particularly during adolescence, increases the likelihood of addiction. Consequently, youth who initiate smoking with menthol cigarettes may be at greater risk for progression from experimentation to established smoking and nicotine dependence than youth who initiate with non-menthol cigarettes.”<sup>26</sup>

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<sup>19</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General; 2012.

<sup>20</sup> 87 FR at 26464.

<sup>21</sup> Truth Initiative. Menthol Cigarettes: Attitudes, Beliefs, and Policies. See <https://truthinitiative.org/research/menthol-cigarettes-attitudes-beliefs-and-policies>.

<sup>22</sup> TPSAC Report.

<sup>23</sup> Le TT, Mendez D. An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018 *Tobacco Control* Published Online First: 25 February 2021. doi: 10.1136/tobaccocontrol-2020-056256

<sup>24</sup> Ibid.

<sup>25</sup> Food and Drug Administration. Scientific Review of the Effects of Menthol on Tobacco Addiction: 1980-2021. April 2022.

<sup>26</sup> Ibid.

A recent study illustrates the impact that menthol has on smoking frequency. The study of 1,096 cigarette smokers between the ages of 12 and 17 found that menthol cigarette smokers smoke 3.1 days more frequently per month compared to non-menthol smokers and are 59% more likely to be a frequent smoker.<sup>27</sup> The study also found that adolescents who switched from menthol to non-menthol cigarettes, smoked less frequently (3.6 fewer days per month) and were 47% less likely to be a frequent smoker.<sup>28</sup>

Menthol cigarette smokers also exhibit signs of increased dependence. For example, a study examining the differences in dependency among menthol and non-menthol daily smokers aged 18-35, found that menthol smokers were more likely to have difficulty refraining from smoking in areas where smoking is prohibited.<sup>29</sup> Young menthol cigarette smokers also report “higher levels of craving for cigarettes, needing a cigarette within one hour after smoking, and increased feelings of restlessness and irritability without smoking” – all signs of nicotine dependence – compared to youth non-menthol smokers.<sup>30</sup>

### ***Menthol Increases Addiction and Makes it Harder to Quit***

Menthol increases the likelihood and degree of addiction and decreases the likelihood that smokers can successfully quit.

As described in the previous section, menthol cigarette smokers exhibit signs of increased nicotine dependence compared to non-menthol smokers. This can be attributed to menthol’s effect on nicotine in the brain. Menthol binds to nicotinic receptors in the brain, increases the number of nicotinic receptors, and, as animal studies demonstrate, increases the level of dopamine released.<sup>31</sup> Studies show that menthol alone can increase the number of nicotinic receptors in the brain, and that menthol cigarette smokers have higher levels of brain nicotinic receptors compared to non-menthol smokers.<sup>32</sup> This not only increases the likelihood that menthol smokers will progress from experimentation to regular smoking, it makes it more difficult for menthol smokers to quit.

Smoking cessation rates illustrate the difficulty for menthol cigarette smokers. While cigarette smoking overall has declined steadily for many years, cessation rates for menthol

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<sup>27</sup> Leas EC, et al. Use of Menthol Cigarettes, Smoking Frequency, and Nicotine Dependence Among US Youth. *JAMA Netw Open*. 2022;5(6):e2217144. doi:10.1001/jamanetworkopen.2022.17144

<sup>28</sup> Ibid.

<sup>29</sup> Fagan P, et al. Comparisons of Three Nicotine Dependence Scales in a Multiethnic Sample of Young Adult Menthol and Non-Menthol Smokers. *Drug and Alcohol Dependence*. April 2015; 149:203-211.

<sup>30</sup> 87 Federal Register 26465. Wackowski, O, et al. Menthol Cigarettes and Indicators of Tobacco Dependence Among Adolescents. *Addictive Behaviors*, 32(9):1964–1969, 2007. Hersey, J., et al. Menthol Cigarettes Contribute to the Appeal and Addiction Potential of Smoking for Youth. *Nicotine & Tobacco Research*, 12(2):S136–S146, 2010.

<sup>31</sup> 87 Federal Register at 26464.

<sup>32</sup> Ibid.

cigarette smokers have declined more slowly.<sup>33</sup> Even though menthol cigarette smokers make more quit attempts than non-menthol smokers, they have a significantly lower success rate.<sup>34</sup> One study using data from the Population Assessment of Tobacco and Health (PATH) found that daily menthol smokers were 24% less likely to quit compared to non-menthol smokers.<sup>35</sup> Another study, which compared 30+ day and 12-month abstinence rates by menthol use, found that using menthol prior to a quit attempt reduced the probability of success by 28%. Conversely, switching from menthol to non-menthol use increased the probability of 30+ day and 12-month abstinence by 58% and 97% respectively.<sup>36</sup>

Research has also shown that menthol makes it more difficult for Black smokers – even when highly motivated – to successfully quit.<sup>37</sup> Data from the same PATH study found that Black daily menthol smokers had significantly lower odds of quitting (3.0%) compared to Black daily non-menthol smokers (6.2%).<sup>38</sup> While a 2019 meta-analysis found that among Black smokers, menthol smokers had 12% lower odds of quitting compared to non-menthol smokers.<sup>39</sup> Black menthol smokers are also less likely to remain abstinent.<sup>40</sup> As the Surgeon General concluded, the lower likelihood of cessation among Black menthol smokers contributes to tobacco-related health disparities.<sup>41</sup>

## **Menthol Has a Disproportionate Impact on Black Americans**

### ***Black Americans Use Menthol at Disproportionately High Rates***

More Black Americans smoke menthol cigarettes than any other racial or ethnic group, regardless of age. Currently, 85% of Black smokers use menthol. This is significantly higher than menthol use by Hispanic (47%), Asian American (41%), and White (30%) smokers.<sup>42</sup> Black smokers are also more likely (93%) to use menthol for their first smoking

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<sup>33</sup> TPSAC Report.

<sup>34</sup> U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General, 2020.

<sup>35</sup> 87 Federal Register at 26466. Mills, S.D., et al. The Relationship Between Menthol Cigarette Use, Smoking Cessation, and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study. *Nicotine & Tobacco Research*, 23(6):966–975, 2021.

<sup>36</sup> Leas EC, et al. Effects of menthol use and transitions in use on short-term and long-term cessation from cigarettes among US smokers. *Tob Control*. 2021 Jul 6: tobaccocontrol-2021-056596.

<sup>37</sup> Keeler C, et al. The Association of Menthol Cigarette Use with Quit Attempts, Successful Cessation, and Intention to Quit Across Racial/Ethnic Groups in the United States. *Nicotine & Tobacco Research*. 2017; 19(12): 1450-1464.

<sup>38</sup> Mills, S.D., et al. The Relationship Between Menthol Cigarette Use, Smoking Cessation, and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study. *Nicotine & Tobacco Research*, 23(6):966–975, 2021.

<sup>39</sup> Smith PH, et al. Use of Mentholated Cigarettes and Likelihood of Smoking Cessation in the U.S.: A Meta-Analysis," *Nicotine & Tobacco Research*, 22(3): 307-316, 2020.

<sup>40</sup> 87 Federal Register at 26467.

<sup>41</sup> U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General, 2020.

<sup>42</sup> U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2019.

experience.<sup>43</sup> Menthol use among Black smokers skyrocketed from less than 10% in the 1950s to the 85% we see today after the tobacco industry started an aggressive marketing campaign targeting Black Americans.<sup>44</sup> One study found that menthol cigarettes alone were responsible for 1.5 million new Black smokers between 1980 and 2018.<sup>45</sup>

### ***The Tobacco Industry Aggressively Targets Black Americans***

The popularity of menthol cigarettes among Black Americans is the result of intentional targeted marketing and advertising by the tobacco industry. The tobacco industry has used a combination of techniques such as media and billboards, corporate sponsorships, and storefront, point-of-sale, and direct-to-consumer advertising, among others to increase menthol use among Black Americans and other communities of color. While the tobacco industry has altered its tactics over the years in response to a series of marketing restrictions – such as moving from print advertisements<sup>46,47,48</sup> to billboards<sup>49,50,51</sup> to retail advertising<sup>52,53,54,55,56,57,58,59</sup> – the tobacco industry has consistently continued to disproportionately focus on communities of color.

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<sup>43</sup> D’Silva J, et al. Differences in subjective experiences to first use of menthol and nonmenthol cigarettes in a national sample of young adult cigarette smokers. *Nicotine Tob Res.* 2018;20(9):1062-68.

<sup>44</sup> Gardiner, PS. The African Americanization of menthol cigarette use in the United States, *Nicotine & Tobacco Research*, February 2004; Roper, B.W. (1953). A Study of People’s Cigarette Smoking Habits and Attitudes Volume I. Philip Morris, Bates No. 2022239249; MSA, Inc.

<sup>45</sup> Mendez D, Le TT. Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980–2018. 2021;0:1–3. doi:10.1136/tobaccocontrol-2021-056748

<sup>46</sup> Primack BA, et al. Volume of tobacco advertising in African American markets: systematic review and meta-analysis. *Public Health Rep.* 2007;122(5):607-615. doi:10.1177/003335490712200508

<sup>47</sup> Pollay RW, et al. Separate, but Not Equal: Racial Segmentation in Cigarette Advertising. *Journal of Advertising.* 1992;21(1):45-57. doi:10.1080/00913367.1992.10673359.

<sup>48</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups: A Report of the Surgeon General. Atlanta, 1998.

<sup>49</sup> Hackbarth DP, Silvestri B, Cosper W. Tobacco and alcohol billboards in 50 Chicago neighborhoods: market segmentation to sell dangerous products to the poor. *J Public Health Policy.* 1995;16(2):213-230.

<sup>50</sup> Stoddard JL, Johnson CA, Sussman S, Dent C, Boley-Cruz T. Tailoring outdoor tobacco advertising to minorities in Los Angeles County. *J Health Commun.* 1998;3(2):137-146. doi:10.1080/108107398127427

<sup>51</sup> Luke D, Esmundo E, Bloom Y. Smoke signs: patterns of tobacco billboard advertising in a metropolitan region. *Tob Control.* 2000;9(1):16-23. doi:10.1136/tc.9.1.16.

<sup>52</sup> John R, Cheney MK, Azad MR. Point-of-sale marketing of tobacco products: taking advantage of the socially disadvantaged? *J Health Care Poor Underserved.* 2009;20(2):489-506. doi:10.1353/hpu.0.0147

<sup>53</sup> Pucci LG, et al. Outdoor tobacco advertising in six Boston neighborhoods: Evaluating youth exposure. *Am J Prev Med.* 1998;15(2):155-159. doi:10.1016/S0749-3797(98)00034-8

<sup>54</sup> Seidenberg AB, et al. Storefront cigarette advertising differs by community demographic profile. *Am J Health Promot.* 2010;24(6):e26-e31. doi:10.4278/ajhp.090618-QUAN-196.

<sup>55</sup> Kirchner TR, et al. Tobacco retail outlet advertising practices and proximity to schools, parks and public housing affect Synar underage sales violations in Washington, DC. *Tob Control.* 2015;24(e1):e52-e58. doi:10.1136/tobaccocontrol-2013-051239.

<sup>56</sup> Moreland-Russell S, Harris J, Snider D, Walsh H, Cyr J, Barnoya J. Disparities and menthol marketing: additional evidence in support of point of sale policies. *Int J Environ Res Public Health.* 2013;10(10):4571-4583. Published 2013 Sep 25. doi:10.3390/ijerph10104571



For example, the tobacco industry began advertising heavily in Black publications, such as *Ebony*, *Jet*, and *Essence* magazines. In 1962, *Ebony* contained twice as many cigarette advertisements as *Life* magazine.<sup>60</sup> From 1998 to 2002, *Ebony* was nearly 10 times as likely to contain menthol cigarette ads as *People*, and *People* in Spanish was nearly three times as likely to contain menthol cigarette ads than *People*.<sup>61</sup> Because tobacco advertisements were a major source of revenue for Black and Hispanic publications, tobacco companies expected – and often received – support for industry positions and limited coverage of the harms of smoking.<sup>62</sup> One study notes that between 1987 and 1994, magazines with a principal readership of African American women (*Jet*, *Ebony*, and *Essence*) ran 1,447 cigarette advertisements but published just nine articles on tobacco-related cancers.<sup>63</sup> A 1995 email from Philip Morris demonstrates the industry’s confidence that their financial support of Black and Hispanic media would ensure their support, stating that: “With all the advertising we offer [national Black and Hispanic publishers’ groups], they will run any editorial we like.”<sup>64</sup>

The tobacco industry also placed more billboards in Black, Hispanic, and Asian neighborhoods. In 1985, 37% of tobacco company spending on eight-sheet billboard advertising went toward billboards in Black neighborhoods, and most billboards in Black communities advertised menthol cigarettes.<sup>65</sup> In 1990, there were five times as many tobacco billboards in minority Chicago wards (i.e., majority Black, Latino, and Asian) as there were in non-Hispanic White wards.<sup>66</sup> A study conducted in Los Angeles found that Black and Hispanic neighborhoods contained a greater density and concentration of tobacco billboard

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<sup>57</sup> Widome R, et al. The relationship of neighborhood demographic characteristics to point-of-sale tobacco advertising and marketing. *Ethn Health*. 2013;18(2):136-151. doi:10.1080/13557858.2012.701273

<sup>58</sup> Henriksen L, et al. Neighborhood Variation in the Price of Cheap Tobacco Products in California: Results From Healthy Stores for a Healthy Community. *Nicotine Tob Res*. 2017;19(11):1330-1337. doi:10.1093/ntr/ntx089

<sup>59</sup> Carroll DM, Carroll DM, Soto C, Baezconde-Garbanati L, et al. Tobacco Industry Marketing Exposure and Commercial Tobacco Product Use Disparities among American Indians and Alaska Natives. *Subst Use Misuse*. 2020;55(2):261-270. doi:10.1080/10826084.2019.1664589.

<sup>60</sup> Pollay RW, et al. Separate, but Not Equal: Racial Segmentation in Cigarette Advertising. *Journal of Advertising*. 1992;21(1):45-57. doi:10.1080/00913367.1992.10673359.

<sup>61</sup> Landrine H, et al. Cigarette advertising in Black, Latino, and White magazines, 1998-2002: an exploratory investigation. *Ethn Dis*. 2005;15(1):63-67.

<sup>62</sup> U.S. Department of Health and Human Services. *Tobacco Use Among U.S. Racial/Ethnic Minority Groups*. 1998.

<sup>63</sup> Hoffman-Goetz L, et al. Cancer coverage and tobacco advertising in African-American women's popular magazines. *J Community Health*. 1997;22(4):261-270. doi:10.1023/a:1025100419474

<sup>64</sup> McCandless PM, Yerger VB, Malone RE. Quid pro quo: tobacco companies and the black press. *Am J Public Health*. 2012;102(4):739-750. doi:10.2105/AJPH.2011.300180.

<sup>65</sup> Davis RM. Current trends in cigarette advertising and marketing. *N Engl J Med*. 1987;316(12):725-732. doi:10.1056/NEJM198703193161206

<sup>66</sup> Hackbarth DP, et al. Tobacco and alcohol billboards in 50 Chicago neighborhoods: market segmentation to sell dangerous products to the poor. *J Public Health Policy*. 1995;16(2):213-230.

advertisements compared with White neighborhood thoroughfares.<sup>67</sup> An analysis of billboards in St. Louis also found that tobacco advertisements were more common in Black neighborhoods than in White ones.<sup>68</sup> Similarly, a 1986 industry memorandum showed that one company intentionally advertised menthol cigarettes in the interior of buses that had “a high percent of Black ridership,” but chose not to put those advertisements on the exterior of buses that passed through neighborhoods with a higher percentage of White residents or on buses that “service White areas, too.”<sup>69</sup>

Much of the industry’s advertising was used to associate menthol cigarettes with Black smokers and Black culture; in essence, “creating a brand with which African Americans could identify and call their own.”<sup>70</sup> This included recruiting Black athletes and celebrities as spokespeople and by associating menthol cigarettes with Black music (jazz and hip hop), Black slang, and Black success (images of Black models partying or consuming luxury products) in advertisements,<sup>71,72,73,74,75</sup> as well as sponsoring important cultural, community, and musical events. However, one of the most high-profile and explicit efforts to sell menthol to Black consumers was R.J. Reynolds’ (RJR) planned introduction of Uptown cigarettes, as part of its Menthol Initiative Program (originally referred to as the “Black Initiative”).<sup>76</sup> RJR advertised that the campaign was based on extensive market research to design, brand, and promote Uptown cigarettes to Black consumers. This prompted outrage and protests among the Black community, leading the company to abandon the product. However, according to a subsequent industry report on the Uptown initiative, this outrage was likely based on the *disclosure* of these tactics rather than their use: “[m]arketing cigarettes to minorities was not new, [but] saying so was.”<sup>77</sup>

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<sup>67</sup> Stoddard JL, et al. Tailoring outdoor tobacco advertising to minorities in Los Angeles County. *J Health Commun.* 1998;3(2):137-146. doi:10.1080/108107398127427

<sup>68</sup> Luke D, et al. Smoke signs: patterns of tobacco billboard advertising in a metropolitan region. *Tob Control.* 2000;9(1):16-23. doi:10.1136/tc.9.1.16.

<sup>69</sup> Lorillard Memorandum. Re: Black Transit. February 12, 1986. <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=zqwh0055>

<sup>70</sup> Mendez D, Le TT. 2021.

<sup>71</sup> Hackbarth DP. 1995.

<sup>72</sup> Cruz TB, et al. The menthol marketing mix: targeted promotions for focus communities in the United States. *Nicotine Tob Res.* 2010;12 Suppl 2:S147-S153. doi:10.1093/ntr/ntq201

<sup>73</sup> Hafez N, Ling PM. Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes. *Tob Control.* 2006;15(5):359-366. doi:10.1136/tc.2005.014258

<sup>74</sup> Sutton CD, Robinson RG. The marketing of menthol cigarettes in the United States: populations, messages, and channels. *Nicotine Tob Res.* 2004;6 Suppl 1:S83-S91. doi:10.1080/14622203310001649504

<sup>75</sup> Yerger VB, et al. Racialized geography, corporate activity, and health disparities: tobacco industry targeting of inner cities. *J Health Care Poor Underserved.* 2007;18(4 Suppl):10-38. doi:10.1353/hpu.2007.0120.

<sup>76</sup> Balbach ED, et al. Reynolds' targeting of African Americans: 1988-2000. *Am J Public Health.* 2003;93(5):822-827. doi:10.2105/ajph.93.5.822.

<sup>77</sup> Ibid.

In addition to advertisements and brand associations with community events, the tobacco industry relied heavily on free samples and coupons to attract new users. Industry documents from 1967 describe “handing out free samples to those who were the ‘kingfish’ in the community and building brand following through barbers, bellhops, and taxi drivers, who also distributed free samples.”<sup>78</sup> In the 1970s and ‘80s, tobacco companies used mobile vans to pass out coupons for free samples of menthol products in predominantly Black, “inner city” neighborhoods.<sup>79</sup> Companies also targeted “inner city” retailers by paying them to expand their inventories of menthol products and exhibit promotional displays and providing bonus incentives for meeting sales goals.<sup>80</sup>

When tobacco companies were prohibited from advertising on billboards, distributing free samples, distributing branded merchandise, and product placement in the media under the terms of the Master Settlement Agreement,<sup>81</sup> the industry shifted its tactics to focus on retailer advertising (e.g., storefront and point-of-sale advertisements and price promotions for menthol cigarettes) and direct-to-consumer advertisements (e.g., direct mail, email, and coupons). As in previous decades, these tactics continued to focus predominately on Black neighborhoods, which have a disproportionate number of tobacco retailers, and other communities of color.

### ***Black Americans Suffer the Greatest Burden from Tobacco***

Black communities suffer some of the greatest burden of tobacco-related death in the U.S.<sup>82</sup> Even though Black Americans usually start smoking at an older age, smoke fewer cigarettes, and are more likely to have made a quit attempt, Black Americans are more likely to die from a smoking-related disease than other racial and ethnic groups.<sup>83</sup> 45,000 Black Americans die from tobacco each year.<sup>84</sup>

Tobacco use is a major contributor to three of the leading causes of death among Black Americans: heart disease, cancer, and stroke.<sup>85</sup> Tobacco use is an independent risk factor for heart disease and is linked to nearly one half of all premature deaths due to cardiovascular

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<sup>78</sup> Wailoo, K. How the Tobacco Industry Hooked Black Smokers on Menthol. Guest Essay. New York Times. May 11, 2022.

<sup>79</sup> Yerger VB, 2007.

<sup>80</sup> Ibid.

<sup>81</sup> Public Health Law Center at Mitchell Hamline School of Law. The Master Settlement Agreement: An Overview. January 2019. <https://www.publichealthlawcenter.org/sites/default/files/resources/MSA-Overview-2019.pdf>.

<sup>82</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups. 1998.

<sup>83</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/tobacco/health-equity/african-american/health-burden.html> and <https://www.cdc.gov/tobacco/health-equity/african-american/quitting-tobacco.html>

<sup>84</sup> HHS. Tobacco Use Among US Racial/Ethnic Minority Groups. 1998.

<sup>85</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/tobacco/campaign/tips/groups/african-american.html>

disease.<sup>86</sup> Black adults are 30% more likely to die from heart disease, and 50% more likely to die from stroke.<sup>87,88</sup> Smoking is also responsible for one-third of all cancer deaths and approximately 85% of all lung cancer deaths.<sup>89</sup> Tobacco use also increases the risk of developing diabetes, another leading cause of death in Black Americans, by 30-40% compared to non-smokers.<sup>90</sup>

Black children and adults are also more likely to be exposed to secondhand smoke than any other racial and ethnic groups.<sup>91</sup> In 2013-2014, 66.1% of all Black children aged 3-11 years, 55.3% of Black adolescents 12-19 years, and 45.5% of Black adults aged 20 and older were exposed to secondhand smoke.<sup>92</sup> Exposure to secondhand smoke can have devastating health effects. Children get sick more frequently, including more severe asthma attacks, respiratory infections, ear infections, and sudden infant death syndrome.<sup>93</sup> Secondhand smoke also causes cardiovascular disease and lung cancer.<sup>94</sup>

A recent study that examined menthol's impact on Black communities found that menthol cigarettes were responsible for 157,000 premature deaths and 1.5 million excess life-years lost between 1980 and 2018.<sup>95</sup> According to the study's authors, this represents 41% of all menthol deaths (over two and a half times their proportional share compared with the general population), and 50% of all life-years lost, even though Black Americans are only 12% of the overall U.S. population.<sup>96</sup> The authors concluded that "without menthol, smoking prevalence among African Americans in 2018 would have been 8.3%, instead of the NHIS reported 14.9% (a 44% reduction)."

### ***Menthol Cigarettes Also Impact Other Communities***

Although menthol cigarettes are heavily marketed to and thereby quite popular with Black smokers (85%), menthol is also popular with Hispanic (47%), Asian American (41%), and

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<sup>86</sup> Bhatnagar A. Environmental Determinants of Cardiovascular Disease. *Circ Res*. 2017;121:162-180.

<sup>87</sup> U.S. Department of Health and Human Services. Office of Minority Health. Heart Disease and African Americans. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlID=19>

<sup>88</sup> U.S. Department of Health and Human Services. Office of Minority Health. Stroke and African Americans. <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlID=28>

<sup>89</sup> Warren GW, et al. Tobacco and lung cancer: risks, trends, and outcomes in patients with cancer. *Am Soc Clin Oncol Educ Book*. 2013:359-64. doi: 10.14694/EdBook\_AM.2013.33.359. PMID: 23714547.

<sup>90</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/diabetes/library/features/smoking-and-diabetes.html>

<sup>91</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/tobacco/health-equity/african-american/secondhand-smoke.html>

<sup>92</sup> Ibid

<sup>93</sup> Centers for Disease Control & Prevention. [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/secondhand\\_smoke/health\\_effects/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm)

<sup>94</sup> Ibid

<sup>95</sup> Mendez D, Le TT. 2021.

<sup>96</sup> Ibid

LGBT (36%) smokers, but at lower rates.<sup>97,98</sup> Menthol use is also higher among people with low levels of income or education<sup>99</sup> or with mental health conditions.<sup>100</sup>

Some of this popularity can be attributed to targeting of these populations. As with Black communities, the tobacco industry tends to advertise more heavily in communities of color and underserved populations. As described above, the tobacco industry supported Hispanic media and advertised more heavily in Spanish language magazines, placed more billboards in areas with Hispanic or Asian residents, and sponsored Hispanic athletic, civic, cultural, and entertainment events. In the 1980s, industry began to apply some of the same strategies it had been using to target Black and Hispanic communities to Asian Americans and American Indian/Alaska Native (AI/AN) consumers. For example, some tobacco companies began appropriating American Indian imagery and language to associate their products with positive American Indian stereotypes (e.g., that products were natural, traditional, mystical, or spiritual), evoke a sense of pride among American Indians, and blur the lines between commercial and traditional tobacco use.<sup>101</sup>

Because menthol has a disproportionate impact on minorities and other underserved communities, removing menthol cigarettes from the market and lowering tobacco use would advance health equity.

### **Benefits of Removing Menthol Cigarettes**

#### ***Reduce Initiation and Use, Increase Cessation***

AHA agrees with the FDA's assessment that prohibiting menthol as a characterizing flavor in cigarettes would reduce cigarettes' appeal, particularly for youth and young adults. Young people would be less attracted to cigarettes, less likely to initiate smoking, and less likely to continue experimenting and progress to regular use.

We also agree that prohibiting menthol would increase the number of smokers who stop using cigarettes. Almost 70% of smokers want to quit smoking,<sup>102</sup> and studies have shown

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<sup>97</sup> U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2019.

<sup>98</sup> Fallin A, et al. Menthol Cigarette Smoking Among Lesbian, Gay, Bisexual, and Transgender Adults. *Am J Prev Med.* 2015 Jan;48(1):93-7. doi: 10.1016/j.amepre.2014.07.044.

<sup>99</sup> FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes. 2013

<sup>100</sup> Young-Wolff KC, et al. Correlates and prevalence of menthol cigarette use among adults with serious mental illness. *Nicotine Tob Res.* 2015;17(3):285-91.

<sup>101</sup> D'Silva J, et al. Tobacco industry misappropriation of American Indian culture and traditional tobacco. *Tob Control.* 2018;27(e1):e57-e64. doi:10.1136/tobaccocontrol-2017-053950.

<sup>102</sup> Babb S, et al. Quitting Smoking Among Adults—United States, 2000–2015. *Morbidity and Mortality Weekly Report* 2017;65(52):1457-64.

that many current menthol smokers would quit tobacco altogether if menthol cigarettes were removed from the market. For example, data from the 2011 National Youth and Adult Health Survey found that 65.7% would quit, while 18.4% would switch to non-menthol cigarettes, and 16% would switch to another tobacco product.<sup>103</sup> A 2021 expert elicitation estimated that a federal menthol cigarette and cigar ban would reduce combustible tobacco use by 30% among menthol smokers ages 18-24 and by 20% among menthol smokers ages 35-54, as well as prevent 39% of young people ages 12-24 who would have initiated menthol cigarette use absent a menthol ban, from initiating tobacco use.<sup>104</sup>

These data are supported by real-world evidence that shows many menthol cigarette smokers do attempt to quit after menthol cigarettes are banned. Only one month after Ontario, Canada banned menthol cigarettes in January 2017, a small study found that 29.1% had already attempted to quit.<sup>105</sup> While a larger, more recent study conducted after Canada implemented a country-wide menthol cigarette ban found that menthol cigarette smokers were significantly more likely than non-menthol smokers to attempt to quit; daily menthol smokers were also significantly more likely to quit (22%) compared to non-menthol smokers (15%).<sup>106</sup> When the study's authors applied Canada's experience to the U.S., they projected that if the U.S. were to remove menthol cigarettes from the market, an additional 1,337,988 smokers would quit, including 381,272 Black smokers.<sup>107</sup>

These data add to the evidence base in support of a menthol ban.

### ***Improve Public Health***

If menthol cigarettes are removed from the market, it will have a tremendous impact on public health, reducing tobacco-related morbidity and mortality. As the Agency is well aware, smoking has been linked to diseases of virtually every organ in the body.<sup>108</sup> Smoking causes heart disease, lung cancer, colorectal cancer, liver cancer, chronic obstructive pulmonary disease, diabetes, rheumatoid arthritis, impaired fertility, and much more.<sup>109</sup> Simply being exposed to secondhand smoke can cause heart disease, cancer, and stroke, as

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<sup>103</sup> Wackowski OA, et al. Young Adults Behavioral Intentions Surrounding a Potential Menthol Cigarette Ban. *Nicotine Tob Res.* 2014 Jun;16(6):876-80. doi: 10.1093/ntr/ntu003. Epub 2014 Feb 10.

<sup>104</sup> Levy DT, Cadham CJ, et al. An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States. *Nicotine Tob Res.* 2021 Oct 7;23(11):1911-1920. doi: 10.1093/ntr/ntab121. PMID: 34097061; PMCID: PMC8496475.

<sup>105</sup> Chaiton M, et al. Association of Ontario's Ban on Menthol Cigarettes with Smoking Behavior 1 Month After Implementation. *JAMA Internal Medicine.* March 5, 2018.

<sup>106</sup> Fong GT, et al. Summary of the ITC Project Evaluation of the Canada-Wide Ban on Menthol Cigarettes: Implications for Projected Increases in Quitting in the United States and California. April 8, 2021.

<sup>107</sup> Ibid.

<sup>108</sup> U.S. Department of Health & Human Services. *The Health Consequences of Smoking: A Report of The Surgeon General.* 2004

<sup>109</sup> Ibid.

well as a number of serious health conditions in children and adolescents. Almost half a million Americans die because of smoking and more than 41,000 die of secondhand smoke exposure in the U.S. each year. On average, male smokers die 12 years earlier and female smokers die 11 years earlier than never-smokers.<sup>110</sup>

The good news is that quitting cigarette smoking has “immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general.”<sup>111</sup> For example, heart rate and blood pressure drop 20 minutes after finishing an acute episode of smoking.<sup>112</sup> As early as two weeks after quitting, circulation improves and lung function increases. One year after quitting, the excess risk of coronary heart disease drops to half that of someone who continued to smoke. Five to ten years after quitting, stroke risk decreases. And fifteen years after quitting, the risk of coronary heart disease reduces to that of a nonsmoker.

If, as a result of this rule, even a small fraction of menthol smokers quit or youth or young adults do not start, it will have a substantial benefit on public health. As the FDA noted in the Federal Register notice, “Even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease in the United States caused by smoking, including reductions in smoking-related morbidity and mortality, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come.”<sup>113</sup>

Research supports the FDA’s conclusion that the benefit will be significant. One recent study estimated that a menthol ban would lead to a 15% decrease in overall smoking in as little as five years (2021-2026) and will save 650,000 lives and reduce life years lost by 8.8% over 40 years (2021-2060).<sup>114</sup> This result is consistent with an earlier modeling study, which projected that a menthol ban would result in 633,252 fewer deaths, including 237,212 fewer deaths among Black Americans, over 40 years (2011-2050), assuming a 30% reduction in initiation and a 30% increase in cessation.<sup>115</sup>

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<sup>110</sup> American Heart Association. Heart Disease and Stroke Statistics - 2022 Update: A Report from the American Heart Association. 2022.

<sup>111</sup> HHS. The Health Consequences of Smoking. 2004.

<sup>112</sup> American Cancer Society. Health Benefits of Quitting Smoking Over Time.

<https://www.cancer.org/healthy/stay-away-from-tobacco/benefits-of-quitting-smoking-over-time.html>

<sup>113</sup> 87 FR at 26485.

<sup>114</sup> Levy DT, et al. Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tob Control*. 2021 Sep 2:tobaccocontrol-2021-056604. doi: 10.1136/tobaccocontrol-2021-056604. Epub ahead of print. PMID: 34475258; PMCID: PMC9210349.

<sup>115</sup> Levy, David T et al. Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States. *American journal of public health* vol. 101,7 (2011): 1236-40. doi:10.2105/AJPH.2011.300179

### ***Lower Health Care Costs***

A reduction in menthol cigarette use would also result in lower health care costs. Between 2010 and 2014, cigarette smoking was estimated to account for 11.7% of annual health care spending, or \$225 billion per year.<sup>116</sup> More than half of this spending was funded by Medicare and Medicaid. Cigarette smoking also costs the U.S. more than \$150 billion in lost productivity attributable to premature death and exposure to secondhand smoke.<sup>117</sup>

While AHA is unable to quantify the specific cost savings that would result from a menthol cigarette ban during this comment period, it is evident that fewer cigarette smokers would result in lower health care costs. Former smokers and never smokers require fewer medical services during their lifetime.<sup>118</sup>

### ***Advance Health Equity***

AHA agrees with the Agency that removing menthol cigarettes from the market is an important step to advance health equity. Menthol cigarettes take the greatest toll on the Black community. Black Americans smoke menthol cigarettes at disproportionately high rates, have the highest levels of exposure to secondhand smoke, suffer some of the highest burden of tobacco-related disease and death, have less access to comprehensive cessation services, and are less likely to successfully quit despite being more likely to try. Consequently, menthol cigarettes are largely responsible for tobacco-related health disparities in this population.

The best way to address tobacco-related health disparities is to eliminate menthol as a characterizing flavor in cigarettes. Because menthol use is heavily concentrated in Black and other underserved communities, menthol cigarette use and adverse tobacco-related health effects in these populations would likely decrease significantly. For example, one recent study that examined the impact of the FDA's proposed menthol cigarette ban on Black Americans, projected that smoking by Black adults would decrease 35.7%, avert 255,895 premature deaths, and result in an increase of 4 million life years over a 40-year period.<sup>119</sup> According to the study's authors, a menthol cigarette ban would have a disproportionately greater health impact on Black Americans, who would receive approximately one-third of the gains in averted deaths and life years lost, even though they only represent 12 to 13% of the overall U.S. population.<sup>120</sup>

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<sup>116</sup> Xin Xu, et al. U.S. healthcare spending attributable to cigarette smoking in 2014, *Preventive Medicine*, Volume 150, 2021. <https://doi.org/10.1016/j.ypmed.2021.106529>

<sup>117</sup> HHS. *The Health Consequences of Smoking*. 2004.

<sup>118</sup> Food and Drug Administration. *Tobacco Product Standard for Menthol in Cigarettes: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis*. 2022.

<sup>119</sup> Issabakhsh M, et al. Public health impact of a US menthol cigarette ban on the non-Hispanic black population: a simulation study. *Tobacco Control* Published Online First: 14 June 2022. doi: 10.1136/tobaccocontrol-2022-057298

<sup>120</sup> *Ibid.*



## **Scope of the Proposed Product Standard**

### ***No Cigarette Should Be Exempt from the Product Standard***

Under the proposed rule, all tobacco products that meet the definition of a “cigarette” would be subject to the new product standard prohibiting menthol as a characterizing flavor. However, the FDA is requesting comments on whether certain products should be eligible to apply for an exemption. Two examples the FDA provides are noncombusted and reduced nicotine cigarettes.

AHA strongly opposes creating an exemption process; all cigarettes should be required to comply with the menthol product standard. Allowing any menthol cigarettes to remain on the market would undermine the public health purpose of this rule.

As the FDA itself explains in the Federal Register notice, “Menthol’s flavor and sensory effects *increase appeal* and make menthol cigarettes easier to use, particularly among children and adults... In addition, data show that menthol cigarettes contribute to *greater nicotine dependence* in youth and young adults than non-menthol cigarettes... [And] Menthol in cigarettes contributes to *reduced cessation success*, particularly among Black smokers” (emphasis added).<sup>121</sup> The FDA also noted that, “Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate among youth, young adults, and other vulnerable populations such as African Americans and other racial and ethnic groups.” It is these concerns that led the FDA to propose removing menthol as a characterizing flavor in cigarettes.

The FDA should apply these same concerns to all menthol cigarettes. Menthol flavoring is highly attractive to youth and young adults. Any cigarette with menthol as a characterizing flavor may appeal to youth and young adults and increase smoking initiation. Likewise, the interaction between menthol and nicotine in the brain that FDA determined enhances nicotine addiction and makes it harder to quit, may apply to other types of cigarettes. In addition, the availability of menthol cigarettes – in any form – could decrease the likelihood that current smokers will quit. As we saw when other flavored cigarettes were removed from the market, current users – especially youth – move to the flavored product(s) that remains.

We are also concerned that allowing select menthol cigarettes to remain on the market could send the wrong message to consumers. Consumers could mistakenly believe that these products were allowed to remain on the market because they are safe, (or safer), or do not pose any risk to the tobacco user.

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<sup>121</sup> 87 FR 26457.

We also have specific concerns with the two types of cigarettes the FDA is considering.

### ***Noncombusted Cigarettes***

For the reasons described above, we do not believe any menthol cigarette should be allowed to remain on the market, including noncombusted cigarettes like IQOS or similar heated tobacco products (HTP).

With IQOS specifically, we are concerned about the lack of research examining this product's appeal to youth and to communities of color, two populations that heavily use menthol cigarettes. It is our understanding that Philip Morris did not provide FDA data on the impact of "Smooth Menthol" or "Fresh Menthol" IQOS heat sticks for either population. However, a study examining interest in IQOS in the U.S., Canada, and England found that 38.6% of youth expressed interest in trying the product, including 40.9% of youth respondents in the U.S.<sup>122</sup> Susceptibility to trying IQOS was 21.8% among youth never smokers or never vapers in the U.S., higher than the rate for conventional cigarettes (19%). This shows that youth interest in IQOS is high. And as the study's authors point out:

It is also worth noting that the current study tested interest and susceptibility for an 'unflavoured' version of the HTP tobacco sticks. However, the MRTP applications to the US FDA and tobacco sticks on the market in different countries include varieties with menthol flavours (e.g., Marlboro Smooth Menthol and Marlboro Fresh Menthol) which are associated with greater appeal among youth and young adults. *Therefore, actual levels of interest and susceptibility among youth may be higher than estimates from the current study.*<sup>123</sup> (emphasis added)

Therefore, allowing menthol IQOS or other similar products to remain on the market could result in increased initiation among youth.

In addition, given the tobacco industry's history of marketing menthol products to Black Americans, it is possible that menthol IQOS will be used to attract new Black users, and may increase the likelihood that current menthol users will switch to this product rather than quit.

### ***Reduced Nicotine Cigarettes***

As with noncombusted products, AHA believes that reduced nicotine cigarettes should be subject to the menthol product standard. Reduced nicotine cigarettes, such as VLN, contain less nicotine but they are still combustible tobacco products; they expose users to the same

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<sup>122</sup> Czoli, Christine D, et al. Awareness and interest in IQOS heated tobacco products among youth in Canada, England and the USA. *Tobacco control* vol. 29,1 (2020): 89-95. doi:10.1136/tobaccocontrol-2018-054654

<sup>123</sup> Ibid.

toxic chemicals and put users at risk for the same tobacco-related diseases and premature death. As we discuss above, we are concerned that consumers may erroneously believe that these cigarettes are safe if they are the only menthol cigarettes that remain on the market, especially if, like VLN, they bear a reduced exposure claim. And, because youth and young adults prefer menthol flavor, it may lead to increased initiation. There is also the potential that youth may start with a reduced nicotine menthol cigarette but later switch to a combustible tobacco product with higher nicotine, sustaining their addiction and risk for morbidity and mortality.

We are also concerned that the availability of reduced nicotine *menthol* cigarettes may lower cessation rates. Smokers may switch to these products rather than attempt to quit. In addition, tobacco industry research found that the addition of menthol to a reduced nicotine cigarette increases the “impact, perceived by the smoker as a ‘kick’ or ‘grab’ in the back of the mouth and throat when inhaling a cigarette, [and] is crucial in providing much of the immediate satisfaction from smoking.”<sup>124</sup> Philip Morris found that “menthol provided this perceived impact because it produced some nicotine-like effects” and “cigarettes without nicotine were preferred more when menthol was added.”<sup>125</sup> Researchers determined that “the use of menthol, especially in low nicotine delivery cigarettes, provides the strength and impact that higher nicotine level cigarettes deliver.”<sup>126</sup> If reduced nicotine menthol cigarettes deliver the same or similar levels of smoker satisfaction as normal nicotine content cigarettes, it is unclear that smokers would be motivated to quit smoking altogether.

Again, we ask the FDA to make all cigarettes subject to the menthol product standard.

## **Characterizing Flavor**

### ***Factors to Identify a Characterizing Flavor***

According to the proposed rule, the FDA intends to use the following four factors to determine if a cigarette has a characterizing flavor:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts
- The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packing) or advertising of tobacco products

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<sup>124</sup> Yerger VB. Menthol's potential effects on nicotine dependence: a tobacco industry perspective. *Tob Control*. 2011;20 Suppl 2(Suppl\_2):ii29-ii36. doi:10.1136/tc.2010.041970

<sup>125</sup> Ibid

<sup>126</sup> Ibid

- Any other means that impart flavor or represent that the tobacco product has a characterizing flavor

We understand the Agency's decision to utilize these "specific, flexible factors"<sup>127</sup> rather than one rigid definition. It would be difficult to develop one definition that adequately covers all the methods the tobacco industry can utilize to produce a flavored product or the sensation of one. It would also be difficult to capture new ingredients or innovations that the tobacco industry may develop in the future. In addition, providing one specific definition might actually make it easier for the tobacco industry to evade the flavoring restriction.

That said, we are still concerned that the tobacco industry will attempt to evade the four factors identified by the FDA. The tobacco industry has a long history of exploiting any loophole it can find. Therefore, we strongly encourage the FDA to consider ways to strengthen and apply the proposed factors. This may include flagging, limiting, or prohibiting the use of ingredients that are not traditionally thought of as flavors but provide some of the same sensory effects as menthol, such as sweeteners, ingredients that have anesthetic properties or that provide a cooling sensation, such as menthol analogs or alternatives. It could also include the use of multiple flavor additives but each in small amounts to evade any specific flavor limit, or the use of a small amount of menthol in conjunction with other ingredients that amplify its flavor or effects.

The factors the FDA ultimately selects must be able to withstand the innovative, persistent, and perpetual efforts the tobacco industry will undoubtedly employ.

### **Possible Countervailing Effects**

#### ***Illicit Trade Market***

In the Federal Register notice, the FDA examines possible countervailing effects that may occur if a menthol product standard is adopted, including an illicit trade market. We agree with the FDA's assessment that a menthol standard is unlikely to create a significant illicit market, that a large number of illicit menthol cigarettes would be available, or that a substantial number of smokers would utilize such products. We also agree that the risks of a potential illicit market do not outweigh the benefits created by this rule.

It is important to recognize that the argument that a menthol cigarette ban will create an illicit market is largely driven by the tobacco industry itself. The tobacco industry has a history of using the threat of an illegal market to argue against tobacco regulations, such as flavor restrictions and increased tobacco taxes. The industry overstates the risks of an illicit market to create opposition to the proposed policy. That is the case again here.

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<sup>127</sup> 87 FR at 26488.

It is unlikely that a large illicit market of menthol cigarettes would develop in the U.S. because the product standard would prohibit the manufacture, distribution, or sale of these products. Cigarette manufacturers would no longer be producing menthol cigarettes for a U.S. market, and it is unlikely that manufacturers would be willing to engage in large scale manufacturing of illegal products. In addition, because the menthol standard would apply nationwide, would-be participants in an illicit market would not be able to obtain menthol cigarettes simply by crossing state lines. Therefore, it would be difficult for entities to secure large quantities of menthol cigarettes to distribute and sell in an illicit market.

In addition, we are unaware of any evidence that other flavor restrictions have led to a significant increase in illicit tobacco. For example, after flavored cigarettes (other than menthol) were removed from the market in 2009 as directed by the Tobacco Control Act, there was no surge in illicit flavored cigarettes. Instead, as the FDA describes in the proposed rule, youth cigarette smoking decreased.<sup>128</sup> There is additional real-world evidence from other U.S. cities that have implemented flavor restrictions, as well as evidence from Canada and England. For example, after the Canadian province of Nova Scotia banned menthol cigarettes, a study found “there was no surge in illicit cigarettes after the 2015 ban on menthol cigarette sales.”<sup>129</sup> And, as the National Research Council and Institute of Medicine concluded in their 2015 report “Understanding the U.S. Illicit Tobacco Market,” “[o]verall, the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”<sup>130</sup>

The FDA and other enforcement agencies also have tools to combat an illicit market and minimize its effects. A recent letter from 23 Attorneys General in support of a menthol cigarette ban described several of those tools, such as preventing the importation of prohibited products (U.S. Customs and Border Protection), inspecting cigarette manufacturers (Alcohol and Tobacco Tax and Trade Bureau), and inspecting tobacco retailers (FDA).<sup>131</sup> The FDA could also implement a track-and-trace system, as required by the Tobacco Control Act. A track-and-trace system would allow the FDA to track tobacco products from their manufacture or importation to the point of retail sale by use of a unique,

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<sup>128</sup> 87 FR at 26470-26471.

<sup>129</sup> Stoklosa M. No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia. *Tobacco Control* 2019;28:702-704.

<sup>130</sup> National Research Council. 2015. *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/19016>.

<sup>131</sup> Attorney General of Connecticut, et al. Comments on Docket No. FDA-2013-P-0435. Citizen Petition to the Federal Food, Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes. Jan 22, 2021.

counterfeit-resistant identification code.<sup>132</sup> Illegal cigarettes that lack the track-and-trace code could be easily identified.

We understand that some opponents of the proposed rule have argued that a menthol cigarette ban would create an illicit market where underage youth could buy tobacco products. They argue it would be safer to keep menthol cigarettes on the market where they are sold by legitimate tobacco retailers who ID customers before purchase. While AHA strongly supports the 2019 federal law that raised the minimum sales age to 21, and we urge all retailers to comply with its requirements, we must note that underage youth are still able to obtain tobacco products. According to the 2021 National Youth Tobacco Survey, 2.55 *million* middle and high school students are current tobacco users.<sup>133</sup> This shows that age restrictions alone are not sufficient to keep youth from obtaining tobacco products. If menthol cigarettes are allowed to remain on the market, underage youth would still be able to access them from retail and social sources.

Opponents have also argued that banning menthol cigarettes will create an illicit market of “unsafe” tobacco products. They argue that menthol cigarettes imported from outside of the U.S. will be unregulated and contain more harmful ingredients. As one trade association explained it:

[I]llicit purveyors will sell unregulated products often imported from outside of the U.S. and containing more harmful ingredients. The tobacco products sold today are all authorized by FDA, meaning that they have undergone intense scrutiny by the agency to ensure that they meet appropriate standards under the Family Smoking Prevention and Tobacco Control Act. Counterfeit cigarettes avoid this scrutiny.<sup>134</sup>

This argument reflects a misunderstanding of the regulatory requirements for tobacco products. Any tobacco product on the U.S. market prior to February 15, 2007 was “grandfathered” and was not required to go through the FDA’s premarket review process; they were not subject to “intense scrutiny” or “authorized by the FDA.” This applies to almost every menthol cigarette currently on the U.S. market. Only three menthol cigarette products have undergone FDA review and received FDA authorization: IQOS Smooth Menthol, IQOS Fresh Menthol, and VLN (Moonlight) Menthol.<sup>135</sup> As such, the argument that menthol

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<sup>132</sup> Action on Smoking and Health, et al. Comments on FDA-2018-N-0529. Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard. July 16, 2018.

<sup>133</sup> Centers for Disease Control and Prevention. Press Release: Approximately 2.55 Million Students Reported Currently Using a Tobacco Product in 2021. March 10, 2022.

<sup>134</sup> The Petroleum & Convenience Marketers of Alabama. Comments to Docket No. FDA-2021-N-1349. Tobacco Product Standards for Menthol in Cigarettes. Posted May 23, 2022.

<sup>135</sup> FDA. Premarket Tobacco Product Marketing Granted Orders. <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>. Accessed June 16, 2022.

cigarettes should remain on the market legally because they are safer for having undergone FDA review is seriously flawed and should not be considered.

Again, we do not believe a menthol product standard will result in a significant illicit market, but, if an illicit market emerges, any potential adverse effects will be outweighed by the substantial public health benefit.

### **Potential Racial and Social Justice Implications**

#### ***Impact of a Menthol Ban on Minority Communities***

In the Federal Register notice, the FDA acknowledges concerns that a menthol cigarette ban may result in illicit trade, increased policing, and criminal penalties in underserved communities, including Black communities. The Agency then requests comments on the “policy considerations related to potential racial and social justice implications of the rule.”<sup>136</sup>

AHA appreciates the FDA requesting comments on this important topic. Racial discrimination and the overpolicing of Black people and other communities of color is a critical issue and one that must be addressed urgently; we share the public’s concern. Unfortunately, the tobacco industry has taken this legitimate issue, twisted, and exploited it, and turned it into a tool to defeat tobacco regulations. The tobacco industry itself is largely responsible for fueling the claim that a menthol cigarette ban will lead to increased policing in Black communities and mass incarcerations. Ironically, the tobacco industry aggressively pushes this talking point, while it continues to target these same communities with products that kill almost half-a-million people in the U.S. each year.

The tobacco industry has enlisted the help of community groups, influential leaders, social media influencers, politicians, and political organizations in its efforts to boost sales and fight tobacco restrictions. For decades, tobacco companies have aligned themselves with Black and Hispanic leaders and provided financial support that is meant to promote name recognition and engender goodwill among members of these communities and encourage trusted community figures to support the tobacco industry’s position on tobacco regulation, such as opposing a menthol cigarette ban.<sup>137,138</sup> For example, R.J. Reynolds (RJR), the manufacturer of Newport cigarettes, has recruited civil rights activist Rev. Al Sharpton and other prominent Black leaders to host town halls on menthol bans and increased

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<sup>136</sup> 87 FR at 26486.

<sup>137</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups: A Report of the Surgeon General. Atlanta, 1998.

<sup>138</sup> National Cancer Institute. The Role of the Media in Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19. Bethesda, MD: NIH Pub. No. 07-6242, June 2008.

criminalization.<sup>139</sup> RJR provides financial support to Rev. Sharpton’s organization, the National Action Network, which notably has come out against menthol cigarette restrictions.<sup>140</sup> A recent investigation by the L.A. Times and The Bureau of Investigative Journalism found that RJR also funds police organizations, such as the Law Enforcement Action Partnership (LEAP), and sponsored a luncheon at a National Black Caucus of State Legislators conference where a LEAP official served as the luncheon’s speaker and warned attendees that “prohibiting menthol cigarettes would increase policing in Black communities and create a new layer of racism.”<sup>141</sup> That investigation also identified other tactics, such as donating to the Congressional Black Caucus (CBC), enlisting lobbyists to fight menthol restrictions or write op-eds without acknowledging their client or the source of their funding, and paying protestors to attend a rally.<sup>142</sup> The tobacco industry has also used television and social media ads to oppose local flavored tobacco restrictions, claiming that it will increase racial profiling by law enforcement.<sup>143</sup> Most recently, the industry has tried to associate itself with the Black Lives Matter movement and concerns about police brutality.

However, the proposed rule is specifically designed not to increase law enforcement interactions with the community. The FDA is clear that the rule will only apply to manufacturers, distributors, wholesalers, importers, and retailers; it will not include a prohibition of individual consumer possession or use.<sup>144</sup> According to the Agency, “FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes.”<sup>145</sup> In addition, the FDA has clarified that state and local law enforcement entities do not and cannot take enforcement action on FDA’s behalf for violations of this restriction. Therefore, a federal ban on menthol cigarettes should not increase the risk of police abuse or racial discrimination within particular communities.

It is also important to recognize that the FDA is not “singling out” menthol cigarettes or purposely targeting the tobacco product many Black smokers prefer. Menthol cigarettes are the *only* flavored cigarette currently on the market; all other flavored cigarettes were removed in 2009 under the Tobacco Control Act, but menthol cigarettes were allowed to remain due to a massive lobbying campaign by the tobacco industry. That decision allowed tobacco companies to continue targeting communities of color, youth, LGBTQ, and others

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<sup>139</sup> Truth Initiative. Menthol: Facts, Stats and Regulations. April 22, 2022. <https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations>.

<sup>140</sup> Baumgaertner E, et al. How Big Tobacco Used George Floyd and Eric Garner to Stoke Fear Among Black Smokers. Los Angeles Times, April 25, 2022. <https://www.latimes.com/world-nation/story/2022-04-25/inside-big-tobaccos-strategy-to-stoke-fear-among-black-smokers-facing-menthol-bans>.

<sup>141</sup> Ibid.

<sup>142</sup> Ibid.

<sup>143</sup> Truth Initiative. Menthol: Facts, Stats and Regulations.

<sup>144</sup> 87 FR at 26488.

<sup>145</sup> 87 FR at 26484.



with these deadly, addictive products. The FDA’s proposal would “just add menthol to the existing list of prohibited flavors”<sup>146</sup> and put an end to that discrimination.

The important public health benefits of the proposed rule have also been recognized by many members of the Black community. The African American Tobacco Control Leadership Council, Association of Black Cardiologists, Black Women’s Health Imperative, Center for Black Health and Equity, NAACP, National Black Nurses Association, National Caucus and Center on Black Aging, and National Medical Association, among others have all voiced strong support for removing menthol cigarettes from the market. In a letter to HHS Secretary Becerra in April 2021, the groups described how “The industry’s successful campaign to hook Black/African Americans on a more addictive cigarette has had devastating consequences” and noted that:

The tobacco industry’s spokespeople have attempted to stoke fears that prohibiting menthol cigarettes is discriminatory, but this could not be further from the truth. The industry has mischaracterized a prohibition on menthol cigarettes as criminalizing Black/African American smokers when the tobacco industry is directly responsible for this disparity in menthol use. Therein lies the true injustice. There are undoubtedly racial injustices in our criminal justice system, but FDA’s rulemaking process should clarify that just as it enforces other tobacco regulations, a prohibition of menthol cigarettes will focus enforcement efforts on manufacturers and retailers, not individual consumers.<sup>147</sup>

A menthol ban is also supported by many Black policy makers. For example, in 2020, a majority of the CBC voted for legislation that would prohibit flavors in tobacco products, including menthol cigarettes. And last year, the CBC Health Braintrust called on HHS to remove menthol cigarettes from the market, stating that “[t]he tobacco industry must no longer be permitted to use menthol cigarettes to profit at the expense of the health of Black Americans.”<sup>148</sup> Support among the general community is also high. A survey of 2,871 adults between the ages of 18 and 64 found that 56.4% support a government policy to ban menthol cigarettes, including 60.5% of Black, 62.5% of Hispanic/Latino, 65.8% of non-Hispanic other, and 50.4% of non-Hispanic White respondents.<sup>149</sup>

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<sup>146</sup> Public Health Law Center. Menthol Ban: Highlighting the Facts and Rebutting Tobacco Industry Misinformation. [Menthol-Ban-Highlighting-the-Facts-and-Rebutting-Tobacco-Industry-Misinformation.pdf](https://publichealthlawcenter.org/Menthol-Ban-Highlighting-the-Facts-and-Rebutting-Tobacco-Industry-Misinformation.pdf) ([publichealthlawcenter.org](https://publichealthlawcenter.org))

<sup>147</sup> African American Tobacco Control Leadership Council, et al. Letter to HHS Secretary Becerra. April 14, 2021. [https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204\\_14\\_21.pdf](https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204_14_21.pdf)

<sup>148</sup> CBC Health Braintrust. Letter to HHS Secretary Becerra. April 15, 2021. [https://www.tobaccofreekids.org/assets/content/press\\_office/2021/CBCletter.pdf](https://www.tobaccofreekids.org/assets/content/press_office/2021/CBCletter.pdf)

<sup>149</sup> Czaplicki L, et al. National Support for a Menthol Cigarette Sales Ban. *Public Health Reports*. 2021;136(2):183-191. doi:10.1177/0033354920966004

Finally, we do not view this proposed rule as an either/or choice where the FDA must choose between protecting people from menthol cigarettes or from biased policing. We must address both issues. We cannot let this opportunity pass us by, and we cannot allow the tobacco industry – the same industry that has spent decades aggressively marketing and advertising its products to communities of color – to falsely frame this debate. Removing menthol cigarettes from the market is one of the most important public health actions the Agency can take to improve health, reduce tobacco-related health disparities, and advance health equity. We urge the FDA to move forward with this important public health action.

### **Effective Date**

#### ***Proposed Effective Date***

According to the proposed rule, a menthol product standard would take effect one year after a final rule is published. AHA agrees that one year is an appropriate timeline. A one-year effective date would be consistent with the statute, and it would give menthol cigarette smokers time to access cessation services and attempt to quit. We know that smoking cessation can be very difficult, and, for many, it takes multiple attempts to permanently quit. Because menthol increases the degree of addiction and makes it harder to quit, menthol smokers may find quitting more difficult, even though most want to quit. We believe one year strikes the appropriate balance between giving current smokers an opportunity to quit and not delaying the effective date for too long and increasing the number of new youth and young adults who start smoking menthol cigarettes. We would strongly oppose extending the effective date beyond one year.

One year would also give the FDA and other federal and state agencies sufficient time to expand cessation resources and to educate the public about the types of services available. To provide menthol smokers with adequate cessation support, the Agency should work with other departments within HHS to:

- Expand the 1-800-QUIT-NOW quit lines and include new options for smokers to access cessation resources, such as including online cessation services
- Expand and adapt the CDC's Tips from Former Smokers campaign to maximize its impact on the populations most affected by menthol cigarettes
- Expand coverage of tobacco cessation treatments and ensure that non-grandfathered group plans, individual insurance plans, and state Medicaid programs provide cessation services as required by the Affordable Care Act
- Launch a public education campaign to explain the nature of the menthol product standard, the reasons for it, and the cessation resources available

We must also assure equitable access to comprehensive cessation therapies for those who want to quit.

### ***Sell-Off Period***

The FDA requests comment on whether it should include a sell-off period, such as 30 days after the effective date of a final rule, to give retailers time to sell through their current inventory of menthol cigarettes. AHA strongly opposes a separate sell-off period. A one-year effective date will provide retailers sufficient time to plan, adjust their orders for menthol cigarettes, and sell any remaining inventory by the time the rule takes effect. There is no justification for a separate sell-off period.

### **Regulatory Impact Analysis**

#### ***Consumer Surplus***

AHA is disappointed that the Regulatory Impact Analysis (RIA) contains a discussion of “consumer surplus” or what is loosely defined as how much a consumer values or benefits from a product. As we have expressed to FDA previously, we do not believe that “consumer surplus” should be applied to tobacco use.

The concept of lost consumer surplus should only be considered when individuals are able to make fully rational and fully informed decisions. However, nearly nine out of 10 smokers start smoking before age 18 and 99% start before age 25.<sup>150</sup> Adolescents are not fully aware of the health consequences of tobacco use, have little concept of their own mortality, and heavily discount the threat of addiction, making their decisions neither fully informed nor rational. It is this premise – that youth may not be able to make fully rational decisions – that led policymakers to create and later raise the minimum sales age for tobacco products.

In addition, tobacco is addictive and once an individual becomes addicted, the decision to continue buying tobacco products is no longer rational. This is particularly true for menthol cigarettes since menthol enhances the addictive effects of nicotine in the brain and increases the likelihood and degree of addiction. Addiction is not a pleasurable experience. Instead, addiction to a deadly product can lead to frustration and anger as individuals find it very difficult to quit using tobacco. Surveys have found that nearly 70% of adult smokers want to stop smoking and 56% have made a serious quit attempt;<sup>151</sup> most wish they had never started.

By applying consumer surplus, the Agency is also ignoring the role that decades of targeted marketing have played in enticing people to use menthol cigarettes. The tobacco industry has gone to great effort and expense to develop products that appeal to young people and

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<sup>150</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, 2012.

<sup>151</sup> Babb, S., et al. Quitting Smoking Among Adults—United States, 2000-2015. Morbidity and Mortality Weekly Report, 65(52):1457-1464. 2017.

other targeted populations and are designed to maximize addictiveness.<sup>152</sup> That means that smoking menthol cigarettes “is not as personal a ‘choice’ as some assume.”<sup>153</sup>

According to the RIA, the FDA recognizes some of the challenges of applying consumer surplus to smoking, noting “it is difficult to disentangle consumption driven by addiction from that which may be driven by rational demand” and “some argue that most consumers do not experience losses from reduced use because they derive little to no pleasure from consumption,” yet the Agency still considers consumer surplus as “appropriate impact to consider.”<sup>154</sup> We disagree and we urge the Agency to remove the concept of consumer surplus or consumer utility change from the RIA.

### **Conclusion**

In closing, we reiterate our strong support for the proposed rule. Prohibiting menthol as a characterizing flavor in cigarettes is appropriate for the protection of public health. Removing menthol cigarettes from the market would reduce initiation, increase cessation, and lower rates of tobacco-related death and disease. This product standard would also lower health care costs, reduce health disparities, and advance health equity. Importantly, it would also eliminate one of the tobacco industry’s most insidious tools to attract and addict new smokers, especially among communities of color and other underserved populations. We applaud the FDA for taking this important step.

To keep the rule strong and maximize its public health benefit, we urge the FDA to:

- Apply the product standard to all tobacco products that meet the definition of a “cigarette;” there must be no exemptions.
- Apply the product standard to all cigarette components, parts, and packaging, including those that are sold separately to consumers.
- Strengthen the factors used to identify a “characterizing flavor” to eliminate loopholes.
- Work with federal and state agencies to expand cessation resources.
- Launch a public education campaign.
- Establish a one-year effective date with no sell-off period.

AHA also encourages the Agency to work as expeditiously as possible to release the final rule. Eleven years have passed since TPSAC first determined that removing menthol cigarettes from the market would benefit public health. During that time, the market share for menthol cigarettes continued to increase and the number of Black, American Indian/Alaska Native

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<sup>152</sup> Public Health Law Center. Menthol Ban: Highlighting the Facts and Rebutting Tobacco Industry Misinformation.

<sup>153</sup> Ibid.

<sup>154</sup> FDA. Tobacco Product Standard for Menthol in Cigarettes: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis. 2022.

and Hispanic youth and adults using these products remained high. We fear that any additional delay will have real, and continuing, public health consequences. Therefore, we urge you to release the final rule by the end of this calendar year.

Prohibiting menthol cigarettes is one of the most important actions the FDA can take “to ensure that tobacco-related disease and death is a part of America’s past, not America’s future.”<sup>155</sup> We look forward to continuing to work with you to achieve this mutual goal.

Thank you for your consideration of our comments.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Senior Regulatory Affairs Advisor, at 202-785-7908 or [susan.k.bishop@heart.org](mailto:susan.k.bishop@heart.org).

Sincerely,

A handwritten signature in black ink that reads "Nancy A. Brown". The signature is written in a cursive, flowing style.

Nancy A. Brown  
Chief Executive Officer  
American Heart Association

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<sup>155</sup> @FDATobacco. May 20, 2002. <https://twitter.com/FDATobacco/status/1527689609261506560>