

TIM BYRON (SBN 277569)
tbyron@byronraphael.com
BYRON RAPHAEL LLP
100 Pine Street, Suite 1250
San Francisco, CA 94111
Telephone: (415) 839-8500
Facsimile: (213) 377-5771

DENNIS A. HENIGAN (Of Counsel)
CONNOR FUCHS (Of Counsel)
dhenigan@tobaccofreekids.org
cfuchs@tobaccofreekids.org
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street, NW, Suite 1200
Washington, D.C. 20005
(202) 296-5469

Attorneys for Proposed *Amici Curiae*

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL
LEADERSHIP COUNCIL, ACTION ON
SMOKING AND HEALTH, AMERICAN
MEDICAL ASSOCIATION, AND NATIONAL
MEDICAL ASSOCIATION,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, XAVIER BECERRA, in his
official capacity as Secretary of the U.S.
Department of Health and Human Services; U.S.
FOOD AND DRUG ADMINISTRATION; JANET
WOODCOCK, in her official capacity as Acting
Commissioner of Food and Drugs; CENTER FOR
TOBACCO PRODUCTS; MITCH ZELLER in his
official capacity as the Director of the Center for
Tobacco Products,

Defendants.

No. 4:24-cv-01992-HSG

**BRIEF OF *AMICI CURIAE* MEDICAL
AND PUBLIC HEALTH GROUPS IN
SUPPORT OF PLAINTIFFS' OPPOSITION
TO DEFENDANTS' MOTION TO DISMISS**

Date: January 16, 2025

Time: 2:00 p.m.

Judge: The Hon. Haywood S. Gilliam, Jr.

Place: Oakland, Courtroom 2, 4th Floor

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1 *Amici*, five national medical and public health organizations, submit this brief in support of
 2 the Plaintiffs and urge the Court to deny Defendants’ Motion to Dismiss.

3 **STATEMENT OF INTEREST OF *AMICI CURIAE***

4 *Amici* are the following national medical and public health organizations: American Cancer
 5 Society Cancer Action Network, American Public Health Association, American Thoracic Society,
 6 Campaign for Tobacco-Free Kids, and Parents Against Vaping E-Cigarettes. As detailed in *amici*’s
 7 motion for leave, each of these groups works on a daily basis to reduce the devastating health harms
 8 of tobacco products, including menthol cigarettes. *Amici* include physicians who treat tobacco-
 9 related disease and counsel patients about the hazards of tobacco use, groups representing parents
 10 and families struggling to free young people from nicotine addiction, and advocates dedicated to
 11 eliminating the death and disease wrought by tobacco products. Each of these organizations has a
 12 direct and immediate interest in curbing the sale of menthol cigarettes, as well as substantial
 13 expertise in the role menthol cigarettes play in increasing youth smoking, decreasing smoking
 14 cessation, and imposing a disproportionate burden on communities of color targeted by the tobacco
 15 industry. Accordingly, *amici* are particularly well suited to inform the Court of the public health
 16 urgency of a final rule prohibiting the manufacture and sale of menthol cigarettes, and the harm
 17 wrought by the Food and Drug Administration’s (“FDA”) unreasonable delay in issuing such a rule.

18 **INTRODUCTION AND SUMMARY OF ARGUMENT**

19 In the Family Smoking Prevention and Tobacco Control Act (“TCA”), Congress tasked
 20 FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) with issuing a “report and
 21 recommendation” on “the impact of the use of menthol cigarettes on the public health, including
 22 such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.”
 23 21 U.S.C. § 387g(e). It has now been more than 13 years since TPSAC issued its report concluding
 24 that “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the
 25 United States.” Yet, FDA has failed to exercise its authority to prohibit the manufacture and sale
 26 of these products, allowing them to remain on the market to this day. FDA’s failure to act is
 27 especially troubling given that: (1) in 2013, FDA’s own staff scientists concluded that menthol
 28 cigarettes pose a risk to public health beyond that posed by nonmenthol cigarettes; (2) a Citizen

Petition filed that same year called on FDA to ban menthol cigarettes; (3) in 2018, the FDA Commissioner committed to issue a proposed rule banning menthol cigarettes; (4) in May 2022, in response to Plaintiffs' earlier lawsuit, FDA proposed a rule to prohibit menthol as a characterizing flavor in cigarettes; and (5) the accumulating data leaves no doubt that menthol as a characterizing flavor in cigarettes: (i) increases initiation of smoking by young people by masking the harshness of cigarette smoke, (ii) makes cigarettes more addictive and harder to quit, and (iii) poses a disproportionate burden of disease and death on African Americans due to decades of targeted marketing by cigarette companies. The most recent estimates establish that menthol in cigarettes slows the decline in smoking prevalence, thus costing many thousands of lives with each passing year. In the face of such clear evidence of the public health toll of these products, FDA's record on this issue is, by any measure, one of "unreasonable delay." Accordingly, the Court should deny Defendants' Motion to Dismiss.

ARGUMENT

I. FDA's Delay in Issuing the Final Menthol Rule Is Inflicting Serious and Ongoing Harm to Public Health.

FDA issued the Proposed Menthol Rule on May 4, 2022, in which it recognized the extraordinary and continuing harm to public health from menthol cigarettes, and the corresponding life-saving benefits from action to prohibit their future production and sale. Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,454 (proposed May 4, 2022) ("Proposed Menthol Rule"). In the preamble to the Proposed Menthol Rule, FDA summarized the public health harms of menthol cigarettes, and the immense benefit of a rule prohibiting their manufacture and sale: "Menthol's flavor and sensory effects increase appeal and make menthol cigarettes easier to use, particularly among youth and young adults." *Id.* A rule banning menthol as a characterizing flavor in cigarettes "would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking." *Id.* It would also "improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation." *Id.* This rule, according to FDA, would

1 “reduce the tobacco-related death and disease associated with menthol cigarette use” and “advance
2 health equity” by reducing tobacco-related health disparities. *Id.*

3 As the discussion below demonstrates, it is precisely those health harms, already recognized
4 by FDA, that justify continued judicial oversight of this case to prevent further undue delay by the
5 agency and to ensure prompt completion of the rulemaking process on menthol cigarettes. Since
6 the Citizen Petition was filed in 2013 by some of the *amici* here, the agency’s unreasonable delay
7 has contributed to many thousands of preventable deaths, and untold suffering from tobacco-related
8 disease. For every additional day that passes, the toll of disease and death continues to mount.

9 **A. Menthol Cigarettes Increase Youth Initiation of Smoking.**

10 Although tobacco companies are well aware that almost all new tobacco users begin their
11 addiction as kids, they also know that, to novice smokers, tobacco smoke can be harsh and
12 unappealing. Menthol cigarettes mask the harshness and sooth the irritation caused by tobacco
13 smoke, thereby making it easier for beginners to experiment with cigarettes and ultimately become
14 addicted.¹ In 1987, the tobacco company Brown & Williamson observed, “Menthol brands have
15 been said to be good starter products because new smokers appear to know that menthol covers up
16 some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy.”²

17 When then-FDA Commissioner Scott Gottlieb stated the agency’s intention to begin a
18 rulemaking to ban menthol cigarettes in 2018, he stated that because “menthol serves to mask some
19 of the unattractive features of smoking that might otherwise discourage a child from smoking,”
20 “these menthol-flavored products represent one of the most common and pernicious routes by
21 which kids initiate on combustible cigarettes.”³ Thus, young smokers are more likely to use
22 menthol cigarettes than any other age group. As FDA has stated, “[m]ultiple studies show a greater
23 use of menthol cigarettes by younger smokers and less usage among older smokers.” Advance

24 ¹ See 87 Fed. Reg. at 26,457.

25 ² Kim Klausner, *Menthol cigarettes and smoking initiation: a tobacco industry perspective*, 20
26 (Supp. 2) TOBACCO CONTROL ii12, ii14 (2011),
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088463/pdf/tobaccocontrol41954.pdf>.

27 ³ FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect*
28 *youth by preventing access to flavored tobacco products and banning menthol in cigarettes* (Nov.
15, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

1 Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294,
 2 12,296 (Mar. 21, 2018). The FDA's TPSAC, after an extensive study of the public health impact
 3 of menthol cigarettes, concluded in its 2011 Report that menthol cigarettes increase the number of
 4 children who experiment with cigarettes and who become regular smokers, thereby increasing
 5 overall youth smoking, and that young people who initiate smoking with menthol cigarettes are
 6 more likely to become addicted and long-term daily smokers.⁴ Since 90% of adult smokers begin
 7 smoking in their teens,⁵ menthol cigarettes, as a starter product for the young, are critical to the
 8 tobacco industry's need to recruit "replacement smokers" for the one-half of long-term smokers
 9 who eventually die from tobacco-related disease. In its 2011 Report, TPSAC projected that by 2020,
 10 about 2.3 million people will have started smoking because of menthol cigarettes, leading to 17,000
 11 premature deaths.⁶ TPSAC concluded that "[r]emoval of menthol cigarettes from the marketplace
 12 would benefit public health in the United States."⁷

13 Two years after submission of the TPSAC Report, FDA completed its own independent,
 14 peer-reviewed evaluation of the science concerning menthol cigarettes. FDA's *Preliminary*
 15 *Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol*
 16 *Cigarettes* ("FDA Report") found that "menthol use is likely associated with increased smoking
 17 initiation by youth and young adults."⁸ It also reached the overall conclusion, consistent with
 18
 19

20 ⁴ TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE ("TPSAC"), FDA, MENTHOL
 21 CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS
 22 109, 121 (2011), [https://wayback.archive-
 23 it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/Committees
 MeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf) ("TPSAC
 Report").

24 ⁵ OFFICE OF THE SURGEON GENERAL ("OSG"), U.S. DEPT. OF HEALTH AND HUMAN SERVICES
 25 ("HHS"), THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE
 26 SURGEON GENERAL 708 (2014), [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/
 Bookshelf_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf).

27 ⁶ TPSAC Report, *supra* note 4, at 221.

28 ⁷ *Id.* at 225.

⁸ FDA, PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF
 MENTHOL VERSUS NONMENTHOL CIGARETTES 6 (2013),
<https://www.fda.gov/media/86497/download> ("FDA Report").

1 TPSAC's own findings, that it is "likely that menthol cigarettes pose a public health risk above that
2 seen with nonmenthol cigarettes."⁹

3 FDA's Proposed Menthol Rule reached similar conclusions: "Menthol's flavor and sensory
4 effects reduce the harshness of cigarette smoking and make it easier for new users, particularly
5 youth and young adults, to continue experimenting and progress to regular use." 87 Fed. Reg. at
6 26,455. Thus, young smokers are more likely to use menthol cigarettes than any other age groups.
7 As FDA observed in the proposed rule, this "disproportionate use of menthol cigarettes by youth
8 and young adult smokers compared to older adults has been consistent over time and across
9 multiple studies with nationally representative populations."¹⁰

10 The impact of menthol cigarettes in attracting and addicting young people has long-term,
11 adverse health effects. FDA has found that "smoking cigarettes during adolescence is associated
12 with lasting cognitive and behavioral impairments, including effects on working memory in
13 smoking teens and alterations in the prefrontal attentional network in young adult smokers."
14 Advance Notice, 83 Fed. Reg at 12,295. "Use of tobacco products," according to the FDA, "puts
15 youth and young adults at greater risk for future health issues, such as coronary artery disease,
16 cancer, and other known tobacco-related diseases." *Id.*

17 The devastating health impact of menthol cigarettes is most starkly shown by a study by
18 researchers from the University of Michigan. With the same methodology used by TPSAC, the
19 study estimates that during the 38-year period from 1980-2018, menthol cigarettes were responsible
20 for 10.1 million extra smokers (approximately 266,000 extra smokers every year) and 378,000
21 additional smoking related deaths (almost 10,000 additional deaths per year).¹¹

22 **B. Menthol Cigarettes Increase Addiction and Reduce Cessation.**

23 The TPSAC Report, 2013 FDA Report, and Proposed Menthol Rule all found that, in
24 addition to increasing initiation of smoking among young people, menthol cigarettes are
25

26 ⁹ *Id.*

27 ¹⁰ *Id.*

28 ¹¹ Thuy T.T. Le & David Mendez, *An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018*, 31 Tobacco Control 564, 566 (2022), <https://tobaccocontrol.bmj.com/content/early/2021/02/09/tobaccocontrol-2020-056256.info>.

1 associated with increased nicotine dependence and reduced success in smoking cessation.¹² In the
 2 Proposed Menthol Rule, FDA explained how menthol enhances “the addictive effects of nicotine
 3 in the brain by affecting mechanisms involved in nicotine addiction, which is especially harmful
 4 to youth and young adults, whose brains are more susceptible to nicotine addiction.” 87 Fed. Reg.
 5 at 26,457. This interaction of menthol and nicotine in the brain “plays a role in making it easier to
 6 experiment, progress to regular smoking and dependence, and harder to quit.” *Id.* at 26,464.

7 Other recent research bolsters FDA’s findings that menthol cigarettes increase addiction
 8 and reduce cessation. The 2020 Surgeon General’s Report on smoking cessation cited numerous
 9 studies that found an association between menthol use and lower cessation rates. The report
 10 concluded that the evidence is suggestive that restricting menthol products would lead to increased
 11 smoking cessation.¹³ A more recent study analyzing PATH data found that smokers who used
 12 menthol cigarettes prior to a quit attempt were 28% less likely to abstain from smoking for more
 13 than 30 days and 53% less likely to abstain for more than one year, compared to non-menthol
 14 smokers.¹⁴

15 Data from the 2017 and 2018 National Youth Tobacco Surveys show that among middle
 16 and high school students, menthol smoking was associated with greater smoking frequency and
 17 intention to continue smoking, compared to non-menthol smoking.¹⁵ Data from the Government
 18 PATH study shows that youth menthol smokers have significantly higher levels of certain measures
 19 of dependence,¹⁶ and that initiation with a menthol-flavored cigarette is associated with a higher
 20
 21

22 ¹² TPSAC Report, *supra* note 4, at 147; FDA Report, *supra* note 8, at 5-6; Proposed Menthol Rule,
 23 87 Fed. Reg. at 26,464-68 .

24 ¹³ OSG, HHS, SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 12 (2020),
<https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

25 ¹⁴ Eric C. Leas et al., *Effects of menthol use and transitions in use on short-term and long-term*
cessation from cigarettes among US smokers, TOBACCO CONTROL 1, 4 (2021),
<https://tobaccocontrol.bmj.com/content/early/2021/07/01/tobaccocontrol-2021-056596>.

26 ¹⁵ Sunday Azagba et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent*
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27 ¹⁶ Sam N. Cwalina et al., *Adolescent menthol cigarette use and risk of nicotine dependence:*
Findings from the national Population Assessment on Tobacco and Health (PATH) study, 206
 28 DRUG & ALCOHOL DEPENDENCE 1, 3 (2020).

1 relative risk of daily smoking.¹⁷ Thus, there is little doubt that menthol cigarettes have led millions
2 of youth into long-term tobacco addiction.

3 The difficulty that menthol smokers have in quitting is reflected in national smoking
4 prevalence trends. From 2008 to 2014, overall smoking rates generally declined, but the proportion
5 of smokers using menthol cigarettes increased significantly. Menthol smoking rates have increased
6 among young adults and remained constant among youth and older adults, while non-menthol
7 smoking has decreased in all three age groups. Overall, about 4 out of 10 (38.8%) smokers used
8 menthol cigarettes in 2012-2014, an increase from 34.7% in 2008-2010.¹⁸ Sales trends echo the
9 patterns seen in menthol smoking prevalence. Between 2009 and 2018, sales of non-menthol
10 cigarettes declined by 33.1% nationally while sales of menthol cigarettes have declined by only
11 8.2% during the same period.¹⁹ Of the decline in cigarette sales between 2009 and 2018, 91% is
12 attributable to non-menthol cigarettes.²⁰

13 There is little question, therefore, that menthol cigarettes not only introduce young people
14 to smoking, they also increase addiction for youth and adults.

15 **C. Menthol Cigarettes Have Led to Significant Health Disparities for African** 16 **Americans.**

17 Menthol cigarettes have played an especially pernicious role in causing disease and death
18 in the African American community. Since at least the 1950s, the tobacco industry has targeted
19 African Americans with marketing for menthol cigarettes through magazine advertising,
20 sponsorship of community and music events, and youthful imagery and marketing in the retail
21

22
23 ¹⁷ Andrea C. Villanti et al., *Association of Flavored Tobacco Use With Tobacco Initiation and*
24 *Subsequent Use Among US Youth and Adults, 2013-2015*, 2 J. AM. MED. ASS'N NETWORK OPEN 1,
12 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

25 ¹⁸ Andrea C. Villanti et al., *Changes in the prevalence and correlates of menthol cigarette use in*
26 *the USA, 2004-2014*, 25 (Supp. 2) TOBACCO CONTROL ii14, ii15 (2016),
https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_2/ii14.full.pdf.

27 ¹⁹ Cristine D. Delnevo et al., *Assessment of Menthol and Nonmenthol Cigarette Consumption in the*
28 *US, 2000 to 2018*, 3 J. AM. MED. ASS'N NETWORK OPEN 1, 1 (2020),
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132>.

²⁰ *Id.*

environment.²¹ For example, the industry has strategically placed menthol cigarette ads featuring Black models in magazines with high Black readership. One study found that from 1998-2002, *Ebony* was 9.8 times more likely than *People* magazine to carry ads for menthol cigarettes.²² The industry marketed menthol brands through popular community events, particularly those focused around music, such as R.J. Reynolds' Salem Summer Street Scenes festivals, Brown & Williamson's Kool Jazz Festival, and Philip Morris's Club Benson & Hedges promotional bar nights, which targeted clubs frequented by Black Americans.²³ R.J. Reynolds estimated that they reached at least half of African Americans in five major cities through their street festivals.²⁴



Figure 1: 1966 Kool Magazine Advertisement, <https://tobacco.stanford.edu/cigarette/img18678/>.

The industry also targets African Americans through culturally appropriated branding and images. For example, in 2004, Brown & Williamson launched an ad campaign for Kool featuring

²¹ See generally CAMPAIGN FOR TOBACCO-FREE KIDS ET AL., STOPPING MENTHOL, SAVING LIVES: ENDING BIG TOBACCO'S PREDATORY MARKETING TO BLACK COMMUNITIES 7-9 (2021), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf ("Tobacco-Free Kids Report").

²² Hope Landrine et al., *Cigarette Advertising in Black, Latino, and White Magazines, 1998-2002: An Exploratory Investigation*, 15 ETHNIC DISPARITIES 63, 65 (2005).

²³ Navid Hafez & Pamela M. Ling, *Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes*, 15 TOBACCO CONTROL 359, 360 (2006); Valerie B. Yerger et al., *Racialized geography, corporate activity, and health disparities: tobacco industry targeting of inner cities*, 18 J. HEALTH CARE FOR POOR & UNDERSERVED 10, 25 (2007); see also R.J. Reynolds, *Black Street Scenes 1993 Review and Recommendations*, in TRUTH TOBACCO INDUSTRY DOCUMENTS, <http://legacy.library.ucsf.edu/tid/onb19d00>.

²⁴ Yerger et al., *supra* note 23, at 25.

1 images of young Black rappers, DJs, and dancers on cigarette packages and in advertising (Figure
 2 2). The campaign also included radio giveaways with cigarette purchases and a hip-hop DJ
 3 competition in major cities.²⁵

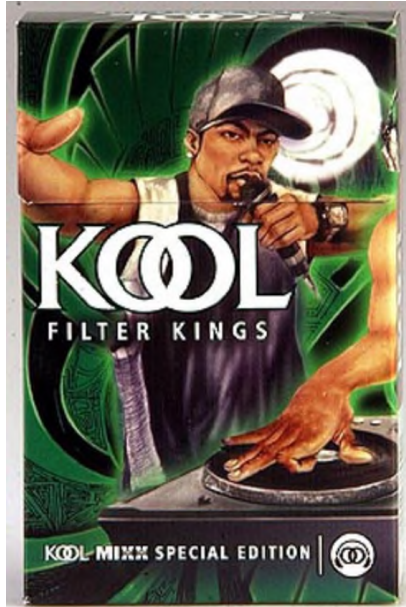


Figure 2: 2004 Kool Mixx Special Edition cigarette pack, <https://tobacco.stanford.edu/cigarette/img6856/>.

14 Today, menthol cigarettes continue to be more heavily advertised and priced cheaper in
 15 Black communities, making them especially appealing to price-sensitive youth. The 2018
 16 California Tobacco Retail Surveillance Study found that menthol advertisements were significantly
 17 more common in neighborhoods with higher proportions of African American residents and school-
 18 age youth.²⁶ Another California study concluded that, as the proportion of African American high
 19 school students in a neighborhood rose, so did the proportion of menthol advertising.²⁷ A 2021
 20 study found that in Los Angeles County, stores located in predominantly African American
 21 neighborhoods had significantly higher odds of selling Newport cigarettes (the most popular
 22 menthol brand) than stores in Hispanic or non-Hispanic White neighborhoods.²⁸ The study also

24 ²⁵ Hafez & Ling, *supra* note 23, at 362-63.

25 ²⁶ Nina C. Schleicher et al., CALIFORNIA TOBACCO RETAIL SURVEILLANCE STUDY 2018, at 3, 22 (2019),
 26 <https://www.cdph.ca.gov/Programs/CCDC/DCDC/CTCB/Pages/FactSheetsAndReports.aspx>.

27 ²⁷ Lisa Henriksen et al., *Targeted Advertising, Promotion, and Price For Menthol Cigarettes in California High School Neighborhoods*, 14 NICOTINE TOBACCO RES. 116, 118 (2012).

28 ²⁸ Sabrina L. Smiley et al., *Retail Marketing of Menthol Cigarettes in Los Angeles, California: a Challenge to Health Equity*, 18 PREVENTING CHRONIC DISEASE (2021),
https://www.cdc.gov/PCD/issues/2021/20_0144.htm.

1 found that the estimated price of a Newport single pack was \$0.38 higher in non-Hispanic White
 2 neighborhoods than in African American neighborhoods.²⁹ The 2024 Surgeon General’s Report on
 3 tobacco-related health disparities concluded that “marketing for menthol cigarettes” is “more
 4 prevalent in neighborhoods with greater percentages of African American residents or of residents
 5 with lower incomes . . .”³⁰

6 The tobacco industry’s use of menthol cigarettes to target African Americans has paid
 7 lucrative, but tragic, dividends. In the early 1950s, 5% of African American smokers preferred
 8 menthol brands.³¹ By 2018, *85% of African American smokers smoked menthol cigarettes*,
 9 compared to 29% of Whites.³² In its 2011 Report, FDA’s TPSAC concluded that menthol cigarettes
 10 are associated with lower levels of smoking cessation among African Americans.³³ TPSAC also
 11 estimated that by 2020, over 460,000 African Americans will have started smoking because of
 12 menthol cigarettes, and 4,700 excess deaths of African Americans will have been attributable to
 13 menthol cigarettes.³⁴ A recent study that used the same methodology as the 2011 TPSAC Report
 14 found that, from 1980-2018, among the African American community, menthol was responsible
 15 for 1.5 million extra smokers, 157,000 smoking-related premature deaths, and 1.5 million excess
 16 life-years lost.³⁵ During this 38-year period, African Americans represented 15% of extra new
 17 smokers, 41% of excess premature deaths, and 50% of excess life-years lost, despite accounting for
 18

19 ²⁹ *Id.*

20 ³⁰ OSG, HHS, ELIMINATING TOBACCO-RELATED DISEASE AND DEATH: ADDRESSING DISPARITIES:
 21 A REPORT OF THE SURGEON GENERAL, EXECUTIVE SUMMARY 9 (2024),
 22 [https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-exec-](https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-exec-summary.pdf)
 23 [summary.pdf](https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-exec-summary.pdf).

24 ³¹ See Phillip S. Gardiner, *The African Americanization of menthol cigarette use in the United*
 25 *States*, 6 (Supp. 1) NICOTINE & TOBACCO RES. S55, S59 (2004); Burns W. Roper, *A Study of*
 26 *People’s Cigarette Smoking Habits and Attitudes Volume I*, in TRUTH TOBACCO INDUSTRY
 27 DOCUMENTS (1953), <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fhcv0035>.

28 ³² Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*,
 29 22 NICOTINE & TOBACCO RES. 1673, 1674 (2020),
 30 <https://pmc.ncbi.nlm.nih.gov/articles/PMC7542641/>.

31 ³³ TPSAC Report, *supra* note 4, at 147.

32 ³⁴ *Id.* at 223.

33 ³⁵ David Mendez & Thuy T.T. Le, *Consequences of a match made in hell: the harm caused by*
 34 *menthol smoking to the African American population over 1980-2018*, TOBACCO CONTROL 1, 2
 35 (2021), <https://tobaccocontrol.bmj.com/content/early/2021/09/16/tobaccocontrol-2021-056748>.

only 12% of the population.³⁶ Menthol cigarettes are a major reason why tobacco use is the number one cause of preventable death among African Americans, who die from smoking-caused diseases at far higher rates than other Americans.³⁷ The 2024 Surgeon General’s Report concluded that “[r]emoving menthol cigarettes from the marketplace should . . . reduce disparities in tobacco initiation, nicotine dependence, cessation success, and tobacco-related health outcomes, especially if policies are comprehensive and equitably implemented.”³⁸

As FDA concluded in the Proposed Menthol Rule, “scientific evidence indicates that menthol cigarettes have historically and continue to be disproportionately marketed in underserved communities and contribute to the longstanding disparities in menthol cigarette smoking and health outcomes observed in vulnerable populations, particularly the Black community.” 87 Fed. Reg. at 26,469. Thus, for every day that passes without action on menthol cigarettes, the tobacco industry’s decades of targeted advertising and promotion has a disproportionate impact on African Americans, worsening existing and deeply entrenched health disparities.

D. The Aggressive Marketing of Menthol Cigarettes Continues.

Cigarette companies continue to engage in aggressive marketing of menthol cigarettes, underscoring the importance of avoiding any further regulatory delay. New products, packaging, and advertisements have appeared in recent years, as leading manufacturers seek to maintain interest in menthol cigarettes by current smokers, while also attracting new smokers. For example, in May 2021, Newport introduced two new menthol products (“Newport Boost” and “Newport Boost Gold”), allowing the smoker to “boost your menthol” by squeezing the filter.³⁹ Newport sponsored a \$50,000 Sweepstakes to promote the new product.⁴⁰ Two similar products

³⁶ *Id.*

³⁷ See generally Tobacco-Free Kids Report, *supra* note 21, at 4 and sources cited therein.

³⁸ OSG, *supra* note 30, at 12.

³⁹ *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, RUTGERS SCHOOL OF PUBLIC HEALTH, <http://trinketsandtrash.org/detail.php?artifactid=15540&page=1> (last accessed Nov. 20, 2024) (capturing Newport Boost ad in May 10, 2021 issue of *Us Weekly*).

⁴⁰ *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, Rutgers Health, Institute for Nicotine and Tobacco Studies, <https://trinketsandtrash.org/detail.php?artifactid=15922> (last accessed Nov. 20, 2024) (capturing an email from Camel about the “Boost Your Menthol Sweepstakes” sent on July 8, 2021).

1 (“Camel Crush Rich” and “Camel Crush Smooth”) were introduced by R.J. Reynolds in 2019 and
 2 2020, respectively.⁴¹ Moreover, a plethora of new packaging has appeared in recent years,
 3 particularly for Camel Crush.⁴² Companies also continue to heavily advertise their menthol
 4 cigarettes, as shown in Figure 4, which is an advertisement for KOOL menthol cigarettes that
 5 appeared in the May 2023 issue of *Maxim* magazine. Finally, promotional discount coupons also
 6 are being used to stimulate demand⁴³ and the targeted marketing to the African American
 7 consumer continues unabated.⁴⁴



Figure 3: May 2023 Kool advertisement in *Maxim* magazine, <https://trinketsandtrash.org/detail.php?artifactid=15862&page=1>.

⁴¹ *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, Rutgers Health, Institute for Nicotine and Tobacco Studies, <https://trinketsandtrash.org/detail.php?artifactid=15921> (last accessed Nov. 20, 2024) (capturing an email from Camel that “Smooth has arrived” and “Smooth Menthol on demand in stores now” sent in July 2020); <https://www.trinketsandtrash.org/detail.php?artifactid=14739> (last accessed Nov. 20, 2024) (capturing an email from Camel about “Introducing Crush Rich” sent on July 19, 2019).

⁴² See, e.g., *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, Rutgers Health, Institute for Nicotine and Tobacco Studies, <https://www.trinketsandtrash.org/detail.php?artifactid=15496> (last accessed Nov. 20, 2024) (capturing an email from Camel sent on Mar. 3, 2021 titled “New Look Same Originality”).

⁴³ *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, RUTGERS SCHOOL OF PUBLIC HEALTH, <http://trinketsandtrash.org/detail.php?artifactid=14212&page=1> (last accessed Aug. 19, 2021).

⁴⁴ *The Lounge*, NEWPORT, <https://www.newport-pleasure.com/secure/lounge/2021/04/streetwear-staples.html> (last accessed Nov. 20, 2024).

1 There is little doubt that the cigarette companies will continue to aggressively promote
 2 menthol cigarettes—to the detriment of public health—until action is taken to end their
 3 manufacture and sale.

4 **II. FDA’s History of Unreasonable Delay in Protecting the Public Against the Health**
 5 **Harms of Menthol Cigarettes Makes Dismissal Inappropriate.**

6 As the preceding discussion demonstrates, FDA has repeatedly recognized the severe and
 7 continuing harm to public health from menthol cigarettes. Yet, its record of addressing this known
 8 health hazard has been one of significant and unreasonable delay.

9 It has been *13 years* since FDA’s TPSAC determined that the “[r]emoval of menthol
 10 cigarettes from the marketplace would benefit public health in the United States” and calculated
 11 the many thousands of additional premature deaths that are occurring because menthol remains a
 12 characterizing flavor in cigarettes.⁴⁵ It has been *11 years* since FDA’s own scientific investigation
 13 reached similar conclusions that menthol cigarettes are associated with youth smoking initiation
 14 and greater addiction, posing “a public health risk above that seen with nonmenthol cigarettes.”⁴⁶
 15 It has been over *six years* since the FDA Commissioner announced that the agency would issue a
 16 Notice of Proposed Rulemaking to ban menthol in combustible tobacco products, including
 17 cigarettes and cigars. Advance Notice, 83 Fed. Reg. 12,294. It has been more than *three years* since
 18 FDA, *as a direct result of Plaintiffs’ prior lawsuit*, announced, yet again, that it planned to initiate
 19 a rulemaking process to ban menthol as a characterizing flavor in cigarettes.⁴⁷ And it has now been
 20 more than *two years* since FDA issued the Proposed Menthol Rule. 87 Fed. Reg. 26,454.

21 Since the proposal of the rule, however, FDA’s delays have resumed. Throughout 2023,
 22 FDA repeatedly pushed back the date by which it expected to finalize the rule. *See* 2d Amend.
 23 Compl. ¶¶ 168-182. Then, on April 26, 2024, HHS Secretary Becerra, announced that finalization
 24 would be postponed indefinitely, stating that “[i]t is clear that there are still more conversations to

25 _____
 26 ⁴⁵ TPSAC Report, *supra* note 4, at 221.

27 ⁴⁶ FDA Report, *supra* note 8, at 6.

28 ⁴⁷ FDA News Release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

1 have, and that will take significantly more time.” *Id.* ¶ 185. The pressure from ongoing litigation
 2 and judicial oversight has proven key to spurring FDA action on this critical public health issue.
 3 Had Plaintiffs not filed their previous lawsuit, there is no reason to believe that FDA would have
 4 proposed a rule to prohibit menthol cigarettes. Here too—if this Court were to grant Defendants’
 5 Motion to Dismiss, there is no reason to believe FDA will do anything but engage in further delay
 6 in issuing a final rule.

7 Under the Administrative Procedure Act (“APA”), agencies have a duty to “conclude a
 8 matter presented to it” “within a reasonable time.” 5 U.S.C. § 555(b). Courts have not hesitated to
 9 find a breach of this duty where an agency has failed to take action for many years after recognizing
 10 and documenting a serious health hazard. For example, in *In Re A Community Voice*, 878 F.3d 779,
 11 787-88 (9th Cir. 2017), the U.S. Court of Appeals for the Ninth Circuit responded to the
 12 Environmental Protection Agency’s (“EPA”) eight years of delay, and failure to offer a “concrete
 13 timetable” for final action on a rule strengthening the existing dust-lead and lead paint standards to
 14 protect children, by ordering EPA to issue a proposed rule within ninety days of the court’s decision
 15 and a final rule within one year after issuance of the proposed rule. In applying the six factors cited
 16 in *Telecomms. Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) (“*TRAC*”) to guide
 17 courts in “unreasonable delay” cases, the *Community Voice* court relied on the length of time that
 18 EPA had recognized the public health hazards of lead but failed to act (eight years, not “months or
 19 a few years”) and the “clear threat to human welfare” from lead poisoning, particularly of children,
 20 due to the inadequacy of the EPA standards. *Community Voice*, 878 F.3d at 787. As the Ninth
 21 Circuit noted, a key factor under *TRAC* is that “delays that might be reasonable in the sphere of
 22 economic regulation are less tolerable when human health and welfare are at stake.” *Id.* at 786
 23 (quoting *TRAC*, 750 F.2d at 80).

24 In *Community Voice*, the Ninth Circuit relied on its own decision two years earlier in
 25 *Pesticide Action Network of N. America v. EPA*, 798 F.3d 809 (9th Cir. 2015). In that case,
 26 environmental groups had petitioned EPA to ban a pesticide, which the agency itself had
 27 determined presented “dangers to human health.” *Pesticide Action Network*, 798 F.3d at 814. The
 28 court in that case relied on the fact that EPA had been considering the petition for eight years, with

1 EPA stating only that it intended to issue a proposed rule after yet another year had passed. *Id.*
 2 Finding that EPA’s response was not a “concrete timetable,” but rather a “roadmap for further
 3 delay,” the court directed EPA to issue either a proposed or final rule or a full and final response to
 4 the administrative petition by a date certain. *Id.* at 814-15. And if the agency decided to issue a
 5 proposed rule, the court ordered it to provide a timeline for finalizing the proposed rule. *Id.* at 815.

6 Here, FDA has provided no indication of when it will make a final determination on whether
 7 to issue a final rule banning menthol cigarettes. Given the agency’s 13-year and counting track
 8 record of delay on this issue, the severe public health hazards of menthol cigarettes, and the
 9 industry’s continued active marketing and promotion of these cigarettes, the Court should reject
 10 Defendants’ Motion to Dismiss and retain jurisdiction until the agency publishes a final rule
 11 banning menthol cigarettes or, in the alternative, makes a final decision against issuance of such a
 12 rule.

13 CONCLUSION

14 For these reasons, the Court should deny Defendants’ Motion to Dismiss.

15
 16 Dated: November 27, 2024

Respectfully submitted,
 17 BYRON RAPHAEL LLP

18 /s/ Tim Byron
 Tim Byron (SBN 277569)
 19 tbyron@byronraphael.com
 100 Pine Street, Suite 1250
 20 San Francisco, CA 94111
 Tel: (415) 839-8500
 21 Fax: (213) 377-5771

22 CAMPAIGN FOR TOBACCO-FREE KIDS
 Dennis A. Henigan (Of Counsel)
 23 Connor Fuchs (Of Counsel)
 dhenigan@tobaccofreekids.org
 24 cfuchs@tobaccofreekids.org
 1400 I St. NW, Suite 1200
 25 Washington, DC 20005
 Tel: (202) 481-9366
 26 Fax: (202) 296-5427

27 Attorneys for Proposed *Amici Curiae*