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17 UNITED STATES DISTRICT COURT FOR THE
18 NORTHERN DISTRICT OF CALIFORNIA
19 OAKLAND DIVISION

20 AFRICAN AMERICAN TOBACCO CONTROL
21 LEADERSHIP COUNCIL, ACTION ON
22 SMOKING AND HEALTH, AMERICAN
23 MEDICAL ASSOCIATION, AND NATIONAL
24 MEDICAL ASSOCIATION,

25 Plaintiffs,

26 v.

27 U.S. DEPARTMENT OF HEALTH AND
28 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. 4:20-cv-4012-KAW

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

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Table of Authorities

Cases

Baker v. Director, United States Parole Commission,
916 F.2d 725 (D.C. Cir. 1990) 18

Center for Biological Diversity v. Kempthorne,
498 F.Supp.2d 293 (D.D.C. 2007) 17, 18

Forest Guardians v. Johanns,
450 F.3d 455 (9th Cir. 2006)..... 15

Hells Canyon Preservation Council v. Richmond,
841 F.Supp. 1039 (D. Or. 1993) 17

In Re A Community Voice,
878 F.3d 779 (9th Cir. 2017)..... 16

McCormack v. Herzog,
788 F.3d 1017 (9th Cir. 2015)..... 18

Norton v. Southern Utah Wilderness Alliance,
542 U.S. 55 (2004)..... 17

Pesticide Action Network of N. America v. EPA,
798 F.3d 809 (9th Cir. 2015)..... 16

Pub. Citizen Health Research Grp. v. Aucther,
702 F.2d 1150 (D.C. Cir. 1983) 17

San Francisco Herring Association v. U.S. Department of the Interior,
946 F.3d 564 (9th Cir. 2019)..... 18

Telecomms. Research & Action Center v. FCC,
750 F.2d 70 (D.C. Cir. 1984) 16

Rules

Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco
Products,
83 Fed. Reg. 12,294 (Mar. 21, 2018)..... 4, 6

Statutes

21 U.S.C. § 387g(e) 2

5 U.S.C. § 555(b) 16, 17

5 U.S.C. § 706(1) 16

Other Authorities

1

2 Andrea C. Villanti et al.,

3 *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent*

4 *Use Among US Youth and Adults, 2013-2015*, 2 J. AM. MED. ASS’N NETWORK
OPEN 1 (2019) 8

5 Andrea C. Villanti et al.,

6 *Changes in the prevalence and correlates of menthol cigarette use in the USA,*

7 *2004-2014*, 25 (Supp. 2) TOBACCO CONTROL ii14 (2016)..... 8

8 Campaign for Tobacco-Free Kids et al.,

9 *Stopping Menthol, Saving Lives: Ending Big Tobacco’s Predatory Marketing*

10 *to Black Communities* (2021)..... 9, 12

11 CDC,

12 *Health Equity Considerations and Racial and Ethnic Minority Groups* (Apr.

13 19, 2021) 12

14 Cristine D. Delnevo et al.,

15 *Assessment of Menthol and Nonmenthol Cigarette Consumption in the US,*

16 *2000 to 2018*, 3 J. AM. MED. ASS’N NETWORK OPEN 1 (2020)..... 8

17 Cristine D. Delnevo et al.,

18 *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, 22

19 NICOTINE & TOBACCO RES. 1673 (2020)..... 6, 11

20 David Mendez & Thuy T.T. Le,

21 *Consequences of a match made in hell: the harm caused by menthol smoking*

22 *to the African American population over 1980-2018*, TOBACCO CONTROL 2

23 (2021)..... 12

24 Eric C. Leas et al.,

25 *Effects of menthol use and transitions in use on short-term and long-term*

26 *cessation from cigarettes among US smokers*, TOBACCO CONTROL 1 (2021) 7

27 FDA,

28 *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and*

Preventing Future Generations of Smokers (Apr. 29, 2021)..... 3, 15

FDA,

Preliminary Scientific Evaluation of the Possible Public Health Effects of

Menthol versus Nonmenthol Cigarettes (2013) 5, 7

FDA,

Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new

steps to protect youth by preventing access to flavored tobacco products and

banning menthol in cigarettes (Nov. 15, 2018) 4

1 Hope Landrine et al.,
 2 *Cigarette Advertising in Black, Latino, and White Magazines, 1998-2002: An*
Exploratory Investigation, 15 ETHNIC DISPARITIES 63 (2005) 9

3 Joanne D’Silva et al.,
 4 *Differences in Subjective Experiences to First Use of Menthol and Nonmenthol*
Cigarettes in a National Sample of Young Adult Cigarette Smokers, 20
 5 NICOTINE & TOBACCO RES. 1062 (2018)..... 6

6 Kim Klausner,
 7 *Menthol cigarettes and smoking initiation: a tobacco industry perspective*, 20
 (Supp. 2) TOBACCO CONTROL ii12 (2011)..... 4

8 Lisa Henriksen et al.,
 9 *Targeted Advertising, Promotion, and Price For Menthol Cigarettes in*
California High School Neighborhoods, 14 NICOTINE TOBACCO RES. 116
 10 (2012)..... 11

11 Navid Hafez & Pamela M. Ling,
 12 *Finding the Kool Mixx: how Brown & Williamson used music marketing to sell*
cigarettes, 15 TOBACCO CONTROL 359 (2006) 9, 10

13 Office of the Surgeon General, HHS,
 14 *Smoking Cessation: A Report of the Surgeon General (2020)* 7

15 Office of the Surgeon General, HHS,
 16 *The Health Consequences of Smoking – 50 Years of Progress: A Report of the*
Surgeon General (2014)..... 5

17 Phillip S. Gardiner,
 18 *The African Americanization of menthol cigarette use in the United States*, 6
 (Supp. 1) NICOTINE & TOBACCO RES. S55 (2004)..... 11

19 Rutgers School of Public Health,
 20 *Trinkets and Trash: Artifacts of the Tobacco Epidemic (May 10, 2021)* 13, 14

21 Sabrina L. Smiley et al.,
 22 *Retail Marketing of Menthol Cigarettes in Los Angeles, California: a*
Challenge to Health Equity, 18 PREVENTING CHRONIC DISEASE (2021)..... 11

23 Sam N. Cwalina et al.,
 24 *Adolescent menthol cigarette use and risk of nicotine dependence: Findings*
from the national Population Assessment on Tobacco and Health (PATH)
 25 *study*, 206 DRUG & ALCOHOL DEPENDENCE 1 (2020) 8

26 Sunday Azagba et al.,
 27 *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent*
Smokers, 66 J. ADOLESCENT HEALTH 545 (2020)..... 7

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Teresa W. Wang et al.,
Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019, 68 MORBIDITY & MORTALITY WKLY. REP. 1 (2019)..... 5

Thuy T.T. Le & David Mendez,
An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018, TOBACCO CONTROL 3 (2021)..... 6

Tobacco Products Scientific Advisory Committee, FDA,
Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (2011)..... passim

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 (2007)..... 9

INTRODUCTION AND SUMMARY OF ARGUMENT

1
2 In the Family Smoking Prevention and Tobacco Control Act (“TCA”), Congress tasked
3 FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”) to issue a “report and
4 recommendation” on “the impact of the use of menthol cigarettes on the public health, including
5 such use among children, African-Americans, Hispanics, and other racial and ethnic minorities,”
6 21 U.S.C. §387g(e). It has now been a decade since TPSAC issued its report concluding that
7 “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United
8 States.” Yet FDA has failed to exercise its authority to prohibit the manufacture and sale of these
9 products, allowing them to remain on the market to this day. FDA’s failure to act is especially
10 troubling given that: (1) in 2013, FDA’s own staff scientists concluded that menthol cigarettes
11 pose a risk to public health beyond that posed by nonmenthol cigarettes; (2) a Citizen Petition
12 filed that same year called on FDA to ban menthol cigarettes; (3) in 2018, the FDA
13 Commissioner committed to issue a proposed rule banning menthol cigarettes; and (4) the
14 accumulating data leaves no doubt that menthol as a characterizing flavor in cigarettes increases
15 initiation of smoking by young people by masking the harshness of cigarette smoke, makes
16 cigarettes more addictive and harder to quit, and poses a disproportionate burden of disease and
17 death on African Americans, a direct result of decades of targeted marketing by cigarette
18 companies. The most recent estimates establish that menthol in cigarettes slows the decline in
19 smoking prevalence, thus costing many thousands of lives with each passing year. In the face of
20 such clarity about the public health toll of these products, FDA’s record on this issue is, by any
21 measure, one of “unreasonable delay.”

22 The question now before the Court is whether FDA’s April 29, 2021 announcement that it
23 plans to issue a proposed rule banning menthol cigarettes within the next year is the only relief
24 available to Plaintiffs, thereby rendering this case moot. In light of the agency’s long record of
25 delay, there is ample legal justification for the Court to exercise its jurisdiction in this case and to
26 set a timeline assuring completion of the rulemaking process and the issuance of a final decision
27 on whether the manufacture and sale of menthol cigarettes will be allowed to continue.
28 Accordingly, the Court should deny Defendants’ Second Motion to Dismiss.

ARGUMENT

I. The Serious and Ongoing Harm to Public Health from Menthol Cigarettes Supports Continued Judicial Oversight until FDA has Completed the Rulemaking Process.

On April 29, 2021, when FDA announced its intention to pursue a rulemaking to prohibit menthol as a characterizing flavor in cigarettes, the agency 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. In its statement announcing the rulemaking, FDA referred to its action as “urgent” and summarized the public health harms from menthol cigarettes:

There is strong evidence that a menthol ban will help people quit. Studies show that menthol increases the appeal of tobacco and facilitates progression to regular smoking, particularly among youth and young adults. Menthol masks unpleasant flavors and harshness of tobacco products, making them easier to start using. Tobacco products with menthol can also be more addictive and harder to quit by enhancing the effects of nicotine.¹

Acting FDA Commissioner Janet Woodcock also noted that a menthol cigarette ban (along with a ban on flavored cigars) would “address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products.”²

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

¹ 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>.

² *Id.*

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

2 Although the tobacco companies are well aware that almost all new tobacco users begin
3 their addiction as kids, they also know that, to novice smokers, tobacco smoke can be harsh and
4 unappealing. By masking the harshness and soothing the irritation caused by tobacco smoke,
5 menthol cigarettes make it easier for beginners to experiment with cigarettes and ultimately
6 become addicted. In 1987, the tobacco company Brown & Williamson observed, “Menthol
7 brands have been said to be good starter products because new smokers appear to know that
8 menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-
9 à-vis candy.”³

10 When FDA Commissioner Scott Gottlieb stated the agency’s intention to begin a
11 rulemaking to ban menthol cigarettes in 2018, he stated that because “menthol serves to mask
12 some of the unattractive features of smoking that might otherwise discourage a child from
13 smoking” “these menthol-flavored products represent one of the most common and pernicious
14 routes by which kids initiate on combustible cigarettes.”⁴ Thus, young smokers are more likely to
15 use menthol cigarettes than any other age group. As FDA has stated, “[m]ultiple studies show a
16 greater use of menthol cigarettes by younger smokers and less usage among older smokers.”⁵
17 The FDA’s TPSAC, after an extensive study of the public health impact of menthol cigarettes,
18 concluded in its 2011 Report that menthol cigarettes increase the number of children who
19 experiment with cigarettes and who become regular smokers, thereby increasing overall youth
20 smoking, and that young people who initiate smoking with menthol cigarettes are more likely to
21 become addicted and long-term daily smokers.⁶ Since 90% of adult smokers begin smoking in
22

23 ³ Kim Klausner, *Menthol cigarettes and smoking initiation: a tobacco industry perspective*, 20
(Supp. 2) TOBACCO CONTROL ii12, ii14 (2011),

24 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088463/pdf/tobaccocontrol41954.pdf>.

25 ⁴ FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to*
26 *protect 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-](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access)
[fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access)

27 ⁵ Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products, 83 Fed.
Reg. 12,294, 12,296 (Mar. 21, 2018).

28 ⁶ TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE (“TPSAC”), FDA, MENTHOL
CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND

1 their teens,⁷ menthol cigarettes, as a starter product for the young, are critical to the tobacco
 2 industry's need to recruit "replacement smokers" for the one-half of long-term smokers who
 3 eventually die from tobacco-related disease. In its 2011 Report, TPSAC projected that by 2020,
 4 about 2.3 million people will have started smoking because of menthol cigarettes, leading to
 5 17,000 premature deaths.⁸ TPSAC concluded that, "Removal of menthol cigarettes from the
 6 marketplace would benefit public health in the United States."⁹

7 Two years after submission of the TPSAC Menthol Report, FDA completed its own
 8 independent, peer-reviewed evaluation of the science concerning menthol cigarettes. FDA's
 9 *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus*
 10 *Nonmenthol Cigarettes* ("FDA Report") reached the overall conclusion, consistent with TPSAC's
 11 own findings, that it is "likely that menthol cigarettes pose a public health risk above that seen
 12 with nonmenthol cigarettes."¹⁰

13 Since the reports from TPSAC and FDA, research has continued to demonstrate the
 14 popularity of menthol cigarettes among youth and menthol's role in smoking initiation.
 15 According to the 2019 National Youth Tobacco Survey ("NYTS"), half of current high school
 16 smokers use menthol cigarettes.¹¹ Another Government survey, the National Survey of Drug Use
 17 and Health, found that preference for menthol among cigarette smokers is inversely correlated
 18

19
 20 RECOMMENDATIONS 109, 121 (2011), [https://wayback.archive-
 21 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
 Menthol Report").

22 ⁷ OFFICE OF THE SURGEON GENERAL ("OSG"), U.S. DEPT. OF HEALTH AND HUMAN SERVICES
 23 ("HHS"), THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE
 SURGEON GENERAL 708 (2014), [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/
 24 Bookshelf_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf).

25 ⁸ TPSAC Menthol Report, *supra* note 6, at 221.

26 ⁹ *Id.* at 225.

27 ¹⁰ FDA, PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF
 MENTHOL VERSUS NONMENTHOL CIGARETTES 6 (2013), [https://www.fda.gov/media/86497/
 28 download](https://www.fda.gov/media/86497/download) ("FDA Report").

¹¹ Teresa W. Wang et al., *Tobacco Product Use and Associated Factors Among Middle and High
 School Students – United States, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 1, 15 (2019),
<https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

1 with age.¹² Data from Truth Initiative’s Young Adult Cohort Study, a national study of 18-34
 2 year olds, likewise showed that 52% of new young adult smokers initiated with menthol
 3 cigarettes.¹³ Initiation with menthol cigarettes was higher among Black smokers (93.1%)
 4 compared to White smokers (43.9%).¹⁴

5 The devastating health impact of menthol cigarettes is perhaps most dramatically shown
 6 by a recent study by researchers from the University of Michigan. With the same methodology
 7 used by TPSAC, the new study estimates that, by slowing down the decline in smoking
 8 prevalence, during the 38-year period from 1980-2018, menthol cigarettes were responsible for
 9 10.1 million extra smokers, or approximately 266,000 additional smokers every year.¹⁵ The study
 10 also found that menthol cigarettes were responsible for 378,000 additional smoking-related deaths
 11 during that period, or almost 10,000 deaths per year.¹⁶

12 The impact of menthol cigarettes in attracting kids, and keeping them addicted, has
 13 profound adverse effects on their health. The FDA has found that “smoking cigarettes during
 14 adolescence is associated with lasting cognitive and behavioral impairments, including effects on
 15 working memory in smoking teens and alterations in the prefrontal attentional network in young
 16 adult smokers.”¹⁷ “Use of tobacco products,” according to the FDA, “puts youth and young
 17 adults at greater risk for future health issues, such as coronary artery disease, cancer, and other
 18 known tobacco-related diseases.”¹⁸

22 ¹² Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*,
 23 22 NICOTINE & TOBACCO RES. 1673, 1673 (2020).

24 ¹³ Joanne D’Silva et al., *Differences in Subjective Experiences to First Use of Menthol and
 25 Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, 20 NICOTINE &
 26 TOBACCO RES. 1062, 1064 (2018).

27 ¹⁴ *Id.*

28 ¹⁵ Thuy T.T. Le & David Mendez, *An Estimation of the Harm of Menthol Cigarettes in the United
 States from 1980 to 2018*, TOBACCO CONTROL 3 (2021),
<https://tobaccocontrol.bmj.com/content/early/2021/09/16/tobaccocontrol-2021-056748>.

¹⁶ *Id.*

¹⁷ Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,295.

¹⁸ *Id.*

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

2 The TPSAC and FDA reports found that, in addition to increasing initiation of smoking
 3 among young people, menthol cigarettes are associated with increased nicotine dependence and
 4 reduced success in smoking cessation, particularly among African American smokers.¹⁹
 5 More recent research bolsters these findings. The 2020 Surgeon General’s Report on smoking
 6 cessation cited numerous studies that found an association between menthol use and lower
 7 cessation rates. The report concluded that the evidence is suggestive that restricting menthol
 8 products would lead to increased smoking cessation.²⁰ Recent research analyzing four waves of
 9 data from the Government’s Population Assessment of Tobacco and Health (“PATH”) study
 10 shows that among daily smokers, menthol cigarette smokers have a 24% lower likelihood of
 11 quitting as compared to non-menthol smokers.²¹ Among daily smokers, African American
 12 menthol smokers had a 53% lower chance of quitting compared to African American non-
 13 menthol smokers, while White menthol smokers had 22% lower odds of quitting compared to
 14 White non-menthol smokers.²² A more recent study analyzing Government PATH data found
 15 that smokers who used menthol cigarettes prior to a quit attempt were 28% less likely to abstain
 16 from smoking for more than 30 days and 53% less likely to abstain for more than one year,
 17 compared to non-menthol smokers.²³

18 Data from the 2017 and 2018 NYTS show that among middle and high school students,
 19 menthol smoking was associated with greater smoking frequency and intention to continue
 20 smoking, compared to non-menthol smoking.²⁴ Data from the Government PATH study shows
 21

22 ¹⁹ TPSAC Menthol Report, *supra* note 6, at 147; FDA Report, *supra* note 10, at 5-6.

23 ²⁰ 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>.

24 ²¹ Sarah D. Mills 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
 25 *Study*, 23 NICOTINE & TOBACCO RES. 966, 970 (2021).

26 ²² *Id.*

27 ²³ 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>.

28 ²⁴ Sunday Azagba et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol*
Adolescent Smokers, 66 J. ADOLESCENT HEALTH 545, 548-549 (2020).

1 that youth menthol smokers have significantly higher levels of certain measures of dependence,²⁵
 2 and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of
 3 daily smoking.²⁶ Thus, there is little doubt that menthol cigarettes have led millions of youth into
 4 long-term tobacco addiction.

5 The difficulty that menthol smokers have in quitting is reflected in national smoking
 6 prevalence trends. From 2008 to 2014, overall smoking rates generally declined, but the
 7 proportion of smokers using menthol cigarettes increased significantly. Menthol smoking rates
 8 have increased among young adults and remained constant among youth and older adults, while
 9 non-menthol smoking has decreased in all three age groups. Overall, about 4 out of 10 (38.8%)
 10 smokers used menthol cigarettes in 2012-2014, an increase from 34.7% in 2008-2010.²⁷ Sales
 11 trends echo the patterns seen in menthol smoking prevalence. Between 2009 and 2018, sales of
 12 non-menthol cigarettes declined by 33.1% nationally while sales of menthol cigarettes have
 13 declined by only 8.2% during the same period.²⁸ Of the decline in cigarette sales between 2009
 14 and 2018, 91% is attributable to non-menthol cigarettes.²⁹

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

17 **C. Menthol Cigarettes Have Led to Significant Health Disparities for African**
 18 **Americans.**

19 Menthol cigarettes have played an especially pernicious role in causing disease and death
 20 in the African American community.

21 _____
 22 ²⁵ 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
 23 DRUG & ALCOHOL DEPENDENCE 1, 3 (2020).

24 ²⁶ Andrea C. Villanti et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2 J. AM. MED. ASS'N NETWORK OPEN
 25 1, 12 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

26 ²⁷ Andrea C. Villanti et al., *Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014*, 25 (Supp. 2) TOBACCO CONTROL ii14, ii15 (2016),
 27 https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_2/ii14.full.pdf.

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

²⁹ *Id.*

1 Since at least the 1950s, the tobacco industry has targeted African Americans with
 2 marketing for menthol cigarettes through magazine advertising, sponsorship of community and
 3 music events, and youthful imagery and marketing in the retail environment.³⁰ For example, the
 4 industry has strategically placed menthol cigarette ads featuring Black models in magazines with
 5 high Black readership. One study found that from 1998-2002, *Ebony* was 9.8 times more likely
 6 than *People* magazine to carry ads for menthol cigarettes.³¹ The industry marketed menthol
 7 brands through popular community events, particularly those focused around music. Industry-
 8 sponsored events included R.J. Reynolds' Salem Summer Street Scenes festivals, Brown &
 9 Williamson's Kool Jazz Festival, and Philip Morris's Club Benson & Hedges promotional bar
 10 nights, which targeted clubs frequented by Black Americans.³² R.J. Reynolds estimated that they
 11 reached at least half of African Americans in five cities through their street festivals.³³



Figure 1: 1966 Kool Magazine Advertisement, Image courtesy of Stanford Research into the Impact of Tobacco Advertising (SRITA), <https://tobacco.stanford.edu/cigarette/mg18678/>.

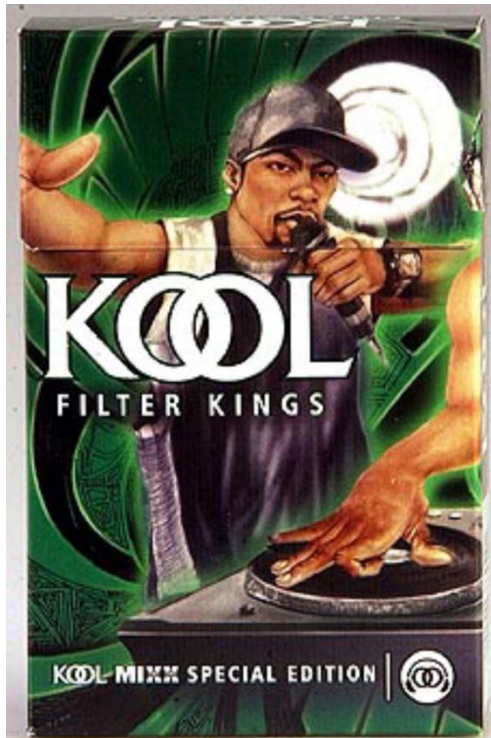
30 See generally CAMPAIGN FOR TOBACCO-FREE KIDS ET AL., STOPPING MENTHOL, SAVING LIVES: ENDING BIG TOBACCO'S PREDATORY MARKETING TO BLACK COMMUNITIES 7-9 (2021), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf ("Tobacco-Free Kids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

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

32 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>.

33 Yerger et al., *supra* note 32, at 25.

1 The industry also targeted African Americans through targeted branding and culturally-
 2 appropriated images. For example, in 2004, Brown & Williamson launched an ad campaign for
 3 Kool featuring images of young Black rappers, DJs, and dancers on cigarette packs and in
 4 advertising. The campaign also included radio giveaways with cigarette purchases and a hip-hop
 5 DJ competition in major cities.³⁴ As TPSAC concluded, “menthol cigarettes are
 6 disproportionately marketed per capita to African Americans. African Americans have been the
 7 subjects of specifically tailored menthol marketing strategies and messages.”³⁵



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 18 Figure 2: 2004 Kool Mixx Special Edition
 cigarette pack. Image courtesy of SRITA,
 19 <https://tobacco.stanford.edu/cigarette/img/6856/>.

20 To this day, African American neighborhoods have a disproportionate concentration of
 21 menthol cigarette advertising and cheaper pricing of menthol cigarettes. The 2018 California
 22 Tobacco Retail Surveillance Study found that menthol advertisements were significantly more
 23 common in neighborhoods with higher proportions of African American residents and school-age
 24 youth.³⁶ Another California study found that, as the proportion of African American high school
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26 ³⁴ Hafez & Ling, *supra* note 32, at 362-63.

27 ³⁵ TPSAC Menthol Report, *supra* note 6, at 92.

28 ³⁶ Nina C. Schleicher et al., CALIFORNIA TOBACCO RETAIL SURVEILLANCE STUDY 2018, at 3, 22
 (2019),
<https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/Pages/FactSheetsAndReports.aspx>.

1 students in a neighborhood rose, so did the proportion of menthol advertising.³⁷ A 2021 study
 2 found that in Los Angeles County, stores located in predominantly African American
 3 neighborhoods had significantly higher odds of selling Newport cigarettes (the most popular
 4 menthol brand) than stores in Hispanic or non-Hispanic White neighborhoods.³⁸ Additionally,
 5 the study found that the estimated price of a Newport single pack was \$0.38 higher in non-
 6 Hispanic White neighborhoods than in African American neighborhoods.³⁹ Finally, another 2021
 7 study concluded that even after “[c]ontrolling for store type, neighbourhood poverty and other
 8 covariates, California tobacco retailers were more likely to advertise menthol cigarettes and
 9 charged less for the most popular brand, Newport, in neighborhoods with greater proportions of
 10 Black residents.”⁴⁰

11 The tobacco industry’s use of menthol cigarettes to target African Americans has paid
 12 lucrative, but tragic, dividends. In the early 1950s, 5% of African American smokers preferred
 13 menthol brands.⁴¹ In 2018, *85% of African American smokers smoked menthol cigarettes*,
 14 compared to 29% of Whites.⁴² In its 2011 TPSAC Report, FDA concluded that menthol
 15 cigarettes are associated with lower levels of smoking cessation among African Americans.⁴³
 16 TPSAC also estimated that by 2020, over 460,000 African Americans will have started smoking
 17 because of menthol cigarettes, and 4,700 excess deaths of African Americans will have been

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 19 ³⁷ Lisa Henriksen et al., *Targeted Advertising, Promotion, and Price For Menthol Cigarettes in California High School Neighborhoods*, 14 NICOTINE TOBACCO RES. 116, 118 (2012).

20 ³⁸ Sabrina L. Smiley et al., *Retail Marketing of Menthol Cigarettes in Los Angeles, California: a Challenge to Health Equity*, 18 PREVENTING CHRONIC DISEASE (2021),
 21 https://www.cdc.gov/PCD/issues/2021/20_0144.htm.

22 ³⁹ *Id.*

23 ⁴⁰ Lisa Henriksen et al., *Menthol cigarettes in black neighbourhoods: still cheaper after all these years*, TOBACCO CONTROL 1, 2 (published online Aug. 12, 2021),
 24 <https://tobaccocontrol.bmj.com/content/early/2021/08/11/tobaccocontrol-2021-056758> (finding
 25 also that Newports cost an estimated 25 cents less per pack in neighborhoods with the highest
 26 proportion of Black residents compared to stores in neighborhoods with the lowest proportion of
 27 Black residents).

28 ⁴¹ See Phillip S. Gardiner, *The African Americanization of menthol cigarette use in the United States*, 6 (Supp. 1) NICOTINE & TOBACCO RES. S55, S59 (2004); Burns W. Roper, *A Study of People’s Cigarette Smoking Habits and Attitudes Volume I*, in TRUTH TOBACCO INDUSTRY DOCUMENTS (1953), <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=fhcv0035>.

⁴² Delnevo et al., *supra* note 12, at 1674.

⁴³ TPSAC Menthol Report, *supra* note 6, at 147.

1 attributable to menthol cigarettes.⁴⁴ A recent study that used the same methodology as the 2011
 2 TPSAC Report found that, from 1980-2018, among the African American community, menthol
 3 was responsible for 1.5 million extra smokers, 157,000 smoking-related premature deaths, and 1.5
 4 million excess life-years lost.⁴⁵ During this 38-year period, African Americans represented 15%
 5 of extra new smokers, 41% of excess premature deaths, and 50% of excess life-years lost, despite
 6 accounting for only 12% of the population.⁴⁶ Menthol cigarettes are a major reason why tobacco
 7 use is the number one cause of preventable death among African Americans, who die from
 8 smoking-caused diseases at far higher rates than other Americans.⁴⁷

9 Indeed, the public health impact of menthol cigarettes on African Americans has been
 10 made especially clear by the COVID-19 pandemic, which has revealed stark health disparities
 11 across our nation. A Harvard University analysis of COVID-19 mortality rates by race and
 12 ethnicity found that Black COVID-19 patients between 25 and 54 years old were approximately
 13 seven to nine times as likely to die from COVID-19 as White COVID-19 patients.⁴⁸ According to
 14 the Centers for Disease Control and Prevention (“CDC”), “COVID-19 has unequally affected
 15 many racial and ethnic minority groups, putting them more at risk of getting sick and dying from
 16 COVID-19.”⁴⁹ The disproportionate burden of COVID-19 on the African American community
 17 has been exacerbated by the disproportionate impact of menthol cigarettes on that community
 18 because smoking increases the vulnerability of smokers to the worst effects of the novel
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21 ⁴⁴ *Id.* at 223.

22 ⁴⁵ David Mendez & Thuy T.T. Le, *Consequences of a match made in hell: the harm caused by*
 23 *menthol smoking to the African American population over 1980-2018*, TOBACCO CONTROL 1, 2
 (2021), <https://tobaccocontrol.bmj.com/content/early/2021/09/16/tobaccocontrol-2021-056748>.

24 ⁴⁶ *Id.*

25 ⁴⁷ See generally Tobacco-Free Kids Report, *supra* note 30, at 4 and sources cited therein.

26 ⁴⁸ Mary T. Bassett et al., *The unequal toll of COVID-19 mortality by age in the United States: Quantifying racial/ethnic disparities* 9 (Harv. Ctr. Population & Dev. Stud. Working Paper Vol. 19, No. 3, 2020), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20_Bassett-Chen-Krieger_COVID-19_plus_age_working-paper_0612_Vol-19_No-3_with-cover.pdf.

27 ⁴⁹ *Health Equity Considerations and Racial and Ethnic Minority Groups*, CDC (Apr. 19, 2021),
 28 <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>.

1 coronavirus. As the CDC has found, “Being a current or former cigarette smoker can make you
2 more likely to get severely ill from COVID-19.”⁵⁰

3 Thus, for every day that passes without action on menthol cigarettes, the tobacco
4 industry’s decades of targeted advertising and promotion has a disproportionate impact on
5 African Americans, worsening existing and deeply-entrenched health disparities.

6 **D. The Aggressive Marketing of Menthol Cigarettes Is Continuing**

7 Cigarette companies continue to engage in aggressive marketing of menthol cigarettes,
8 underscoring the importance of ensuring against further regulatory delay. New products and
9 packaging have appeared in recent months, as leading manufacturers seek to maintain interest in
10 menthol cigarettes by current smokers, while also attracting new smokers. For example, in May
11 2021, Newport introduced two new menthol products (“Newport Boost” and “Newport Boost
12 Gold”), allowing the smoker to “boost your menthol whenever you want it” by squeezing the
13 filter.⁵¹ Newport sponsored a \$50,000 Sweepstakes to promote the new product.⁵² A similar
14 product (“Camel Crush Smooth”) was introduced by RJ Reynolds in the summer of 2020.⁵³
15 Moreover, a plethora of new packaging has appeared recently, for Newport (“Introducing Pack
16 Designs by Nigel Xavier”) (“Introducing Pack Designs by Fred Foster”) and Camel Crush
17 (“Limited-Time Specialty Packs Celebrating Off-Center Sound”) (“New Look. Same Crush”).⁵⁴
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19 ⁵⁰ *People with Certain Medical Conditions*, CDC (last updated Aug. 20, 2021),
20 <https://stacks.cdc.gov/view/cdc/109075>.

21 ⁵¹ *Trinkets and Trash: Artifacts of the Tobacco Epidemic*, RUTGERS SCHOOL OF PUBLIC HEALTH,
22 <http://trinketsandtrash.org/detail.php?artifactid=15540&page=1> (last accessed Aug. 19, 2021)
(capturing Newport Boost ad in May 10, 2021 issue of *Us Weekly*); *Products*, NEWPORT,
23 <https://www.newport-pleasure.com/secure/products.html> (last accessed June 28, 2021).

⁵² *Promotions*, NEWPORT, <https://www.newport-pleasure.com/secure/promotions/boost.html> (last
accessed June 28, 2021).

24 ⁵³ *Products*, CAMEL, <https://prod2.camel.com/products/crush> (last accessed July 20, 2020).

25 ⁵⁴ *Limited Time Pack Designs*, NEWPORT, [https://www.newport-pleasure.com/secure/limited-
time-packs/nigel-xavier.html#](https://www.newport-pleasure.com/secure/limited-time-packs/nigel-xavier.html#) (last accessed June 28, 2021) (“Introducing Pack Designs by Nigel
26 Xavier”); *Limited Time Pack Designs*, NEWPORT, [https://www.newport-pleasure.com/secure/
limited-time-packs/fred-foster.html](https://www.newport-pleasure.com/secure/limited-time-packs/fred-foster.html) (last accessed June 28, 2021) (“Introducing Pack Designs by
27 Fred Foster”); *Products*, CAMEL, [https://prod2.camel.com/products /camel-creations](https://prod2.camel.com/products/camel-creations) (last
28 accessed July 24, 2020) (“Limited-Time Specialty Packs Celebrating Off-Center Sound”); *New
Look Same Crush*, USPTO.REPORT, <https://uspto.report/TM/90331204> (last accessed Aug. 19,
2021).

1 Promotional discount coupons also are being used to stimulate demand⁵⁵ and the targeted
2 marketing to the African American consumer continues unabated.⁵⁶



9 Figure 3: Newport Limited Time Pack Designs, captured June 28, 2021, <https://www.newport-pleasure.com/secure/limited-time-packs/fred-foster.html>.

10 There is little doubt that the cigarette companies will continue to aggressively promote
11 menthol cigarettes, to the detriment of public health, until action is taken to end their manufacture
12 and sale.

13 **II. FDA’s History of Unreasonable Delay in Protecting the Public Against the Health**
14 **Harms of Menthol Cigarettes Makes Dismissal Inappropriate and Justifies a**
15 **Court-Ordered Timeline for Regulatory Proceedings.**

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

19 It has been ten years since FDA’s TPSAC determined that the “[r]emoval of menthol
20 cigarettes from the marketplace would benefit public health in the United States” and calculated
21 the many thousands of additional premature deaths that are occurring because menthol remains a
22 characterizing flavor in cigarettes. It has been eight years since FDA’s own scientific
23 investigation reached similar conclusions that menthol cigarettes are associated with youth
24 smoking initiation and greater addiction, posing “a public health risk above that seen with
25 nonmenthol cigarettes.” It has been almost three years since the FDA Commissioner announced

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27 ⁵⁵ *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).

28 ⁵⁶ *The Lounge*, NEWPORT, <https://www.newport-pleasure.com/secure/lounge/2021/04/streetwear-staples.html> (last accessed June 28, 2021).

1 that the agency would issue a Notice of Proposed Rulemaking to ban menthol in combustible
2 tobacco products, including cigarettes and cigars. Yet no additional action was taken until April
3 29, 2021 when, *as a direct result of this lawsuit*, FDA announced, yet again, that it planned to
4 initiate a rulemaking process to ban menthol as a characterizing flavor in cigarettes. Moreover,
5 during the eight-year period of 2013-2021, FDA failed to substantively respond, in any way, to
6 the Citizen Petition filed in 2013 setting forth the scientific case for a menthol prohibition and
7 calling on the agency to “prohibit menthol as a characterizing flavoring of cigarettes”⁵⁷ Had
8 this lawsuit not been filed, there is no reason to believe that FDA would have announced any
9 action to prohibit menthol cigarettes.

10 Indeed, even as FDA announced its intention to begin a rulemaking on menthol cigarettes,
11 it committed itself to no timeline for completion of the rulemaking, saying only that it “is working
12 toward issuing” proposed product standards on mentholated cigarettes and flavored cigars “within
13 the next year.”⁵⁸ The agency has offered no explanation for why it should take as much as a year
14 to issue a *proposed* rule on menthol cigarettes, given that its own Scientific Advisory Committee
15 documented the health harms of menthol cigarettes *ten years before* and FDA has never wavered
16 from the conclusion of its own internal scientific review in 2013 that menthol cigarettes have
17 adverse consequences for public health. As discussed above, the evidence of those health harms
18 has continued to mount since those FDA reports. Despite FDA’s April 29 announcement, it does
19 not moot this case because relief in the form of a court-ordered timeline for a rulemaking is
20 available and warranted. *See Forest Guardians v. Johanns*, 450 F.3d 455, 461 (9th Cir. 2006)
21 (“[A] case is not moot when *any* effective relief may be granted.”) (emphasis in original). When
22 considered against the backdrop of the agency’s history of neglecting this recognized health
23 hazard, it is especially important that the Court retain jurisdiction and set its own timeline for this
24 rulemaking to ensure against additional delay.

25 Where an agency has failed to take action for many years after recognizing and
26 documenting a serious health hazard presented to it in an administrative petition, courts have not

27 ⁵⁷ *Tobacco Control Legal Consortium et al. Citizen Petition*, FDA Dkt. No. FDA-2013-P-0435-
28 0001, at 1 (Apr. 12, 2013), <https://www.regulations.gov/document/FDA-2013-P-0435-0001>.

⁵⁸ FDA News Release, *supra* note 1.

1 hesitated to find a breach of the duty imposed by the Administrative Procedure Act (APA) to
 2 “conclude a matter presented to it“ “within a reasonable time,”⁵⁹ and to enter an order requiring
 3 that action be taken within a specified time, consistent with the obligation of courts under the
 4 APA to “compel agency action . . . unreasonably delayed.”⁶⁰ Thus, in *In Re A Community Voice*,
 5 878 F.3d 779, 787-88 (9th Cir. 2017), the U.S. Court of Appeals for the Ninth Circuit responded
 6 to the Environmental Protection Agency’s (“EPA”) eight years of delay, and failure to offer a
 7 “concrete timetable” for final action on a rule strengthening the existing dust-lead and lead paint
 8 standards to protect children, by ordering EPA to issue a proposed rule within ninety days of the
 9 court’s decision and a final rule within one year after issuance of the proposed rule. In applying
 10 the six factors cited in *Telecomms. Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir.
 11 1984) (“*TRAC*”) to guide courts in “unreasonable delay” cases, the *Community Voice* court relied
 12 on the length of time that EPA had recognized the public health hazards of lead but failed to act
 13 (eight years, not “months or a few years”) and the “clear threat to human welfare” from lead
 14 poisoning, particularly of children, due to the inadequacy of the EPA standards. *Community*
 15 *Voice*, 878 F.3d at 787. As the Ninth Circuit noted, a key factor under *TRAC* is that “delays that
 16 might be reasonable in the sphere of economic regulation are less tolerable when human health
 17 and welfare are at stake.” *Id.* at 786 (quoting *TRAC*, 750 F.2d at 80).

18 In *Community Voice*, the Ninth Circuit relied on its own decision two years earlier in
 19 *Pesticide Action Network of N. America v. EPA*, 798 F.3d 809 (9th Cir. 2015). In that case,
 20 environmental groups had petitioned EPA to ban a pesticide, which the agency itself had
 21 determined presented “dangers to human health.” *Pesticide Action Network*, 798 F.3d at 814.
 22 The court in that case relied on the fact that EPA had been considering the petition for eight years,
 23 with EPA stating only that it intended to issue a proposed rule after yet another year had passed,
 24 *id.*, a situation remarkably similar to the present case. Finding that EPA’s response was not a
 25 “concrete timetable,” but rather a “roadmap for further delay,” the court directed EPA to issue
 26 either a proposed or final rule or a full and final response to the administrative petition by a date
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28 ⁵⁹ 5 U.S.C. §555(b).

⁶⁰ 5 U.S.C. §706(1).

1 certain. *Id.* at 814-15; *see also Pub. Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150,
2 1154, 1158-59 (D.C. Cir. 1983) (court directed OSHA to issue notice of proposed rulemaking
3 limiting workplace exposure to potentially carcinogenic chemical within thirty days of decision,
4 finding “a more than three-year span from Public Citizen’s petition to projected final regulation is
5 not tolerable.”).

6 The cases cited in the Government’s Second Motion to Dismiss counseling against
7 judicial interference with the regulatory process are not to the contrary. The decision in *Hells*
8 *Canyon Preservation Council v. Richmond*, 841 F. Supp. 1039 (D. Or. 1993) actually supports the
9 authority of courts to impose a regulatory timetable as a remedy for unreasonable delay. After
10 ruling that the absence of final agency action is no barrier to an action for unreasonable delay, the
11 court held that the Forest Service had engaged in unreasonable delay in issuing final regulations
12 governing uses of the Hells Canyon area. *Hells Canyon*, 841 F. Supp. at 1045. The court
13 concluded that “a timeline for publication of proposed rules, notice and comment, and issuance of
14 final regulations is appropriate,” with adoption of final regulations required “no later than 120
15 days following close of the comment period.” *Id.* at 1049-50. The Supreme Court’s decision in
16 *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (“*SUWA*”) merely stands
17 for the proposition that a claim invoking a court’s authority under the APA to compel agency
18 action “unlawfully withheld or unreasonably delayed” must first establish that the agency “failed
19 to take a *discrete* agency action that it is *required to take*” (emphasis in original). This element is
20 met here by FDA’s ongoing failure to “conclude a matter presented to it” “within a reasonable
21 time” under 5 U.S.C. §555(b), i.e., to finally determine whether to ban menthol as a
22 characterizing flavor in cigarettes, as requested eight years ago in the Citizen Petition. Unlike in
23 *SUWA*, Plaintiffs here do not seek to entangle the Court in “abstract policy disagreements,” 542
24 U.S. at 66, but rather to ensure against further FDA delay in making a final policy judgment about
25 menthol cigarettes, whatever that judgment turns out to be at the conclusion of the rulemaking.

26 Finally, in *Center for Biological Diversity v. Kempthorne*, 498 F. Supp. 2d 293 (D.D.C.
27 2007), the D.C. District Court dismissed plaintiff’s claim as moot after the agency granted
28 plaintiff’s rulemaking petition because the only relief plaintiff’s complaint had requested was a

1 final decision regarding its petition.⁶¹ Here, the Government’s reliance on *Kempthorne* is
 2 misplaced for two independent reasons. First, Plaintiffs’ complaint here *did request additional*
 3 *relief* beyond only a response to its Citizen Petition. *See, e.g.*, 2d. Am. Compl. at 51, ¶5
 4 (requesting “[a]n Order directing defendants to provide for publication in the Federal Register,
 5 the basis for defendants’ decision to either (a) add menthol to the list of banned characterizing
 6 flavors for combustible cigarettes, or else (b) not add menthol to such list, within 60 days of the
 7 date of such Order”). Second, the Ninth Circuit, in analyzing mootness, considers whether “any
 8 effective relief” can be granted, not just the “precise relief sought” in plaintiffs’ complaint. *See,*
 9 *e.g., McCormack v. Herzog*, 788 F.3d 1017, 1024 (9th Cir. 2015).⁶²

10 Accordingly, given the severe public health hazards of menthol cigarettes, the industry’s
 11 continued active marketing and promotion of those cigarettes, FDA’s history of inaction to
 12 protect the public, particularly young people and African Americans, from the disease and death
 13 caused by these products, and the availability – and appropriateness – of relief in the form of a
 14 court-ordered timetable for completion of a rulemaking proceeding, the Court should reject
 15 FDA’s Second Motion to Dismiss and retain jurisdiction until the agency publishes a final rule
 16 banning menthol cigarettes or, in the alternative, makes a final decision against issuance of such a
 17 rule.

18 CONCLUSION

19 For these reasons, the Court should deny Defendants’ Second Motion to Dismiss.
 20

21 ⁶¹ In its Reply in Support of its Second Motion to Dismiss, the Government asserted that the
 22 *Kempthorne* plaintiffs “sought a final rule, as well as judicial oversight over the rulemaking
 23 process after the agency granted the plaintiffs’ petition.” Dkt. No. 59, at 8. That is inaccurate.
 24 *See Kempthorne*, 498 F. Supp. 2d at 296 (“[P]laintiff requests the Court to order defendants to
 issue a final, judicially-reviewable decision on its petition within forty-five days as relief....[N]o
 other relief is sought in the complaint.”).

25 ⁶² Other cases cited by the Government are simply far afield of the issues in this case. *San*
 26 *Francisco Herring Association v. U.S. Department of the Interior*, 946 F.3d 564 (9th Cir. 2019)
 27 was not an “unreasonable delay” case at all, but concerned whether Park Service notices
 28 prohibiting herring fishing in certain waters was final agency action for purposes of judicial
 review. *Baker v. Director, United States Parole Commission*, 916 F.2d 725 (D.C. Cir. 1990)
 concerns a court’s authority to dismiss a complaint *sua sponte* under the Federal Rules of Civil
 Procedure, having no relevance to a court’s authority to remedy agency action unreasonably
 delayed.

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Attorneys for Proposed *Amici Curiae*

1 **ADDENDUM**

2 **Description of *Amici Curiae***

3 1. **American Academy of Pediatrics**

4 The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit
5 organization dedicated to furthering the interests of children’s health and pediatric specialty.
6 Since its inception, the membership of the AAP has grown from the original group of 60
7 physicians specializing in children’s health to 67,000 pediatricians. Since its founding, the AAP
8 has become a powerful voice for children’s health through education, research, advocacy, and
9 expert advice and has demonstrated a continuing commitment to protect the well-being of
10 America’s children. The AAP has engaged in broad and continuous efforts to prevent harm to the
11 health of children and adolescents cause by the use of tobacco products and exposure to
12 secondhand tobacco smoke.

13 2. **American Cancer Society Cancer Action Network**

14 The American Cancer Society Cancer Action Network (ACS CAN) is the nation’s leading voice
15 advocating for public policies that are helping to defeat cancer. As the nonprofit, nonpartisan
16 advocacy affiliate of the American Cancer Society, ACS CAN educates the public, government
17 officials, and candidates about cancer’s devastating impact on public health and encourages them
18 to make fighting cancer a top priority. ACS CAN has volunteers nationwide, many of whom
19 advocate for effective tobacco control at the federal, state, and local levels. In 2021, an estimated
20 235,760 people in the US will be diagnosed with lung and bronchus cancer, the vast majority of
21 which is attributable to tobacco use. This devastating impact makes regulation of tobacco
22 products critical to our mission.

23 3. **American College of Physicians**

24 The American College of Physicians (ACP) is the largest medical specialty organization in the
25 United States with members in more than 145 countries worldwide. ACP membership includes
26 161,000 internal medicine physicians (internists), related subspecialists, and medical students.
27 Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise
28 to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to

1 complex illness. ACP provides evidence-based clinical resources on tobacco cessation and
2 advocates for policies to reduce tobacco use.

3 4. American Heart Association

4 The American Heart Association (AHA) is the nation's oldest and largest voluntary organization
5 dedicated to fighting heart disease and stroke. Founded in 1924, AHA now includes more than 40
6 million volunteers and supporters, with local chapters in all 50 states, as well as in Washington,
7 D.C., and Puerto Rico. The association invests in research, professional and public education, and
8 advocacy so people from across American can live longer, healthier lives. AHA has long been
9 active before Congress and regulatory agencies on tobacco and other health-related matters and
10 has petitioned the Food and Drug Administration on several occasions seeking regulation of
11 cigarettes, cigars, and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

12 5. American Lung Association

13 The American Lung Association is the nation's older voluntary health organization. Because
14 smoking is a major cause of lung cancer and chronic obstructive pulmonary disease (COPD), the
15 American Lung Association has long been active in research, education, and public policy
16 advocacy regarding the adverse health effects caused by tobacco use, including the use of cigars,
17 as well as efforts to regulate the marketing, manufacture and sale of tobacco products.

18 6. American Public Health Association

19 The American Public Health Association (APHA) champions the health of all people and all
20 communities, strengthens the profession of public health, shares the latest research and
21 information, promotes best practices, and advocates for public health policies grounded in
22 research. APHA represents over 24,000 individual members and is the only organization that
23 combines a nearly 150-year perspective and a broad-based member community with an interest in
24 improving the public's health. APHA advocates for tobacco control measures to protect the
25 public's health from the adverse effects of tobacco products.”

26 7. American Thoracic Society

27 The American Thoracic Society is the world's leading medical society dedicated to accelerating
28 the advancement of global respiratory health through multidisciplinary collaboration, education,

1 and advocacy. ATS members care for patients with tobacco-induced respiratory disease and are
2 committed to reducing and ending the needless death, emotional destruction and costs of tobacco-
3 related disease.

4 8. Association of Black Cardiologists

5 Founded in 1974, the Association of Black Cardiologists, Inc., (ABC) is a nonprofit organization
6 with an international membership of over 2,000 health professionals, lay members of the
7 community (Community Health Advocates), corporate members, and institutional members. The
8 ABC is dedicated to eliminating the disparities related to cardiovascular disease in all people of
9 color. Today, the ABC's public and private partnerships continue to increase our impact in
10 communities across the nation. ABC's mission is to promote the prevention and treatment of
11 cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health
12 equity for all through the elimination of disparities.

13 9. Black Women's Health Imperative

14 The Black Women's Health Imperative (BWHI) is the oldest national organization dedicated
15 solely to improving the health and wellness of our nation's 21 million Black women and girls –
16 physically, emotionally and financially. BWHI's mission is to lead the effort to solve the most
17 pressing health issues that affect Black women and girls in the U.S. Through investments in
18 evidence-based strategies, BWHI delivers bold new programs and advocate health-promoting
19 policies.

20 10. Campaign for Tobacco-Free Kids

21 The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its
22 deadly toll in the United States and around the world. The Campaign envisions a future free of the
23 death and disease caused by tobacco, and it works to save lives by advocating for public policies
24 that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

25 11. Kaiser Permanente

26 Kaiser Permanente (KP) is the largest private integrated health care delivery system in the United
27 States, serving more than 12.5 million members in eight states and the District of Columbia. KP's
28 mission is not just to provide health care to our members, but also to create healthier

1 communities. We are looked to as having expertise in clinical care, including tobacco prevention
2 and cessation programs, and for our efforts in the broader community to promote equitable Public
3 Health policies. KP is a staunch advocate for removing menthol cigarettes from the market
4 because there is likely no other tobacco control policy that could do more to address intractable
5 tobacco-related health disparities. The expeditious removal of menthol cigarettes from the market
6 will have a positive impact on KP's steadfast mission to improve the health of our members and
7 communities we serve.

8 12. National Black Nurses Association

9 The National Black Nurses Association (NBNA), established in 1971, represents the over
10 300,000 African American registered nurses, with 111 chapters in 34 states. Many years ago,
11 NBNA decided that tobacco use in any form, including vaping, causes physical harm particularly
12 to African American adults and children. NBNA has been involved in American Smoke Out
13 activities; established an Ad Hoc Committee on Substance Abuse to include educational and
14 awareness sessions on the affects of tobacco; holds continuing education sessions at chapter and
15 national levels promoting tobacco cessation.

16 13. National LGBT Cancer Network

17 The National LGBT Cancer Network works to improve the lives of LGBT cancer survivors and
18 those at risk by educating the LGBT community about our increased cancer risks and the
19 importance of screening and early detection; training health care providers to offer more
20 culturally-competent, safe and welcoming care; and advocating for LGBT survivors in
21 mainstream cancer organizations, the media and research.

22 14. Parents Against Vaping e-cigarettes

23 Parents Against Vaping e-cigarettes (PAVe) is a national grassroots organization founded in 2018
24 by three New York City moms as a response to the youth vaping epidemic.

25 15. Save a Girl, Save a World

26 Save a Girl, Save a World (SAGSAW) is a multi-generational mentoring and esteem building
27 program with an annual retreat held at HBCU's each Fall for the purposes of assisting young girls
28 and young women with a continued pipeline of support through mentorship. SAGSAW has

1 assembled a network of some of the brightest and most accomplished women from coast to coast
2 to work as mentors. SAGSAW's Speak Up program gives young Black women the opportunity to
3 share their thoughts, concerns and findings regarding Health Disparities, including tobacco use,
4 that challenge their future to be the best they can be.

5 16. The Center for Black Health and Equity

6 The Center for Black Health & Equity (formerly the National African American Tobacco
7 Prevention Network) is a non-profit, 501(c)(3) organization whose mission is to facilitate public
8 health programs to benefit communities and people of African descent. The Center is an
9 established and community trusted national network that was formed in July 2000 to address
10 tobacco-related health disparities affecting African Americans. We have more than two decades
11 of demonstrated experience educating our communities, managing federal awards and working
12 with public health partners to improve the quality and performance of public health programs
13 affecting African Americans. We use our multifaceted national network to support the Center for
14 Disease Control and Prevention (CDC) in disseminating clinical guidelines and best practices for
15 the prevention and control of chronic and infectious diseases that disproportionately impact
16 African Americans. In addition, we extend our network to reach sub-populations that may be at
17 increased risk due to various social and political determinants of health. We have extensive
18 experience facilitating national dialogues, advancing evidence-based policies and mobilizing
19 local communities and we are uniquely qualified to ensure that our communities are informed and
20 prepared to respond to public health policies that are not centered in equity.

21 17. Trinity Health

22 Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the
23 nation. It serves people and communities in 22 states from coast to coast with 93 hospitals, and
24 120 continuing care locations — including home care, hospice, PACE and senior living facilities
25 — that provide nearly 2.5 million visits annually. Trinity Health employs more than 97,000 full-
26 time colleagues, including 5,300 employed physicians. Tobacco use is one of the largest driver of
27 health care costs. Chronic diseases are the most common and costly of all health problems, but
28

1 are also the most preventable. For these reasons, Trinity Health has prioritized tobacco control
2 policy.

3 18. Truth Initiative

4 Truth Initiative Foundation d/b/a Truth Initiative (Truth Initiative) is a 501(c)(3) Delaware
5 corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation
6 brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S.
7 cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports
8 programs in the United States to reduce youth smoking, vaping and nicotine use and to prevent
9 diseases associated with tobacco products. Its nationally recognized truth® campaign has
10 educated hundreds of millions of young people about the health effects and social costs of
11 tobacco.

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