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12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 OAKLAND DIVISION

15 AFRICAN AMERICAN TOBACCO)
16 CONTROL LEADERSHIP COUNCIL,)
17 ACTION ON SMOKING AND HEALTH,)
18 NATIONAL MEDICAL ASSOCIATION,)
19 AMERICAN MEDICAL ASSOCIATION,)
20 LISA MITCHELL, DARYL THOMAS, LILA)
21 JUNE, LASHELLE ULLIE, and BEN SMITH,)

22 Plaintiffs,)

23 vs.)

24 U.S. DEPARTMENT OF HEALTH AND)
25 HUMAN SERVICES; XAVIER BECERRA, in)
26 his official capacity as Secretary of the U.S.)
27 Department of Health and Human Services;)
28 U.S. FOOD AND DRUG)
ADMINISTRATION; ROBERT CALIFF, in)
his official capacity as Commissioner of the U.S.)
Food and Drug Administration; CENTER FOR)
TOBACCO PRODUCTS; and BRIAN KING)
in his official capacity as the Center for Tobacco)
Products, Director,)

Defendants.)

Case No.: 4:24-cv-1992-HSG

SECOND AMENDED COMPLAINT
(Administrative Procedure Act Case)

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1 4. Although it did not ban menthol at that time, Congress recognized that menthol
2 cigarettes might “pose unique health risks to those who smoke them.”² Congress was “especially
3 concerned about proportionately higher rates of menthol cigarette use among African American
4 smokers”; “the historic targeting of African Americans for menthol cigarette use by tobacco
5 companies”; “the high rates of [menthol cigarette] use among ... African American youth”; as
6 well as the “higher rates of lung cancer documented among African American smokers as
7 compared to non-African American smokers[.]”³

8 5. As a result, Congress ensured that the FDA’s “early focus” would be on menthol
9 cigarettes, and that the agency would have “the authority to deal with these and other
10 products.”⁴ Congress furthermore expressed its belief that it would be “critical for the Secretary
11 to move quickly to address the unique public health issues posed by menthol cigarettes.” H.
12 Rept., Part 1 at 37–39.

13 6. By 2020, however—i.e., over a decade later—the Defendants had still not decided
14 whether to ban menthol cigarettes from the market. This despite the fact that the FDA’s own
15 Tobacco Products Scientific Advisory Committee had recommended removing menthol
16 cigarettes from the market to protect the public health in 2011; FDA’s own peer-reviewed
17 examination of the scientific literature concerning menthol in 2013, confirming and otherwise
18 bolstering the Advisory Committee’s earlier work; FDA’s funding of three additional studies in
19 2013, examining the role of menthol in cigarettes; a 2013 Citizen Petition filed by Plaintiffs and
20 over 20 public health advocacy groups, asking the FDA to make a determination on menthol;
21 and two FDA-initiated Advanced Notices of Proposed Rulemaking in 2013 and 2018, calling on
22 the public for additional comments and scientific data concerning the potential regulation of
23 menthol in cigarettes.

24
25 ² *Id.* at 38.

26 ³ *Id.*

27 ⁴ Cong. Rec.—House, H4318, H4339 (Vol. 155, No. 55) (Apr. 1, 2009); Cong. Rec.—House,
28 H6630, H6652 (Vol. 155, No. 88) (June 12, 2009). *Available at*
<https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-2>.

1 7. Defendants’ years of inaction, meanwhile, was harming the public health:

2 a. In 2009, Congress noted that menthol cigarettes represented over 25% of all
3 cigarettes smoked in the United States. *See* H. Rept., Part 1 at 39. By 2020,
4 however, the percentage of menthol smokers had increased to 36%.⁵

5 b. In 2009, Congress observed that more than 12 million smokers used menthol
6 cigarettes. *See* H. Rept., Part 1 at 39. But by 2020, over 19 million smokers were
7 using menthol cigarettes—i.e., a majority of the estimated 34 million smokers in
8 the United States.⁶

9 c. In 2009, Congress expressed its concern that nearly 70% of African Americans
10 who smoked, used menthol cigarettes. *See* H. Rept., Part 1 at 39. By 2020, that
11 figure had risen to over 85%.⁷

12 8. In short, despite Congress’ expressed concern over the critical public health issue
13 of menthol in cigarettes, Defendants’ inaction was harming the public health—i.e., through
14 menthol cigarettes’ well recognized harms of increased youth smoking, decreased quit attempts
15 among smokers, and more lives lost to a lifetime of nicotine addiction.

16 9. To address Defendants’ inaction, the Plaintiffs African American Tobacco
17 Control Leadership Council, Action on Smoking on Health, National Medical Association,
18 American Medical Association sued the Defendants in 2020, for violations of the Tobacco

19 _____
20 ⁵ *See* Fed. Trade Comm., Cigarette Rept. for 2017, Table 7B (issued 2019). *Available at*
21 [https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-](https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2017-federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_2017.pdf)
22 [report-2017-federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_2017.pdf](https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_2017.pdf).

23 ⁶ *See* FDA, Menthol and Other Flavors in Tobacco Products. *Available at*
24 [https://web.archive.org/web/20200617110626/https://www.fda.gov/tobacco-](https://web.archive.org/web/20200617110626/https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products)
25 [products/products-ingredients-components/menthol-and-other-flavors-tobacco-products](https://web.archive.org/web/20200617110626/https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products) (noting
26 that “[m]ore than 19.5 million people are current smokers of menthol cigarettes”); Centers for
27 Disease Control and Prevention, Smoking & Tobacco Use, Current Cigarette Smoking Among
28 Adults in the United States (identifying an estimated 34.2 million adults who smoked cigarettes in
2018). *Available at*
[https://web.archive.org/web/20200609191658/https://www.cdc.gov/tobacco/data_statistics/f](https://web.archive.org/web/20200609191658/https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm)
[act_sheets/adult_data/cig_smoking/index.htm](https://web.archive.org/web/20200609191658/https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm).

⁷ *See* FDA, Menthol and Other Flavors in Tobacco Products, *id.* (noting that 85.8 percent of African American smokers use menthol cigarettes).

1 Control Act and Administrative Procedure Act, Pub. L. No. 404, 60 Stat. 237, ch. 324, §§ 1–12
2 (1946). See *African American Tobacco Control Leadership Council et al. v. U.S. Dep’t of Health and Human*
3 *Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.) (“*Menthol Lit. F*”). In that action, the
4 Plaintiffs sought to compel the Defendants’ (a) formal determination on menthol, consistent with
5 21 U.S.C. § 387g(a)(5) (i.e., to determine whether menthol should be added to the list of banned
6 characterizing flavors, based on the available medical, scientific, and technological data), and (b)
7 substantive response to Plaintiffs’ Citizen Petition, which had requested the FDA’s promulgation
8 of a final rule banning menthol as a characterizing flavor.

9 10. Through that litigation, the Defendants formally responded to Plaintiffs’ Citizen
10 Petition, and determined—for the first time, nearly 12 years after Congress’ initial direction—
11 that menthol should be added to the list of banned characterizing flavors.

12 11. At this Court’s strong urging, the Defendants later issued a May 2022 Notice of
13 Proposed Rulemaking that proposed banning menthol cigarettes. See HHS / FDA, *Tobacco*
14 *Product Standard for Menthol in Cigarettes*, Dkt. No. FDA-2021-N-1349, 87 Fed. Reg. 26454 (May 4,
15 2022) (RIN 0910-AI60, adding part 1162 to subchapter K) (“Proposed Menthol Rule” or
16 “Notice”).⁸ If implemented, this “landmark policy”⁹ would, *inter alia*, save hundreds of thousands
17 of people from a premature smoking-related death, save millions of lives from a lifetime of
18 nicotine addiction, and result in medical cost savings of between \$100 billion and \$300 billion
19 annually.

20 12. To date, however, Defendants have unduly delayed promulgating and publishing
21 such a final rule, in violation of the Tobacco Control Act and Administrative Procedure Act. And
22 once again, Defendants’ unlawful inaction is harming the public health.

23
24
25 ⁸ Available at <https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes>.

26
27 ⁹ Nat’l Cancer Institute, *FDA Proposed Rule Prohibiting Menthol Cigarettes* (June 27, 2022), available at
28 <https://www.cancer.gov/news-events/cancer-currents-blog/2022/fda-proposes-rule-prohibiting-menthol-cigarettes>.

1 13. The Tobacco Control Act mandates that the HHS Secretary “shall” promulgate a
2 regulation establishing a tobacco product standard, if certain pre-conditions are met, 21 U.S.C.
3 § 387g(d)(1), namely:

- 4 a. The Secretary has published a Notice of Proposed Rulemaking in the Federal
5 Register and the comment period has closed, *see id.*;
- 6 b. The Secretary has considered
- 7 i. comments submitted in response to the Notice,
- 8 ii. comments concerning the “technical achievability of compliance with such
9 standard,”
- 10 iii. “all other information submitted in connection with a proposed standard,
11 including information concerning the countervailing effects of the tobacco
12 product standard on the health of adolescent tobacco users, adult tobacco
13 users, or nontobacco users, such as the creation of a significant demand for
14 contraband or other tobacco products that do not meet the requirements
15 of this subchapter and the significance of such demand,” and
- 16 iv. any report from the Tobacco Products Scientific Advisory Committee
17 (“TPSAC”); and
- 18 c. The Secretary “determines that the standard would be appropriate for the
19 protection of public health,” *id.* § 387g(d)(1)(A).

20 14. As detailed further below, each pre-condition to finalizing the Proposed Menthol
21 rule exists here: As of August 2022, the comment period to Defendants’ Notice of Proposed
22 Rulemaking has closed. Through their many years of study and repeated calls for public
23 comments, the Defendants have already considered the necessary comments and information
24 identified by Subsection (d)(1). Finally, the Secretary has already determined as of January 4,
25 2023 (if not earlier), that the proposed Menthol Rule would be “appropriate for the protection of
26 public health[.]”

27 15. Under such facts, this Court’s help is needed. Defendants’ inaction continues to
28 harm Plaintiffs and the public health. The Defendants have furthermore repeatedly shown that

1 they are unwilling to act on the issue of menthol in cigarettes without judicial intervention. Thus,
2 Plaintiffs respectfully ask this Court to once again direct Defendants to fulfill their duty to protect
3 the public health—in this case, by promulgating and publishing the proposed Menthol Rule.

4 **JURISDICTION & VENUE**

5 16. Jurisdiction: This Court has jurisdiction over this action, pursuant to 28 U.S.C.
6 §§ 1331 and 1346. Plaintiffs allege violations of the federal Administrative Procedure Act and
7 Tobacco Control Act. The United States is also a Defendant. Plaintiffs’ requested relief is
8 furthermore authorized by 5 U.S.C. § 706(1) and (2) and 28 U.S.C. §§ 1361 and 1651.

9 17. Venue: Venue in this district is appropriate, pursuant to 28 U.S.C. § 1391(e)(1).
10 Plaintiff African American Tobacco Control Leadership Council resides in this district.

11 18. Intradistrict Assignment: Pursuant to Civil L.R. 3-2(c), intradistrict assignment is
12 proper in the San Francisco or Oakland Division. This is because Plaintiff African American
13 Tobacco Control Leadership Council maintains its principal place of business in the County of
14 San Francisco, and because this action arises from, and touches on issues raised in, litigation
15 previously assigned to the Oakland Division, *see African American Tobacco Control Leadership Council et*
16 *al. v. U.S. Dep’t of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.).

17 **PARTIES**

18 **I. Plaintiffs**

19 19. Plaintiff African American Tobacco Control Leadership Council (“AATCLC”)
20 brings this action on behalf of itself and its members—a cadre of dedicated community activists,
21 academics, public health advocates, and researchers. Based in San Francisco, California, the
22 AATCLC was formed to educate the Black community and public about tobacco use and
23 cessation.

24 20. The AATCLC’s mission is to save lives (*see* www.savingblacklives.org) by
25 partnering with community stakeholders, elected officials, and public health agencies from across
26 the nation (e.g., Boston, Washington, D.C., Columbus, Chicago, Minneapolis, Denver, Berkeley,
27 Oakland, Sacramento, and Los Angeles), to inform and affect the direction of tobacco policy,
28

1 practices, and priorities, particularly as they affect the lives of Black Americans and African
2 immigrant populations.

3 21. The AATCLC has led the fight to expose the predatory marketing of menthol
4 cigarettes and flavored little cigars in the Black community. Its work includes educating the
5 public about the effects of tobacco on these populations, and the need to regulate flavored
6 tobacco products, including menthol cigarettes; shaping the national discussion and direction of
7 tobacco control policy, practices, and priorities; and elevating the regulation of mentholated and
8 other flavored tobacco products at the local, state, and federal levels, including influencing the
9 national tobacco control agenda.

10 22. Such work includes providing testimony at FDA hearings held in 2010 and 2011,
11 when the agency was first considering removing menthol cigarettes from the marketplace. The
12 AATCLC also played a crucial part in the Chicago fight to establish a 500-foot radius around
13 schools that banned the sale of menthol and flavored tobacco products—the first menthol
14 restriction in the nation. These efforts further led to major Black leadership and civic
15 organizations such as the National Association for the Advancement of Colored People
16 (“NAACP”) and the National Black Nurses Association to adopt national resolutions, supporting
17 a ban on all menthol products and other flavored tobacco products. The AATCLC’s efforts also
18 led to the City and County of San Francisco enacting the first comprehensive, city-wide flavor
19 ban that ended the sale of menthol cigarettes and all other flavored tobacco products.

20 23. In 2013, the AATCLC together with several other public health organizations,
21 filed a Citizen Petition with the FDA, asking the agency to begin the rulemaking process for
22 banning menthol cigarettes, and to provide cessation support to menthol smokers who wished to
23 quit. And more recently, the AATCLC testified on Capitol Hill to support legislation prohibiting
24 the manufacture and sale of menthol and flavored tobacco products; helped to lead the fight in
25 Massachusetts, which became the first state to prohibit the sale of menthol tobacco products
26 including menthol cigarettes; and was a pivotal force during California’s successful journey to
27 enact its statewide ban on menthol and other flavors.

1 24. In June 2020, the AATCLC together with its partner Action on Smoking and
2 Health (“ASH”) filed a lawsuit against the Defendants for their unlawful delay in removing
3 menthol cigarettes from the marketplace, despite overwhelming scientific evidence showing that
4 it would immediately save lives. *See African American Tobacco Control Leadership Council et al. v. U.S.*
5 *Dep’t of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.). The American
6 Medical Association (“AMA”) and National Medical Association (“NMA”) later joined as co-
7 Plaintiffs, and through that litigation, finally forced the FDA to respond to Plaintiffs’ Citizen
8 Petition and determine whether to add menthol to the list of banned characterizing flavors.

9 25. The Defendants’ ongoing refusal to ban menthol in combustible cigarettes makes
10 the AATCLC’s work more difficult, and forces the AATCLC to continue devoting resources and
11 efforts to educate the public about the dangers of menthol cigarettes. But for Defendants’ actions,
12 AATCLC could instead be directing its resources and efforts to advancing the AATCLC’s other
13 organizational goals, such as helping to reduce the harms of tobacco on society (e.g., through the
14 promotion of a federal tax that would support tobacco control and cessation efforts).

15 26. Plaintiff Action on Smoking and Health (“ASH”) is a non-profit organization
16 headquartered in Washington, D.C. Founded in 1967, ASH has spent the last 50 years
17 protecting society against the harms caused by the tobacco industry and its products. Its mission
18 is to advocate for innovative legal and policy measures to end the global tobacco epidemic.
19 ASH’s past accomplishments include helping to achieve restrictions on tobacco advertising and
20 smoking bans in workplaces and various forms of public transit.

21 27. ASH believes that the production, marketing, and sale of cigarettes violates
22 human rights that have been recognized through international law and national constitutions.
23 This is because the tobacco industry not only manufactures, distributes, markets, and sells
24 products that are addictive and harmful when used as intended, but also often targets their
25 marketing to specific populations based on gender, race, sexual identity, and age. Some groups
26 smoke at much higher rates than the general population, and yet they are all protected by various
27 international and regional human rights treaties and instruments.

1 28. ASH is currently working to address the negative impacts of the tobacco industry
2 on human rights through (a) work with the Human Rights Council, the WHO Framework
3 Convention on Tobacco Control Conference of the Parties, and other international bodies;
4 (b) using human rights reporting mechanisms to alert of the impact of tobacco on human rights
5 and encourage governments to advance tobacco control within their own countries; (c) providing
6 legal resources, training, and support to advocates on how to use human rights norms to advance
7 local tobacco control measures; and (d) maintaining a repository of human rights resources to
8 assist allies in taking a human rights approach.

9 29. ASH's efforts include menthol-related initiatives at the local, national, and
10 international level. For example, on January 2, 2020, ASH staff attended a public hearing of the
11 D.C. City Council Judiciary and Public Safety Committee, which was considering a ban on the
12 sale of flavored tobacco products. ASH gave formal testimony and urged the Council to include a
13 menthol ban in the final law. ASH also provided information to the Committee concerning the
14 Council's authority to phase out the sale of tobacco products in the city.

15 30. ASH led a submission, signed by 97 organizations, to the United Nations'
16 Committee on the Elimination of Racial Discrimination ("CERD").¹⁰ This letter asked CERD to
17 encourage the United States to protect African Americans' right to health against the tobacco
18 industry's malfeasance—a step that would further social justice. ASH also led an additional 207
19 signatories from 61 countries to call on CERD to maintain and strengthen its call to country
20 parties in the Draft General Recommendation n°37 on Racial Discrimination in the enjoyment
21 of the right to health to reduce or prevent the harms of tobacco.

22 31. The Defendants' unlawful refusal to ban menthol in combustible cigarettes, makes
23 ASH's work more difficult, and forces ASH to continue devoting resources and efforts to
24 educating the public about the dangers of menthol cigarettes. But for Defendants' actions, ASH
25 could instead be directing its resources and efforts to advancing ASH's other organizational
26

27 ¹⁰ See ASH, *97 Organizations Agree, U.N. Human Rights Committee Must Address Menthol* (Apr. 21,
28 2021). Available at <https://ash.org/cerd2021/>.

1 goals, such as helping to reduce the harms of tobacco on society (e.g., by eliminating the sale of
2 cigarettes altogether).

3 32. Plaintiff National Medical Association (“NMA”) is a Maryland corporation
4 headquartered in Silver Spring, Maryland. It is a 501(c)(3) national professional and scientific
5 organization representing the interests of approximately 50,000 African American physicians and
6 the patients they serve—the largest and oldest such organization in the United States. The NMA
7 is committed to improving the quality of health in communities of color and among
8 disadvantaged people through its membership, professional development, community health
9 education, advocacy, research, and partnerships with federal and private agencies.

10 33. The NMA is particularly steadfast in its commitment to the elimination of health
11 disparities and the promotion of healthy lifestyles among African Americans and other
12 underserved populations. To further these goals, the NMA conducts national consumer
13 education programs on cancer, cardiovascular disease and stroke, HIV/AIDS, women’s health,
14 asthma, smoking cessation, immunization, breastfeeding, clinical trials, and other issues that
15 impact the lives of African Americans. Throughout its history, the NMA has focused primarily
16 on health issues related to African Americans and medically underserved populations; however,
17 its principles, goals, initiatives, and philosophy encompass all racial and ethnic groups.

18 34. As the nation’s only organization devoted to the needs of African American
19 physicians, health professionals, and their patients, the NMA serves as the conscience of the
20 medical profession in the ongoing fight to eliminate health disparities in the nation’s health care
21 delivery system. The NMA has been an unwavering advocate for health policies that improve the
22 quality and availability of health care for African Americans and other underserved populations.
23 For instance, the NMA was the force behind such landmark reforms as Medicare and Medicaid.

24 35. Today, the NMA continues to provide leadership in shaping the national health
25 policy agenda through continued involvement in a variety of critical policy matters, including
26 with respect to smoking. For example, the NMA passed a resolution on August 3, 2017, during
27 their Annual Meeting of the House of Delegates, supporting a ban on the sale of flavored tobacco
28 products, including menthol cigarettes. As noted on the NMA’s website, African Americans have

1 the highest surveyed rate of desire to quit smoking but are less successful in quit attempts than
2 white and Hispanic smokers. This is due in part to the anesthetic effects of menthol in
3 mentholated cigarettes and the high rate of mentholated cigarette use among African Americans.
4 This is precisely the type of health disparity the NMA seeks to eliminate.

5 36. The Defendants' unlawful refusal to comply with their Tobacco Control Act
6 obligations and address menthol cigarettes undermines the NMA's efforts to eliminate health
7 disparities, to promote healthy lifestyles among African Americans and other underserved
8 populations, and to achieve parity and justice in medicine. Among other things, the Defendants'
9 unlawful conduct hinders the efforts of the NMA and its members to promote smoking cessation,
10 and forces them to divert resources that could be used for other health policies.

11 37. Plaintiff American Medical Association ("AMA") is an Illinois not-for-profit
12 corporation headquartered in Chicago, Illinois. The AMA is the largest professional association
13 of physicians, residents, and medical students in the United States. Each state medical association
14 and most of the major specialty medical societies are represented in the AMA House of
15 Delegates, with the AMA serving as the overall umbrella and voice of organized medicine in the
16 United States. The AMA represents virtually all United States physicians, residents, and medical
17 students through its policymaking process. AMA members practice and reside in all States,
18 including California. AMA members practice in all areas of medical specialization.

19 38. The AMA's objectives are to promote the science and art of medicine and the
20 betterment of public health. Since its founding in 1847, the AMA has played a crucial role in the
21 development of medicine in the United States. For the last fifty years, it has also devoted
22 substantial resources to anti-tobacco efforts aimed at improving public health. In keeping with
23 this objective, the AMA and its members work tirelessly to educate the public about and protect
24 the public from the devastating health consequences of tobacco use, the leading cause of
25 preventable death in the United States. This work includes reviewing and synthesizing the latest
26 scientific knowledge, preparing and distributing resources concerning tobacco use and cessation,
27 and advocating for regulation and taxation of tobacco products at the federal, state, and local
28 levels.

1 39. More recently, the AMA has also increased its focus on health equity. The AMA
2 recognizes that systemic bias and institutionalized racism contribute to inequities across the U.S.
3 health care system. The AMA is committed to fighting for greater health equity by identifying
4 and eliminating inequities through advocacy, community leadership and education. This
5 includes working to eliminate the use of menthol-flavored tobacco products, which represent a
6 disproportionate and growing share of tobacco use by African Americans, and the direct cause of
7 thousands of preventable deaths in the African American community. For example, the AMA
8 has sent numerous letters to and attended meetings with government officials to encourage the
9 elimination of menthol-flavored cigarettes.

10 40. Plaintiff Lisa Mitchell is an African American resident of Madison, Wisconsin,
11 and a daily menthol cigarette smoker. Despite Plaintiff Mitchell's best efforts to break her
12 menthol cigarette addiction, Plaintiff Mitchell has been unsuccessful. Plaintiffs' continuing
13 addiction and related harms are the predictable result of (a) the tobacco companies' decades of
14 targeted advertising, marketing, and promotion of menthol cigarettes aimed at Plaintiff and the
15 Black community; and (b) Defendants' continuing inaction on promulgating a final Menthol
16 Rule—a rule that if promulgated, would encourage Plaintiff Mitchell to break her menthol
17 cigarette addiction. *See Mills SD, et al., The Impact of Menthol Cigarette Bans: A Systematic Review and*
18 *Meta-Analysis*, Nicotine Tob Res. (Feb. 21, 2024) (concluding that “Menthol cigarette bans
19 promote smoking cessation”).

20 41. Plaintiff Daryl Thomas is an African American resident of Pasadena, California,
21 and a daily menthol cigarette smoker. Despite Plaintiff Thomas' best efforts to break his menthol
22 cigarette addiction, Plaintiff Thomas has been unsuccessful. Plaintiff's continuing addiction and
23 related harms are the predictable result of (a) the tobacco companies' decades of targeted
24 advertising, marketing, and promotion of menthol cigarettes aimed at Plaintiff and the Black
25 community; and (b) Defendants' inaction on promulgating a final Menthol Rule—a rule that if
26 promulgated, would encourage Plaintiff Thomas to break his menthol cigarette addiction.

27 42. Plaintiff Lila June is an African American resident of Brooklyn, New York, and a
28 menthol cigarette smoker. Despite Plaintiff June's best efforts to break her menthol cigarette

1 addiction, Plaintiff June has been unsuccessful. Plaintiff’s continuing addiction and related harms
2 are the predictable result of (a) the tobacco companies’ decades of targeted advertising,
3 marketing, and promotion of menthol cigarettes aimed at Plaintiff and the Black community; and
4 (b) Defendants’ inaction on promulgating a final Menthol Rule—a rule that if promulgated,
5 would encourage Plaintiff June to break her menthol cigarette addiction.

6 43. Plaintiff Lashelle Ullie is an African American resident of Los Angeles, California,
7 and a daily menthol cigarettes smoker. Despite Plaintiff Ullie’s best efforts to break his menthol
8 cigarette addiction, Plaintiff Ullie has been unsuccessful. Plaintiff’s continuing addiction and
9 related harms are the predictable result of (a) the tobacco companies’ decades of targeted
10 advertising, marketing, and promotion of menthol cigarettes aimed at Plaintiff and the Black
11 community; and (b) Defendants’ inaction on promulgating a final Menthol Rule—a rule that if
12 promulgated, would encourage Plaintiff Ullie to break his menthol cigarette addiction.

13 44. Plaintiff Ben Smith is an African American resident of Buffalo, New York, and a
14 former menthol cigarette smoker. Although Plaintiff Smith was able to break his menthol
15 cigarette addiction, Plaintiff Smith’s addiction to menthol cigarettes has left his body with
16 numerous health ailments, and a higher risk of relapsing into his addiction, *see* Pletcher MJ et al.,
17 *Menthol Cigarettes, Smoking Cessation, Atherosclerosis, and Pulmonary Function: The Coronary Artery Risk*
18 *Development in Young Adults (CARDIA) Study*, Arch Intern Med., 1915–22 (2006).
19 doi:10.1001/archinte.166.17.1915 (“In a longitudinal analyses, menthol smokers were less likely
20 to exhibit sustained smoking cessation ... and nearly twice as likely to relapse”).

21 45. Plaintiff Smith’s son is also African American, has smoked menthol cigarettes for
22 years, and is a daily menthol cigarette smoker. Despite Plaintiff Smith’s best efforts to encourage
23 his son to break his menthol cigarette addiction, Plaintiff Smith’s son remains addicted. His
24 continuing addiction and related harms caused by such addiction, are the predictable result of (a)
25 the tobacco companies’ decades of targeted advertising, marketing, and promotion of menthol
26 cigarettes aimed at Plaintiff Smith’s son and the Black community; and (b) Defendants’ inaction
27 on promulgating a final Menthol Rule—a rule that if promulgated, would (i) encourage Plaintiff
28

1 Smith's son to break their menthol cigarette addiction, and (ii) further protect Plaintiff Smith
2 from the risk of relapsing into his menthol cigarette addiction.

3 46. Plaintiff Smith has a close, personal relationship with his son, who he sees on a
4 regular basis each week. Plaintiff Smith cares deeply about his son's health, and his son's
5 availability to be present with his daughter (i.e., Plaintiff Smith's granddaughter). In short,
6 Plaintiff Smith deeply enjoys his time, conversation, and shared family history with his son.

7 **II. Defendants**

8 47. Defendant U.S. Department of Health and Human Services ("HHS") is the
9 federal agency responsible for administering the Food, Drug and Cosmetic Act, 21 U.S.C. § 301
10 *et seq.* (1982). HHS is headquartered in Washington, D.C.

11 48. Defendant Xavier Becerra is sued in his official capacity as the Secretary of the
12 U.S. Department of Health and Human Services. As Secretary, Mr. Becerra is responsible for
13 HHS's activities and policies and for implementing the Tobacco Control Act. Although the
14 Secretary has delegated many responsibilities under the Act to the FDA Commissioner,¹¹ the
15 Secretary has nonetheless reserved the authority to (a) establish procedural rules applicable to
16 tobacco products, such as menthol cigarettes; and (b) present highly significant public issues
17 involving the availability and marketability of tobacco products, including menthol cigarettes.

18 49. Defendant U.S. Food and Drug Administration ("FDA") is the federal agency
19 charged with regulating the manufacture, distribution, and marketing of tobacco products in the
20 United States, including menthol in combustible cigarettes. By statute, the FDA "shall (1)
21 promote the public health by promptly and efficiently reviewing clinical research and taking
22 appropriate action on the marketing of regulated products in a timely manner[.]" 21 U.S.C. §
23 393(b); *see also* Tobacco Control Act findings, P.L. 111-31, Div A, § 2, 123 Stat. 1776, 1780 (June
24 22, 2009) (noting further that the FDA possesses a "mandate to promote health and reduce the
25 risk of harm"). The FDA is headquartered in Silver Spring, Maryland.

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28 ¹¹ *See Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 23 n.1 (D.C. Cir. 1984).

1 50. Defendant Robert M. Califf is sued in his official capacity as Commissioner of the
2 FDA. The FDA administers programs at HHS related to tobacco products. As Acting
3 Commissioner, Mr. Califf is responsible for the FDA’s activities and policies, including the
4 agency’s implementation of the Tobacco Control Act.

5 51. Defendant Center for Tobacco Products (“CTP”) is the federal agency responsible
6 for implementing the Tobacco Control Act and related matters assigned by the FDA
7 Commissioner. *See* 21 U.S.C. § 387a(e). The Center is established within the FDA and reports to
8 the FDA Commissioner. *See id.* The Center is headquartered in Silver Spring, Maryland.

9 52. Defendant Brian King is sued in his official capacity as the Center for Tobacco
10 Products, Director. The Center implements the Secretary and the FDA’s responsibilities under
11 the Tobacco Control Act.

12 **FACTUAL & LEGAL BACKGROUND**

13 **I. Defendants are unlawfully delaying acting on menthol cigarettes.**

14 53. Congress first presented the issue of menthol in cigarettes to Defendants in 2009.
15 Since that time, however, Defendants have been unwilling to resolve this issue, much less
16 promulgate and publish a final rule prohibiting menthol as a characterizing flavor in cigarettes.

17 54. Because Defendants’ inaction harms the public health and violates the Tobacco
18 Control Act and Administrative Procedure Act, this Court’s intervention is once again required.

19 **A. Congress directed Defendants to address menthol cigarettes in 2009.**

20 55. In 2009, Congress passed—and President Obama signed into law—the Tobacco
21 Control Act.

22 56. As noted earlier, this Act established the FDA’s authority to regulate tobacco
23 products, 21 U.S.C. § 387a, and prohibited all flavors in cigarettes, save for tobacco and
24 menthol, *id.* § 387g(a)(1) (the “flavor ban”). Although it did not ban menthol at that time,
25 Congress recognized that menthol cigarettes might “pose unique health risks[.]” Congress was
26 especially concerned with the “proportionately higher rates of menthol cigarette use” among
27 African American smokers, including African American youth, and therefore took steps to ensure
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1 that menthol cigarettes would be “an early focus” for the FDA and that the agency would have
2 “the authority to deal with these and other products.”

3 **1. Congress authorized and empowered the Secretary to address**
4 **the problem of menthol in cigarettes.**

5 57. Among other things, Congress authorized the Secretary “to require product
6 changes in current and future tobacco products, such as the reduction or elimination of
7 ingredients, additives, and constituents[.]” H. Rept., Part 1 at 4. Congress also ensured that the
8 Tobacco Control Act did not limit the Secretary’s authority to act on menthol. *See* 21 U.S.C. §
9 387g(a)(1)(A).

10 58. To assist the Defendants in addressing this issue, Congress directed the Secretary
11 to create a Tobacco Products Scientific Advisory Committee within six months of the Tobacco
12 Control Act’s enactment. *See id.* § 387q(a). “Immediately upon” this Committee’s establishment,
13 the Tobacco Control Act directed the Secretary to refer to the Committee for report and
14 recommendation “the issue of the impact of the use of menthol in cigarettes on the public health,
15 including such use among children, African-Americans, Hispanics, and other racial and ethnic
16 minorities.” *Id.* § 387g(e)(1).

17 59. The Committee would then specifically review and address the considerations that
18 the FDA would need to address in adopting a new tobacco product standard (e.g., to ban
19 menthol as a characterizing flavor in cigarettes), *see id.* § 387g(e)(1), including the “scientific
20 evidence” concerning the risks and benefits of a proposed standard, *see id.* § 387g(a)(3)(B)(i)¹²; “the
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25 ¹² “In making a finding described in subparagraph (A), the Secretary [i.e., FDA] shall consider
26 scientific evidence concerning (I) the risks and benefits to the population as a whole, including
27 users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased
28 likelihood that existing users of tobacco products will stop using such products; and (III) the
increased or decreased likelihood that those who do not use tobacco products will start using such
products.” 21 U.S.C. § 387g(a)(3)(B)(i).

1 technical achievability of compliance with such standard,” *id.* § 387g(b)(1); and all “other
2 information submitted in connection with a proposed standard,” *id.* § 387g(b)(2)¹³.

3 60. To ensure Defendants’ quick action on the issue of menthol in cigarettes, the
4 Tobacco Control Act further directed the Committee to submit a report and recommendation to
5 the Secretary, “not later than 1 year after its establishment,” *id.* § 387g(e)(2).

6 61. And significantly, the Tobacco Control Act directed Defendants to “periodic[ally]
7 evaluat[e]” the “tobacco product standards established under this section [including the flavor
8 ban, *id.* § 387g(a)(1)(A),] to determine whether such standards should be changed to reflect new
9 medical, scientific, or other technological data.” *Id.* § 387g(a)(5).

10 62. Following such an evaluation and determination (e.g., to include menthol as a
11 banned characterizing flavor in combustible cigarettes), the Act then directs the Secretary to
12 promulgate and publish the new tobacco product standard, if certain pre-conditions to
13 promulgation exist, namely:

- 14 a. The Secretary has published a Notice of Proposed Rulemaking in the Federal
15 Register and the comment period has closed, *see id.*;
- 16 b. The Secretary has considered—
- 17 i. Comments submitted in response to the Notice, *id.* (referring to 21 U.S.C.
18 § 387g(c));
- 19 ii. Comments concerning the “technical achievability of compliance with
20 such standard,” *id.* (referring to 21 U.S.C. § 387g(b)(1));
- 21 iii. “[A]ll other information submitted in connection with a proposed
22 standard, including information concerning the countervailing effects of
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24 ¹³ “The Secretary [i.e., FDA] shall consider information submitted in connection with a proposed
25 standard regarding the technical achievability of compliance with such standard.” 21 U.S.C. §
26 387g(b)(1). “The Secretary [i.e., FDA] shall consider all other information submitted in
27 connection with a proposed standard, including information concerning the countervailing
28 effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco
users, or nontobacco users, such as the creation of a significant demand for contraband or other
tobacco products that do not meet the requirements of this chapter and the significance of such
demand.” *Id.* § 387g(b)(2).

1 the tobacco product standard on the health of adolescent tobacco users,
2 adult tobacco users, or nontobacco users, such as the creation of a
3 significant demand for contraband or other tobacco products that do not
4 meet the requirements of this subchapter and the significance of such
5 demand,” *id.* (referring to 21 U.S.C. § 387g(b)(2)); and

6 iv. Any report from the Tobacco Products Scientific Advisory Committee
7 (“TPSAC”), *id.*; and

8 c. The Secretary “determine[d] that the standard would be appropriate for the
9 protection of public health,” *id.* § 387g(d)(1)(A).

10 63. Taken together, these provisions equipped Defendants with the necessary tools to
11 fully address the issue of menthol in cigarettes.

12 **2. Congress directed the Defendants to address the issue of**
13 **menthol in cigarettes “quickly.”**

14 64. Beyond providing such tools to Defendants, however, Congress also emphasized
15 the speed by which it expected the Defendants to act—i.e., “quickly.”

16 65. The Tobacco Control Act’s primary sponsor and committee member in charge
17 Rep. Henry A. Waxman, made clear that Congress considered menthol to be an urgent public
18 health concern and intended the FDA to move “quickly” to address it. Per the Act’s
19 accompanying Committee Report:

20 *Section 907. Tobacco product standards* Consistent with the overall intent
21 of the bill to protect the public health, including by reducing the
22 number of children and adolescents who smoke cigarettes, section
23 907(a)(1) is intended to prohibit the manufacture and sale of
24 cigarettes with certain “characterizing flavors” that appeal to youth.
25 ...

26 **The Committee recognizes the unique issues**
27 **surrounding menthol cigarettes and urges the Secretary**
28 **to address these issues as quickly as practicable.** The

1 Committee is especially concerned about proportionately higher
2 rates of menthol cigarette use among African American smokers, as
3 well as the historic targeting of African Americans for menthol
4 cigarette use by tobacco companies. ... [T]he Committee recognizes
5 that menthol cigarettes may pose unique health risks to those who
6 smoke them. Given the high rates of use among African American
7 smokers, including African American youth, as well as higher rates
8 of lung cancer documented among African American smokers as
9 compared to non-African American smokers, the Committee
10 believes that **it is critical for the Secretary to move quickly**
11 **to address the unique public health issues posed by**
12 **menthol cigarettes.**

13 H. Rept., Part 1 at 37–39 (emphasis added).

14 66. Rep. Waxman’s floor statements further emphasized his efforts “with members of
15 the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus” of
16 attention by the FDA.¹⁴

17 **B. Defendants begin examining options to regulate menthol in 2009.**

18 67. At the time, the Defendants acknowledged Congress’ urgency in addressing the
19 critical health problem of menthol in cigarettes. On September 22, 2009, the FDA announced
20 that it would be “examining options” for regulating menthol cigarettes:

21 The FDA’s ban on candy and fruit-flavored cigarettes ... highlights
22 the importance of reducing the number of children who start to
23 smoke, and who become addicted to dangerous tobacco products.

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26 ¹⁴ Cong. Rec.—House, H4318, H4339 (Vol. 155, No. 55) (Apr. 1, 2009 floor statement), *available*
27 *at* [https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-](https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-2)
28 [2](https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-2); Cong. Rec.—House, H6630, H6652 (Vol. 155, No. 88) (June 12, 2009 floor statement),
available at [https://www.congress.gov/congressional-record/2009/06/12/house-](https://www.congress.gov/congressional-record/2009/06/12/house-section/article/H6630-1)
[section/article/H6630-1](https://www.congress.gov/congressional-record/2009/06/12/house-section/article/H6630-1).

1 The FDA is also examining options for regulating both menthol
2 cigarettes and flavored tobacco products other than cigarettes.¹⁵

3 68. And in response to questions from journalists, Dr. Lawrence Deyton—the Center
4 for Tobacco Products’ Director at the time—noted that the Center would be “studying” and
5 “discussing” the issue of menthol cigarettes with the agency’s Advisory Committee:

6 Jennifer Corbett: The question I have is—and you mentioned
7 in your press release—that you’re looking at
8 menthol cigarettes, because my
9 understanding (about) is the—that’s the
10 biggest flavor out there that ...

11 Lawrence Deyton: Yes, the menthol issue is also specifically
12 addressed in the Family Smoking Prevention
13 and Tobacco Control Act, and that is an issue
14 again which we will be discussing with our
15 Scientific Advisory Committee and studying.
16 **We’ve been asked specifically by the**
17 **[A]ct to study that.**

18 Sept. 22, 2009 Tr. for the FDA’s Media Briefing, at 8–9 (emphasis added).¹⁶

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21 ¹⁵ FDA, News & Events, *Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First*
22 *Under New Tobacco Law* (Sept. 22, 2009) (noting that “[a]lmost 90 percent of adult smokers start
23 smoking as teenagers. These flavored cigarettes are a gateway for many children and young
24 adults to become regular smokers,” said FDA Commissioner Margaret A. Hamburg, M.D.
25 Flavors make cigarettes and other tobacco products more appealing to youth. Studies have
26 shown that 17 year old smokers are three times as likely to use flavored cigarettes as smokers over
27 the age of 25. ... “FDA’s ban on these cigarettes will break that cycle for the more than 3,600
28 young people who start smoking daily.”) (footnote omitted). *Available at*
[https://web.archive.org/web/20090924140101/http://www.fda.gov/NewsEvents/Newsroom/
PressAnnouncements/ucm183211.htm](https://web.archive.org/web/20090924140101/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm).

¹⁶ *Available at*
[https://web.archive.org/web/20091104012525/http://www.fda.gov/downloads/NewsEvents/
Newsroom/MediaTranscripts/UCM183533.pdf](https://web.archive.org/web/20091104012525/http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM183533.pdf).

1 69. In similar statements, Dr. Deyton reiterated that the Center would be addressing
2 the issue of menthol cigarettes:

3 Miriam Falco: ... I got to say I'm a little confused. Your
4 answers are all very government-speak, if I
5 may say so. If you know that young people
6 prefer menthol cigarettes, then why aren't
7 they included in this?

8 Lawrence Deyton: **In terms of the question of menthol,**
9 **the law specifically asks us to look at**
10 **menthol separately. And we will be**
11 **doing that.**

12 *Id.* at 15 (emphasis added).

13 **C. Since at least 2011, Defendants have known that removing menthol**
14 **cigarettes from the market would benefit public health.**

15 70. Following Congress' passage of the Tobacco Control Act, the Defendants timely
16 formed and organized the Tobacco Product Scientific Advisory Committee ("TPSAC").

17 71. That Committee was comprised of "a panel of leading public health, scientific
18 experts and representatives of various parts of the tobacco industry," and was charged with
19 "providing advice, information, and recommendations to the FDA on health issues related to
20 tobacco products and other issues relating to the regulation of tobacco products." FDA, Dr.
21 Lawrence R. Deyton, CTP Director, *FDA Remarks on the Report and Recommendation on the Public*
22 *Health Impact of Menthol Cigarettes* (Mar. 18, 2011) ("2011 FDA Remarks on Menthol Cigarettes
23 Rept.").¹⁷

24 72. The full Committee first met in March 2010, and 11 more times thereafter. *See*
25 *FDA Rept. to Congress, Progress and Effectiveness of the Implementation of the Family Smoking Prevention*
26

27 ¹⁷ Available at [https://wayback.archive-](https://wayback.archive-it.org/7993/20170112125250/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm)
28 [it.org/7993/20170112125250/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm](https://wayback.archive-it.org/7993/20170112125250/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm).

1 *and Tobacco Control Act*, at 15 (2013). There were also two meetings of the Tobacco Products
2 Constituents Subcommittee of the TPSAC and two meetings of the Menthol Report
3 Subcommittee. *See id.* Each Committee and Subcommittee meeting covered a broad range of
4 materials, presentations, and public submissions. *See* FDA 2010 TPSAC Mtg. Materials and
5 Info.;¹⁸ *see also* FDA 2011 TPSAC Mtg. Materials and Info.¹⁹

6 **1. The Committee’s 2011 report and findings.**

7 73. On March 23, 2011, the TPSAC submitted its formal report, *Menthol Cigarettes and*
8 *Public Health: Review of the Scientific Evidence and Recommendations* (2011) (“2011 TPSAC Menthol
9 Rept.”) to the FDA.²⁰ This Report—also known as the TPSAC Report—contained several
10 findings and conclusions, based on the best available scientific evidence.

11 **i. Menthol masks nicotine’s irritating effects.**

12 74. Among other things, the Report found that menthol is a flavor additive that
13 possesses a minty taste and aroma. *See* 2011 TPSAC Menthol Rept. at 16. While regulated as a
14 drug in certain medicinal products (e.g., cough drops), menthol was not regulated in tobacco
15 products. *See id.* Menthol was also present in 90% of tobacco products, including cigarettes not
16 marketed as menthol cigarettes. *See id.*

17 75. The Report further found that menthol produced a variety of sensory effects,
18 including cooling, soothing, and anesthetic effects. *See id.* at 23. For example, “[i]n cigarettes with
19 low levels of tar and nicotine, the addition of menthol can enhance the ‘bite’ or ‘throat grab’ of
20 the smoke, making such cigarettes more acceptable to consumers. Conversely, the addition of
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23 ¹⁸ Available at [https://wayback.archive-
it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting
24 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm](https://wayback.archive-it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm).

25 ¹⁹ Available at [https://wayback.archive-
it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting
26 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm](https://wayback.archive-it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm).

27 ²⁰ Available at [https://wayback.archive-
it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/Commit
28 teesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf).

1 menthol to cigarettes high in tar and nicotine can reduce the irritating effect of nicotine ...
2 making these cigarettes more palatable.” *Id.* at 24.

3 76. Significantly, the Report found that the tobacco companies “manipulated the
4 concentration of menthol to achieve a desired taste, aroma, and cooling sensation based on
5 anticipated consumer preference and demand.” *See id.* at 55.

6 **ii. The tobacco companies targeted youth, women, and**
7 **minorities with menthol cigarettes.**

8 77. The Report also found that the tobacco industry spent “as much or more on
9 magazine advertising for menthol [cigarette brands] as for non-menthol brands, even though
10 menthol brands represent a much smaller share of the market.” 2011 TPSAC Menthol Rept. at
11 61. In addition, the Committee found that menthol cigarettes “are marketed disproportionately
12 to younger people,” *id.* at 92; menthol use is higher among youth and young adult smokers, *see*
13 *id.*; women “have been targets of tailored menthol marketing efforts,” *id.*; and menthol cigarettes
14 are “disproportionately marketed per capita to African Americans. African Americans have been
15 the subjects of specifically tailored menthol marketing strategies and messages. Billboard
16 advertising and point-of-sale advertising for menthol cigarettes has been over-represented in
17 neighborhoods with a high percentage of African Americans and in magazines with high African
18 American readership, and more so than non-menthol cigarette advertising. Consistent with these
19 targeted marketing efforts, menthol cigarettes are disproportionately smoked by African
20 American smokers,” *id.*

21 78. The Report further found that “although cigarette smoking is becoming less
22 prevalent, menthol cigarette smoking is declining at [a] slower rate than is non-menthol cigarette
23 smoking.” *Id.* at 148. In addition, menthol cigarettes were associated with “increased transition to
24 greater or established smoking and dependence.” *Id.* at 149.

25 79. In sum, the 2011 Report noted that sufficient evidence existed to conclude that
26 the availability of menthol cigarettes—

- 27 a. increases experimentation and regular smoking, *id.* at 216;

1 b. increases the likelihood of addiction and the degree of addiction in youth smokers,
2 *id.*; and

3 c. results in a lower likelihood of smoking cessation success in African Americans,
4 compared to smoking non-menthol cigarettes, *id.* at 217.

5 80. The availability of menthol cigarettes was also found to “increase the likelihood of
6 experimentation and regular smoking beyond the anticipated prevalence if such cigarettes were
7 not available, in the general population and particularly in African Americans.” *Id.* at 219. In
8 addition, the Committee found a “causal relationship between the availability of menthol
9 cigarettes and regular smoking among youth.” *Id.* And, it found that menthol cigarette marketing
10 increased the prevalence of smoking “beyond anticipated prevalence if such cigarettes were not
11 available for the whole population, and for youth and African Americans.” *Id.* at 220.

12 **iii. Conclusion: Menthol in cigarettes harms public health.**

13 81. Based on the Committee’s findings, the 2011 Report made two overall
14 conclusions: (1) “Menthol cigarettes have an adverse impact on public health in the United
15 States”; and (2) “There are no public health benefits of menthol compared to non-menthol
16 cigarettes.” 2011 TPSAC Menthol Rept. at 220.

17 82. As explained by the Committee, “the availability of menthol cigarettes has led to
18 an increase in the number of smokers,” which in turn adversely affects public health in the
19 United States. *Id.* at 220. “[O]f particular concern was the high rate of menthol cigarette
20 smoking among youth and the trend over the last decade of increasing menthol cigarette smoking
21 among 12–17 year olds, even as smoking of non-menthol cigarettes declines. ... Thus, the
22 availability of menthol cigarettes increases initiation and reduces cessation, thereby increasing the
23 number of people who are smoking. This increase in the number of smokers represents an
24 adverse impact of the availability of menthol cigarettes on public health.” *Id.* at 220–21.

25 83. Notably, the Committee found that if menthol cigarettes had been removed from
26 the market in 2010, then by 2020, roughly 17,000 premature deaths would have been avoided,
27 and about 2.3 million people would not have started smoking. By 2050, the cumulative gains
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1 would have resulted in over 327,000 premature deaths avoided, and over 9.1 million people that
2 would not have started smoking. *See id.* at 221.

3 84. For African Americans, this would have meant that by 2020, roughly 4,700
4 premature deaths would have been avoided, and about 461,000 African Americans would not
5 have started smoking. By 2050, over 66,000 premature deaths would have been avoided, and
6 over 1.6 million African Americans would not have started smoking. *See id.* at 223.

7 **2. Recommendation: Removing menthol cigarettes from the**
8 **marketplace “would benefit the public health”.**

9 85. As a result of the Committee’s findings and conclusions, the Committee then
10 made the following “overall recommendation” to the FDA: **“Removal of menthol cigarettes**
11 **from the marketplace would benefit public health in the United States.”** 2011
12 TPSAC Menthol Rept. at 225 (emphasis in original).

13 86. Per the Committee, the tobacco companies’ marketing of menthol cigarettes “has
14 been successful”:

15 Menthol cigarettes are now smoked by most African American
16 smokers and there is a concerning rise of menthol cigarette smoking
17 among youth. Menthol cannot be considered merely a flavoring
18 additive to tobacco. Its pharmacological actions reduce the
19 harshness of smoke and the irritation from nicotine, and may
20 increase the likelihood of nicotine addiction in adolescents and
21 young adults who experiment with smoking. Furthermore, the
22 distinct sensory characteristics of menthol may enhance the
23 addictiveness of menthol cigarettes, which appears to be the case
24 among youth. **[The Committee] has found that the**
25 **availability of menthol cigarettes has an adverse impact**
26 **on public health by increasing the numbers of smokers**
27 **with resulting premature death and avoidable morbidity.**

28 *Id.* at 225 (emphasis added).

1 87. Specifically, removing menthol from cigarettes could result in a substantial
2 reduction in cigarette smoking by encouraging smokers to quit smoking. *See id.* at 227.

3 **D. Defendants engage in a series of half-measures, doublespeak, and**
4 **foot-dragging.**

5 88. Armed with the knowledge that removing menthol from the marketplace would
6 save lives and protect the public health, the Defendants could have proposed a new tobacco
7 product standard that banned the manufacture, sale, and distribution of menthol cigarettes.

8 89. Instead, the Defendants allowed menthol cigarettes to remain in the market,
9 thereby “increasing the numbers of smokers with resulting premature death and avoidable
10 morbidity,” and adversely impacting public health. *See* 2011 TPSAC Menthol Rept. at 225.

11 90. The following section outlines Defendants’ several efforts (e.g., through repeated
12 calls for more study) to avoid deciding whether to add menthol to the list of banned
13 characterizing flavors, or else respond formally to Plaintiffs’ Citizen Petition.

14 91. Following the release of the Advisory Committee’s March 2011 findings and
15 report, the FDA announced that it would conduct a “thorough review” of the TPSAC report
16 with the agency’s own experts. *See* 2011 FDA Remarks on Menthol Cigarettes Rept.

17 92. The FDA further acknowledged “the strong interest in this issue among all
18 stakeholders” and committed itself to “continu[ing] to communicate the steps FDA is taking as it
19 determines what future regulatory actions, if any, are warranted.” *See* 2011 FDA Remarks on
20 Menthol Cigarettes Rept. (noting further that “FDA intends to provide its first progress report on
21 the review of the science in approximately 90 days”).

22 93. The FDA then reiterated that “a top priority for FDA is to protect the public
23 health from the harmful effects of tobacco use[.]” *Id.* As explained by the Center of Tobacco
24 Products’ Director, “Tobacco is the leading cause of preventable disease, disability, and death in
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1 the United States. Tobacco products are responsible for approximately 443,000 deaths and \$193
2 billion on medical expenditures and lost productivity each year in the United States.” *Id.*²¹

3 94. But instead of taking decisive action to protect the public health, the Defendants
4 stalled. For the remainder of 2011 and all of 2012, Defendants made no visible progress or public
5 announcements concerning their plans to regulate menthol in cigarettes.

6 **1. Plaintiffs’ 2013 Citizen Petition seeks Defendants’ action on**
7 **menthol cigarettes.**

8 95. Given the FDA’s continuing silence, the Public Health Law Center— together
9 with nearly 20 public health advocacy groups and advocates, including the Plaintiff African
10 American Tobacco Control Leadership Council—filed a Citizen Petition in April 2013, asking
11 the FDA to (a) add menthol to the list of additives and constituents in the prohibition on
12 characterizing flavors in cigarettes and cigarette smoke directed by section 907(a)(1)(A) of the
13 Federal Food, Drug, and Cosmetic Act; and (b) work with appropriate entities to provide support
14 to menthol smokers’ efforts to quit as the result of the requested prohibition on menthol in
15 cigarettes. *See Tobacco Control Legal Consortium et al. Citizen Petition*, Dkt. ID FDA-2013-P-0435-0001,
16 at 9–10 (“Citizen Petition”).²²

17 96. The Citizen Petition cited extensive evidence that (a) smoking continued to be a
18 critical public health issue; (b) the availability of menthol cigarettes hurt the public health,
19 particularly youth and minority smokers; and (c) prohibiting menthol cigarettes in the
20 marketplace would benefit the public health. *See id.*

21 97. The FDA did not immediately respond to Public Health Law Center or Plaintiff
22 AATLC’s call to action.

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25 ²¹ At around this same time, the tobacco industry submitted to the FDA a competing Industry
26 Menthol Report. *See The Industry Menthol Report* (Mar. 23, 2011). *Available at*
27 [https://wayback.archive-
it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/Commit
teesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf](https://wayback.archive-it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf).

28 ²² *Available at* <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

2. The FDA seeks more study—thereby delaying any action on menthol in cigarettes

98. Instead, the FDA issued an Advance Notice of Proposed Rulemaking in July 2013, to solicit additional information and public comment on the “potential regulation of menthol in cigarettes.” FDA, Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco Products*, Dkt. No. FDA-2013-N-0521, 78 Fed. Reg. 44484, 44484 (July 24, 2013).²³

99. As part of this advance notice, the FDA shared its preliminary scientific evaluation of public health issues relating to the use of menthol in cigarettes. *See* FDA, Prelim. Scientific Eval. of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes (“2013 FDA Findings”).²⁴ This undertaking was yet another “thorough review of the available science concerning menthol cigarettes.” *Id.* at 3. To do this, the FDA “weighed the collective body of evidence for the impact of the use of menthol in cigarettes on public health”; “considered the source of information, the type of study, and the quality of study methods and data”; “evaluated the peer-reviewed literature, industry submissions and other materials provided to TPSAC”; and “performed or commissioned additional analyses in an attempt to fill in and inform some of the gaps in the literature.” *Id.* at 3.

100. The FDA then submitted its findings to a peer-review panel, which provided comments to which the FDA then responded to. *See* FDA Rept. to Congress, *Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act*, at 15 (2013).²⁵ The agency also posted the peer reviewed comments, and its response to those comments. *See id.*

101. In their review, the FDA found that the weight of the evidence, among other things, supported the following conclusions:

²³ Available at <https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-in-cigarettes-tobacco-products-request-for-comments>.

²⁴ *See* FDA, Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco Products*, 78 Fed. Reg. 44484, at Reference 1, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*, ID No. FDA-2013-N-0521-0001 (July 24, 2013). Available at <https://www.regulations.gov/document?D=FDA-2013-N-0521-0001>.

²⁵ Available at <https://www.fda.gov/media/86670/download>.

- a. Menthol in cigarettes was “likely associated with altered physiological responses to tobacco smoke”;
- b. A majority of African American smokers used menthol cigarettes;
- c. Younger populations had the highest rate of smoking menthol cigarettes;
- d. Female smokers were more likely to smoke menthol cigarettes than male smokers;
- e. The marketing of menthol cigarettes is associated with menthol brand preference among adolescents and the African American community;²⁶ and
- f. Menthol in cigarettes was likely associated with—
 - i. increased initiation and progression to regular cigarette smoking;²⁷
 - ii. increased dependence;²⁸ and
 - iii. reduced success in smoking cessation, especially among African American menthol smokers.²⁹

2013 FDA Findings at 4–6.

102. In short, the FDA concluded that menthol in cigarettes was associated with greater addiction, menthol smokers were less likely to successfully quit smoking, and menthol cigarettes likely posed “a public health risk above that seen with nonmenthol cigarettes”:

The impact of cigarette smoking upon public health is indisputable. More than 400,000 deaths per year in the

²⁶ “The available data show that advertising is a strong driver of brand preference among adolescents and that it is likely that the standard marketing mix approach of price, promotion, product, and place has been used to drive menthol cigarette preference among the urban African American community.” 2013 FDA Findings, at 5.

²⁷ “Data show that newer smokers prefer menthol at levels substantially above that of the general population, with an inverse correlation between age and menthol preference that reaches a plateau in adulthood.” 2013 FDA Findings, at 5.

²⁸ “There were consistent findings that menthol smokers more likely to smoke their first cigarette within five minutes of waking.” 2013 FDA Findings, at 6.

²⁹ “In the reviewed studies, menthol smokers, especially African American menthol smokers, were less likely to successfully stop smoking than their nonmenthol smoking counterparts. This is consistent with the observation that menthol smokers appear to be more nicotine dependent than nonmenthol smokers which can be an important factor in smoking cessation success.” 2013 FDA Findings, at 6.

1 **United States are caused by tobacco use.** Consistent patterns
2 have emerged as a result of FDA’s evaluation of the scientific
3 evidence relevant to the impact of menthol tobacco products on
4 public health. ... [A]dequate data suggest that **menthol use is**
5 **likely associated with increased smoking initiation** by
6 youth and young adults. Further, the data indicate that **menthol in**
7 **cigarettes is likely associated with greater addiction.**
8 Menthol smokers show greater signs of nicotine dependence and are
9 less likely to successfully quit smoking. These findings, combined
10 with the evidence indicating that menthol’s cooling and anesthetic
11 properties can reduce the harshness of cigarette smoke and the
12 evidence indicating that menthol cigarettes are marketed as a
13 smoother alternative to nonmenthol cigarettes, make it likely that
14 **menthol cigarettes pose a public health risk above that**
15 **seen with nonmenthol cigarettes.**

16 *Id.* at 6 (emphasis added).

17 103. Given these findings, the Center for Tobacco Products Director Mitch Zeller
18 restated what was, by that time, obvious: “Menthol cigarettes raise critical public health
19 questions.” Michael Felberbaum, *FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23,
20 2013).³⁰

21 104. Despite these findings—which substantially mirrored if not duplicated the
22 Committee’s earlier 2011 Report—the FDA withheld making any recommendations about
23 whether to limit or ban menthol cigarettes. *See id.*; *see also* FDA 2013 Findings, at 7.

24 105. And while Director Zeller noted that there was “no holdup” by the FDA
25 proposing restrictions on menthol, there were still (purportedly) “some important questions” that
26 needed to be answered. *See FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23, 2013).

27 _____
28 ³⁰ Available at <https://www.usatoday.com/story/news/nation/2013/07/23/fda-menthol-cigarettes-health-risk/2578331/>.

1 Thus, the FDA would be funding three menthol-related studies looking at (a) whether genetic
2 differences explained whether certain racial and ethnic populations were more likely to use
3 menthol cigarettes; (b) menthol cigarettes' smoke-related toxins and carcinogens as compared to
4 nonmenthol cigarettes; and (c) the effects of menthol and nonmenthol compounds in various
5 tobacco products, with respect to both tobacco addiction and the toxicants of tobacco smoke. *See*
6 *FDA Invites Public Input on Menthol in Cigarettes*, The ASCO Post, Vol. 4, Issue 13, at 21 (Aug. 13,
7 2013).³¹

8 106. The FDA would also “review[] all of the available information from this
9 assessment and the anticipated public comments, from the [2011 Tobacco Product Scientific
10 Advisory Committee] report and associated public comments, and from the tobacco industry
11 perspective document[.]” *Id.* Upon completing this review, the FDA would then “determine[]”
12 whether “restrictions on the sale and/or distribution of menthol cigarettes or product standards
13 should be established[.]” *Id.*

14 107. On information and belief, the FDA completed and reviewed the results of these
15 menthol studies years ago.

16 108. Following the FDA's stall for additional time, the Center for Tobacco Products
17 Director Mitch Zeller then responded to Plaintiff AATCLC's Citizen Petition as follows:

18 FDA has been unable to reach a decision on your petition because
19 it raises significant, complex issues requiring extensive review and
20 analysis by Agency officials. As you may know, FDA issued an
21 advance notice of proposed rulemaking on July 24, 2013, seeking
22 comments, including comments on FDA's preliminary scientific
23 evaluation of public health issues related to the use of menthol in
24 cigarettes, and data, research, or other information that may inform
25 regulatory actions FDA might take with respect to menthol in
26

27
28 ³¹ Available at https://issuu.com/ascopost/docs/tap_vol_4_issue_13.

1 cigarettes (78 FR 44484). ... We will respond to your petition as soon
2 as we have reached a decision on your request.

3 109. For the remainder of 2013, however, Defendants made no visible progress or any
4 announcement concerning their plans to regulate menthol in cigarettes. Defendants also did not
5 respond to or otherwise supplement their response to Plaintiff AATCLC's Citizen Petition.

6 110. Defendants' silence and inaction continued for all of 2014, 2015, 2016, and the
7 first half of 2017. Around this same time, however, many other countries had already banned
8 menthol flavored cigarettes.³²

9 **3. Defendants' "accelerate[d]" rulemaking on menthol cigarettes**
10 **stalls.**

11 111. In July 2017, Defendants announced the FDA's intention to, among other things,
12 issue yet another Advance Notice of Proposed Rulemaking³³ to "seek public comment on the role
13 that flavors (including menthol) in tobacco products play in attracting youth[.]" See FDA
14 Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease
15 Death (July 27, 2017).³⁴

16 112. Then, in March 2018, Defendants announced that they were seeking yet even
17 more comments "on the role that flavors—including menthol—play in initiation, use and
18

19
20 ³² For example, in 2012, Brazil approved a ban on all flavors, including menthol, in all tobacco
21 products. In 2016, the European Union banned all flavored cigarettes including menthol
22 (effective 2020). And in 2017, Canada banned the sale of menthol cigarettes. See Campaign for
23 Tobacco-Free Kids, *Brazil's Highest Court Upholds Ban on Flavored Tobacco Products* (Feb. 1, 2018).
24 Available at [https://www.tobaccofreekids.org/press-releases/2018_02_01_brazil-court-upholds-
25 flavor-ban](https://www.tobaccofreekids.org/press-releases/2018_02_01_brazil-court-upholds-flavor-ban) (last visited March 31, 2024); World Health Org., *Advisory Note: Banning Menthol in
26 Tobacco Products*, 49–50 (2016). Available at
27 [https://apps.who.int/iris/bitstream/handle/10665/205928/9789241510332_eng.pdf;jsessionid=
28 =6D55886EDA1A8FDA032CA2B42F4409FC?sequence=1.](https://apps.who.int/iris/bitstream/handle/10665/205928/9789241510332_eng.pdf;jsessionid=6D55886EDA1A8FDA032CA2B42F4409FC?sequence=1)

³³ See *Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 238 U.S. App. D.C. 271, 740
F.2d 21, 34 (1984) (noting in a similar context that the FDA, "by issuing an advance notice of
proposed rulemaking, 'has embarked on the least responsive course short of inaction.'").

³⁴ Available at [https://www.fda.gov/news-events/press-announcements/fda-announces-
comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.](https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death)

1 cessation of tobacco products.” FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D.* (Mar. 14,
2 2018).³⁵

3 113. The FDA’s call for additional study, of course, covered many of the same areas
4 previously covered by the FDA’s 2011 Tobacco Products Scientific Advisory Committee report,
5 the Plaintiffs’ 2013 Citizen Petition, as well as the FDA’s 2013 “preliminary” findings. The FDA
6 Commissioner noted, for example, that “youth consistently report product flavoring as a leading
7 reason for using tobacco products. Flavors may disguise the taste of tobacco. But flavored
8 cigarettes ... are every bit as addictive as any other tobacco products, have the same harmful
9 health effects and may even make it harder to quit. ... Additionally, youth and young adult
10 smokers are disproportionately more likely to smoke menthol than nonmenthol cigarettes. And
11 we know that youth who initiate smoking with menthol cigarettes ... may be at greater risk of
12 progression from experimentation to established smoking and nicotine dependence.” FDA,
13 *Statement from FDA Commissioner Scott Gottlieb, M.D.* (Mar. 19, 2018).³⁶

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16 ³⁵ Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to
17 dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or
18 non-addictive levels (Mar. 14, 2018). Available at [https://www.fda.gov/news-events/press-
19 announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-
20 dramatically-reduce-smoking](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking).

21 The three advance notices of proposed rulemaking were later published that same month: *See*
22 FDA, *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*, Dkt. No. FDA-2017-N-6189,
23 83 Fed. Reg. 11818 (Mar. 16, 2018). Available at [https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-
24 standard-for-nicotine-level-of-combusted-cigarettes](https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes); FDA, *Regulation of Flavors in Tobacco Products*,
25 Dkt. No. FDA-2017-N-6565, 83 Fed. Reg. 12294 (Mar. 21, 2018). Available at [https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-
26 tobacco-products](https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products); FDA, *Regulation of Premium Cigars*, Dkt. No. FDA-2017-N-6107, 83 Fed. Reg.
27 12901 (Mar. 26, 2018). Available at [https://www.federalregister.gov/documents/2018/03/26/2018-06047/regulation-of-premium-
28 cigars](https://www.federalregister.gov/documents/2018/03/26/2018-06047/regulation-of-premium-cigars).

³⁶ FDA, *Statement from FDA Commission Scott Gottlieb, M.D., on efforts to reduce tobacco use, especially
among youth, by exploring options to address the role of flavors—including menthol—in tobacco products* (Mar.
19, 2018). Available at [https://www.fda.gov/news-events/press-announcements/statement-fda-
commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-especially-among-youth](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-especially-among-youth).

1 114. Around this same time, the FDA also released a “Draft Concept Paper: Illicit
2 Trade in Tobacco Products After Implementation of a Food and Drug Administration Product
3 Standard, and Request for Comments,” Dkt. No. FDA-2018-N-0529, 83 Fed. Reg. 26,697 (Mar.
4 16, 2018).³⁷ Without mentioning menthol, the paper noted that “FDA is also considering
5 establishing a product standard prohibiting the manufacture, sale, and distribution of tobacco
6 products with certain characterizing flavors.” FDA, *Illicit Trade in Tobacco Products after*
7 *Implementation of an FDA Product Standard*, at 4 (Mar. 15, 2018).³⁸

8 115. In October 2018, FDA Commissioner Gottlieb then announced that “he was
9 revisiting [the FDA’s consideration of] the use of menthol in certain products, which has been of
10 particular concern in African-American communities targeted by makers of menthol cigarettes
11 like Newport and Kools in years past. **‘It was a mistake for the agency to back away on**
12 **menthol,’** he said.” Sheila Kaplan, *Altria to Stop Selling Some E-Cigarette Brands That Appeal to Youths*,
13 *The New York Times* (Oct. 25, 2018) (emphasis added).³⁹

14 116. The next month, the FDA Commissioner announced that the agency would
15 “advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible
16 tobacco products, including cigarettes and cigars, informed by the comments on our Advanced
17 Notice of Proposed Rulemaking (ANPRM).” Statement from FDA Commissioner Scott Gottlieb,
18 M.D. (Nov. 15, 2018).⁴⁰ Commissioner Gottlieb described his reasoning as follows:

19 _____
20 ³⁷ Available at [https://www.federalregister.gov/documents/2018/06/08/2018-12370/draft-](https://www.federalregister.gov/documents/2018/06/08/2018-12370/draft-concept-paper-illicit-trade-in-tobacco-products-after-implementation-of-a-food-and-drug)
21 [concept-paper-illicit-trade-in-tobacco-products-after-implementation-of-a-food-and-drug](https://www.federalregister.gov/documents/2018/06/08/2018-12370/draft-concept-paper-illicit-trade-in-tobacco-products-after-implementation-of-a-food-and-drug).

22 ³⁸ Available at <https://www.regulations.gov/document/FDA-2018-N-0529-0002>. Notably, 24
23 State Attorneys General noted that when other flavors were banned in 2009, an illicit market for
24 flavored cigarettes was not created; rather, such ban expanded the market for other legally
25 available, flavored tobacco products (i.e., cigars and cigarillos). *See* Ltr. to FDA from 24 State
26 Attorneys Gen., at 6 (July 16, 2018), available at
27 <https://oag.ca.gov/sites/all/files/agweb/pdfs/tobacco/ag-illicit-trade-letter-fda-071618.pdf>.

28 ³⁹ Available at [https://www.nytimes.com/2018/10/25/health/altria-vaping-](https://www.nytimes.com/2018/10/25/health/altria-vaping-cigarettes.html?module=inline)
[cigarettes.html?module=inline](https://www.nytimes.com/2018/10/25/health/altria-vaping-cigarettes.html?module=inline).

⁴⁰ FDA, Statement from FDA Commission 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). Available at <https://www.fda.gov/news-events/press->

1 I'm deeply concerned about the availability of menthol-flavored
2 cigarettes. I believe these menthol-flavored products represent one
3 of the most common and pernicious routes by which kids initiate on
4 combustible cigarettes. The menthol serves to mask some of the
5 unattractive features of smoking that might otherwise discourage a
6 child from smoking. Moreover, I believe that menthol products
7 disproportionately and adversely affect underserved communities.
8 And as a matter of public health, they exacerbate troubling
9 disparities in health related to race and socioeconomic status that
10 are a major concern of mine.

11 ...

12 I noted that the popularity of menthol cigarettes with youth is
13 especially troubling. In fact, youth smokers are more likely to use
14 menthol cigarettes than any other age group. More than half (54
15 percent) of youth smokers ages 12–17 use menthol cigarettes,
16 compared to less than one-third of smokers ages 35 and older.
17 Prevalence of menthol use is even higher among African-American
18 youth, with data showing that seven out of 10 African-American
19 youth smokers select menthol cigarettes. *Id.* .

20 117. These expressed concerns were, of course, the same concerns and conclusions
21 voiced by Congress in 2009; the FDA's Advisory Committee in 2011, Plaintiffs' Citizen Petition
22 in 2013, and the FDA's own preliminary findings issued five years earlier.

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25
26 [announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-](https://www.fda.gov/oc/announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=El)
27 [youth-preventing-](https://www.fda.gov/oc/announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=El)
28 [access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=El](https://www.fda.gov/oc/announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=El)
[oqua.](https://www.fda.gov/oc/announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=El)

1 118. Nonetheless, the FDA Commissioner expressed his agency’s intention to
2 “accelerate” the proposed rulemaking process to ensure that the FDA’s policies on flavored
3 tobacco products protected the public health. *Id.*

4 119. But what had sounded like “accelerate[d]” rulemaking, again turned to visible
5 inaction and delay. In March 2019, FDA Commissioner Scott Gottlieb resigned. Norman E.
6 “Ned” Sharpless, M.D. was then appointed Acting FDA Commissioner the following month.

7 120. And by June 2019, without explanation, the FDA reversed course and decided not
8 to initiate its previously announced rulemaking process. At that time, then-Acting FDA
9 Commissioner Sharpless and Center for Tobacco Products Director Mitch Zeller announced the
10 FDA’s Achievements in Tobacco Regulation Over the Past Decade and Beyond.⁴¹ Among other
11 things, that announcement noted the FDA’s plan “to take action on flavored cigars and continue
12 to explore other issues related to flavored tobacco products.” *Id.* Absent from Defendants’
13 announcement, however, was any plan to regulate menthol cigarettes.

14 121. Similarly, when HHS published its Spring 2019 Agenda (i.e., “the regulatory
15 activities that the Department [i.e., Defendants HHS, FDA, and CTP] expects to undertake in
16 the foreseeable future,” HHS Regulatory Agenda, 84 Fed. Reg. 29623, 29624 (June 24, 2019)⁴²),
17 HHS and the Defendants omitted any mention of regulating menthol cigarettes. *See id.*, generally;
18 HHS, Agency Rule List – Spring 2019.

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23 ⁴¹ *See* FDA, Achievements in Tobacco Regulation Over the Past Decade and Beyond (June 20,
24 2019). Available at <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/achievements-tobacco-regulation-over-past-decade-and-beyond>.

25 ⁴² Available at <https://www.federalregister.gov/documents/2019/06/24/2019-12004/regulatory-agenda>. *See also* HHS, Agency Rule List – Spring 2019. Available at
26 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201904&showStage=active&agencyCd=0900&csrf_token=AC9CA9308A92E9EACBFB612B667086E9017C80260FDDB0D9364F9F5F2137B6554EA1929687D28B0AFFBE211B4AB531B5D1F4.
27
28

1 122. Likewise, Defendants omitted including any plans to regulate menthol as part of
2 HHS’s Fall Regulatory Agenda. *See* HHS Regulatory Agenda, 84 Fed. Reg. 71129 (Dec. 26,
3 2019).⁴³

4 123. The same was true of the 2019 Unified Agenda, which was compiled by the
5 Regulatory Information Services Center for the Office of Information and Regulatory Affairs
6 (“OIRA”). *See* Regulatory Info. Services Ctr., *Introduction to the Unified Agenda of Federal Regulatory*
7 *and Deregulatory Actions*, Dkt. No. 2019-12557, 84 Fed. Reg. 29591 (June 24, 2019)⁴⁴; Regulatory
8 Info. Services Ctr., *Intro. to the Fall 2019 Regulatory Plan*, Dkt. No. 2019-26533, 84 Fed. Reg. 71085
9 (Dec. 26, 2019)⁴⁵. This Unified Agenda provides data on regulatory and deregulatory activities
10 under development or review throughout the federal government—e.g., advance notices of
11 proposed rulemaking, notices of proposed rulemaking, final rules, and long-term plans. *See*
12 OIRA, *About the Unified Agenda*.⁴⁶

13 124. If anything, it confirmed that Defendants had no plans to undertake any
14 regulatory action on menthol in cigarettes. *See id.* (identifying Defendants’ regulatory actions at
15 the pre-rule, proposed rule, and final rule stages of development and review). Indeed, HHS did
16 not even list menthol regulation on its list of “Long-Term Actions,” which identifies actions that
17 the agency intends to pursue but does not anticipate taking action on in the following year.

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22 ⁴³ Available at [https://www.federalregister.gov/documents/2019/12/26/2019-26539/regulatory-](https://www.federalregister.gov/documents/2019/12/26/2019-26539/regulatory-agenda)
23 [agenda](https://www.federalregister.gov/documents/2019/12/26/2019-26539/regulatory-agenda). *See also* HHS, Agency Rule List – Fall 2019. Available at
24 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=0900&csrf_token=AC9CA9308A92E9EACBFB612B667086E9017C80260FDDB0D9364F9F5F2137B6554EA1929687D28B0AFFBE211B4AB531B5D1F4,

25 ⁴⁴ Available at [https://www.federalregister.gov/documents/2019/06/24/2019-](https://www.federalregister.gov/documents/2019/06/24/2019-12557/introduction-to-the-unified-agenda-of-federal-regulatory-and-deregulatory-actions)
26 [12557/introduction-to-the-unified-agenda-of-federal-regulatory-and-deregulatory-actions](https://www.federalregister.gov/documents/2019/06/24/2019-12557/introduction-to-the-unified-agenda-of-federal-regulatory-and-deregulatory-actions).

27 ⁴⁵ Available at [https://www.federalregister.gov/documents/2019/12/26/2019-](https://www.federalregister.gov/documents/2019/12/26/2019-26533/introduction-to-the-fall-2019-regulatory-plan)
28 [26533/introduction-to-the-fall-2019-regulatory-plan](https://www.federalregister.gov/documents/2019/12/26/2019-26533/introduction-to-the-fall-2019-regulatory-plan).

⁴⁶ Available at https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp.

1 OIRA Long Term Actions, Agency Rule List – Spring 2019, HHS (identifying Defendants’ long-
2 term actions)⁴⁷, OIRA Long Term Actions, Agency Rule List – Fall 2019, HHS⁴⁸.

3 **II. Plaintiffs filed suit in 2020 to compel FDA to protect public health.**

4 125. By 2020, Defendants appeared to abandon any effort to regulate menthol in
5 cigarettes. And contrary to Defendants’ prior statements—e.g., to “communicate . . . what future
6 regulatory actions” the FDA might take with respect to menthol, to keep as a “top priority” the
7 protection of the public health from the harmful effects of tobacco use, and to “accelerate” the
8 rulemaking process with respect to menthol—it seemed that Defendants were content to keep
9 menthol cigarettes in the marketplace (thereby increasing the likelihood that youth would initiate
10 smoking), and to allow the public health crisis caused by menthol cigarettes to worsen.

11 126. To address Defendants’ inaction and these harms to public health, the Plaintiffs
12 African American Control Leadership Council and Action on Smoking and Health filed suit
13 against the Defendants on June 17, 2020. *See African American Tobacco Control Leadership Council et al.*
14 *v. U.S. Dep’t of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.) (“*Menthol*
15 *Lit. I*”). The American Medical Association and National Medical Association then later joined
16 as co-Plaintiffs.

17
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21 ⁴⁷ Available at

22 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201904&showStage=longterm&agencyCd=0900&Image58.x=66&Image58.y=13; *see generally* OIRA, About the Unified Agenda, available at
23 https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp (“[A]n agency may list in the
24 ‘Long-Term Actions’ section of its agenda those rules it expects will have the next regulatory
25 action more than 12 months after publication of the agenda.”).

26 ⁴⁸ Available at

27 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201910&showStage=longterm&agencyCd=0900&csrf_token=243A419EF187585EFFD83CD9CFA7CB8F1D8F1155635D087656DF62F1D717959D8C6B90FE425F27A717CEC962B0EECE3D5800.

A. Plaintiffs’ 2020 lawsuit seeks to compel the FDA’s formal determination on the issue of menthol.

127. The Plaintiffs’ 2020 complaint alleged three claims: (a) Defendants’ undue delay in determining whether menthol in cigarettes should be added to the list of banned characterizing flavors, a violation of the Administrative Procedure Act and Tobacco Control Act (Count I); (b) Defendants’ undue delay in formally responding to Plaintiffs’ 2013 Citizen Petition (Count II); and (c) in the alternative, Defendants’ arbitrary and capricious decision to keep menthol cigarettes in the market, in light of numerous scientific studies finding that banning menthol cigarettes would benefit the public health (Count III). *See Menthol Lit. I*, Compl. (ECF No. 1).

128. Defendants responded by quickly agreeing to provide a “final response” to Plaintiffs’ Citizen Petition—a concession that would effectively address Plaintiffs’ Citizen Petition claim (Count II). That final response was later provided on April 29, 2021.

129. At the same time, Defendants also moved to dismiss Plaintiffs’ Counts I and III. In essence, the parties disputed whether Section 387g(a)(5) of the Tobacco Control Act required the FDA to “determine” whether the Act’s tobacco product standards should be changed to reflect new data concerning menthol in cigarettes. Plaintiffs asserted that this Section required FDA to make a specific determination concerning whether menthol should be added to the flavor ban established by Section § 387g(a)(1). Defendants argued that the Act imposed no duty on the Defendants to revise the existing tobacco product standard or else adopt new ones, and only required “periodic evaluations”—a requirement that the FDA argued that it had satisfied by undertaking various preliminary evaluations of menthol cigarettes.

130. At oral argument, the Defendants went even further, suggesting that the FDA could make a never-ending series of “tentative” decisions on menthol, and put off making a final determination indefinitely.

131. This Court correctly addressed Defendants’ argument as “bizarre,” *Menthol Lit I*, Nov. 5, 2020 Hr’g Tr. at 19–20 (ECF No. 36; filed Nov. 13, 2020), and ultimately rejected it on several grounds: “Defendants argued that they are entitled to make ‘tentative decisions’

1 indefinitely, none of which would be reviewable. This argument appears to go to the merits, not
2 subject matter jurisdiction. Moreover, to the extent Defendants are essentially suggesting that
3 they are permitted to not make a final decision indefinitely, this could constitute a failure to act in
4 a reasonable amount of time.” Order Denying Defs.’ Mot. to Dismiss, at 8 (ECF No. 34; filed
5 Nov. 12, 2020).

6 132. This Court furthermore credited Plaintiffs’ position that the Tobacco Control Act
7 required the Defendants to “engage in an ongoing process, accounting for new information and
8 periodically evaluating the tobacco product standards – including the flavor ban – to determine if
9 the standard should be changed to reflect new data and protect the public health [consistent with
10 Section 378g(a)(5)].” *Id.* at 7. Given the Act’s structure and language, that duty extended to
11 Defendants “determination” as to whether menthol in cigarettes should be added to the flavor
12 ban.

13 133. As a result of this Court’s decision, Defendants then offered to include their
14 menthol determination within their substantive response to Plaintiffs’ Citizen Petition. Plaintiffs
15 accepted Defendants’ offer, supplemented their 2013 Citizen Petition (with updated scientific
16 data and signatories), and awaited Defendants’ response.

17 **B. Defendants HHS Secretary Becerra and FDA announce Defendants’**
18 **intention to ban menthol cigarettes.**

19 134. On April 29, 2021, the FDA provided their substantive Citizen Petition Response
20 and menthol determination. *See Menthol Lit. I*, 2d Jt. Mgmt. Attachment A (ECF No. 50-1; filed
21 May 18, 2021) (“the FDA Response”).

22 135. After considering the available scientific evidence, the FDA determined that
23 “eliminating menthol as a characterizing flavor in cigarettes would benefit public health and,
24 therefore, the Agency intends to issue a proposed rule to prohibit menthol as a characterizing
25
26
27
28

1 flavor in cigarettes.” *Id.* at 10. The FDA’s news release also announced the FDA’s intention to
 2 ban menthol cigarettes.⁴⁹

3 136. That same day, Defendant HHS Secretary Becerra appeared on MSNBC to
 4 explain why his agency was moving ahead to ban menthol cigarettes:

5 **Well, first, the case is closed on this one.** There is no doubt
 6 that smoking cigarettes kills Americans, that it causes great health
 7 concerns throughout the country, and costs taxpayers a ton of
 8 money. **And so, it’s time we move. Menthol which we**
 9 **know is an attractive additive that makes smoking more**
 10 **tolerable, is not only not good, but it seems to target**
 11 **principally communities of color.** The Black community,
 12 smokers in the Black community [are] predominantly smokers of
 13 menthol cigarettes. The health effects, consequences—grave. **And**
 14 **so, it’s time to act. The science is driving this. But again,**
 15 **the verdict is already in on what we have to do.**

16 HHS Secy. Becerra Backs Menthol Cigarette Ban: ‘The Case Is Closed on This
 17 One’ | MSNBC (Apr. 29, 2021) (emphasis added). *Available at*
 18 <https://www.youtube.com/watch?v=MStdhPEgbmM>.

19 137. Defendant HHS Secretary Becerra also spoke with theGrio’s April Ryan, to
 20 further explain why the Biden administration and Defendant HHS were moving at that time to
 21 ban menthol in cigarettes:

22 _____
 23 ⁴⁹ As further explained by Acting FDA Commissioner Janet Woodcock, M.D.: “**Banning**
 24 **menthol**—the last allowable flavor—in cigarettes and banning all flavors in cigars **will help**
 25 **save lives**, particularly among those disproportionately affected by these deadly products. With
 26 these actions, the FDA **will help significantly reduce youth initiation, increase the**
 27 **chances of smoking cessation among current smokers, and address health**
 28 **disparities experienced by communities of color, low-income populations, and**
LGBTQ+ individuals, all of whom are far more likely to use these tobacco products.” FDA,
FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers
 (Apr. 29, 2021). *Available at* <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

1 **President Joe Biden is saying,** I get four years, maybe eight
2 years, **I'm going to get it done. So, menthol in cigarettes,**
3 **yeah, it's time to get it out.** It makes sense, especially for the
4 Black community, April, I think you know that. **We want to save**
5 **lives in the Black community, [and] get menthol out of**
6 **cigarettes.**

7 ...

8 So, we're going to be driven by the science and the studies. Where
9 we go will depend on that. **What we do know is that the**
10 **science is in. And when you inject menthol into**
11 **cigarettes, you cause people to want to smoke them**
12 **more and you cause them to stay on the smoking habit**
13 **longer** because this menthol cloaks some of the harshness of the
14 cigarette, of the tobacco, and your brain feeds off of the menthol as
15 well. And so, we understand that because the science has shown it
16 to us. **It's time to move, because the consequences of**
17 **cigarettes, and menthol in cigarettes, is that more and**
18 **more people are continuing to smoke, can't get off it and**
19 **die.** And it costs the American health system a whole bunch of
20 money. **It's time to act. That's all it is. The facts are in.**
21 **The science has spoken.**

22 ...

23 [W]here we're going on tobacco is game changing. We're trying to
24 make sure that Americans know you can live a healthy life, and
25 you should know what you're putting into your system. No reason
26 to cloak it with menthol. You should know what you're doing to
27 your body when you smoke that cigarette. And **menthol hides**
28

1 **what you're doing to your body. It's time. The science is**
 2 **in.**

3 Secretary Becerra on Changing the Game of Menthol, theGrio (May 4, 2021)
 4 (emphasis added). Available at <https://www.youtube.com/watch?v=PybjNSxXlk>.

5 138. Unfortunately, neither of Defendant HHS Secretary Becerra's interviews or else
 6 FDA's formal response, determination, or news release, identified *when* the Defendants would
 7 be issuing the proposed rule. At most, the FDA's news release indicated the following aspirational
 8 goal: "The FDA is **working toward issuing proposed product standards within the**
 9 **next year** to ban menthol as a characterizing flavor in cigarettes[.]" FDA, *FDA Commits to*
 10 *Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021)
 11 (emphasis added).⁵⁰

12 **1. Defendants' history of undue delay and missed deadlines.**

13 139. Given Defendants' earlier pronouncements of "accelerate[d]" rulemaking
 14 followed by years of inaction and broken promises, Plaintiffs had their concerns. Such concerns
 15 were based in part, on the FDA's long history of undue delay and missed deadlines—all at the
 16 expense of public health.

17 140. In *Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 724 F. Supp.
 18 1013 (1989), for example, the court there found that the FDA's delay in promulgating a final rule
 19 standardizing tampon absorbency labeling reflected "an insensitivity to a long-existing and
 20 clearly identifiable problem [i.e., Toxic Shock Syndrome]. Its delay is particularly disturbing
 21 since the public health and human lives are at stake." *Id.* at 1022 (noting elsewhere that the FDA
 22 had "drag[ged] their feet" in promulgating this regulation, *id.* at 1021, and allowed women to
 23 "needlessly subject themselves to a risk of serious injury, and even death from Toxic Shock
 24 Syndrome," *id.* at 1019).⁵¹

25 _____
 26 ⁵⁰ Available at <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

27 ⁵¹ Noting the FDA's "history of delays and missed deadlines," the court found that a court-
 28 imposed schedule was necessary to protect the public health. *Id.* at 1020. Observing that

1 141. Other instances of the FDA’s pattern and practice of unlawful and undue delay
 2 abound: *See, e.g., Tummino v. Torti*, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009) (holding that the
 3 FDA’s repeated delays in issuing a decision concerning Plan B was suspect, and the likely result
 4 of improper political considerations)⁵²; *NRDC v. United States the FDA*, 884 F. Supp. 2d 108, 119
 5 (S.D.N.Y. 2012) (holding that the FDA’s 30+ years of inaction constituted undue delay, where
 6 the FDA failed to initiate and complete the withdrawal of certain antibiotics being used for non-
 7 therapeutic purposes in livestock); *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin.*, No. 1:16-cv-
 8 11985, 330 F. Supp. 3d 657, 667 (D. Mass. 2018), Mem. and Order Granting Inj. Relief, (Mar.
 9 5, 2019) (finding that the FDA had unreasonably delayed issuing the graphic warning label rule,
 10 and setting a deadline for the FDA to issue a final rule); *Am. Acad. of Pediatrics v. U.S. Food & Drug*
 11 *Admin*, No. 8:18-cv-883, 399 F. Supp. 3d 479, 487 (D. Md. Mar. 27, 2018) (holding that the
 12 FDA’s delay in reviewing new tobacco products was unreasonable, and imposing deadlines on
 13 the FDA’s review in light of the important public health interests at stake).

14 142. The FDA has also consistently missed its own goals for completing rulemaking—
 15 in many instances, even when Congress has set a deadline for the agency to act.

16
 17
 18 “Defendants’ justification for its continued delay in promulgating a regulation is lame at best and
 19 wholly irresponsible at worst,” the court found it appropriate to note the following: **“We have**
 20 **seen it happen time and time again, ... action ... for the protection of public health**
 21 **all too easily becomes hostage to bureaucratic recalcitrance, factional infighting,**
 22 **and special interest politics. At some point, we must lean forward from the bench**
 23 **to let an agency know, in no uncertain terms, that enough is enough.”** 724 F. Supp.
 at 1021 (emphasis added) (quoting *Public Citizen Health Research Group v. Brock*, 823 F.2d 626, 627
 (D.C. Cir. 1987)). As a result, the court there found that “good cause” existed to direct the FDA
 to promulgate its final regulation in approximately 60 days following the district court’s decision,
 and to make such rule effective at such time. *See id.* at 1022.

24 ⁵² **“These political considerations, delays, and implausible justifications for**
 25 **decision-making [by the FDA] are not the only evidence of a lack of good faith and**
 26 **reasoned agency decision-making.** Indeed, the record is clear that the FDA’s course of
 27 conduct regarding Plan B departed in significant ways from the agency’s normal procedures”
 28 *Tummino*, 603 F. Supp. 2d at 523 (emphasis added) (vacating the FDA’s denial of the Citizen
 Petition, and remanding to FDA for reconsideration where FDA failed to present “any evidence
 to rebut plaintiff’s showing that it [FDA] acted in bad faith and in response to political
 pressure.”).

1 143. In 2009, for example, the Tobacco Control Act directed the FDA to issue
2 regulations governing (a) non-face-to-face sale of tobacco products, with a statutory deadline of
3 18 months following the date of the Act’s enactment (on June 22, 2009), *see* 21 U.S.C.
4 § 387f(d)(4)(A)(i); (b) marketing and promotion of such products, with a statutory deadline of 24
5 months following the Act’s enactment, *see id.* § 387f(d)(4)(A)(ii); and (c) testing and reporting of
6 tobacco product constituents, ingredients, and additives, with a statutory deadline of 36 months
7 following the Act’s enactment, *see id.* § 387o(a). The FDA then proceeded to acknowledge these
8 deadlines and set various timelines for the completion of such rulemaking (as reflected in its
9 Unified Agenda and Regulatory Plan Agendas, *see* RIN 0910-AG43 and RIN 0910-AG59), but
10 in 2017, withdrew any planned regulatory action to address these directives from Congress.

11 144. Similarly, in 2013, the FDA proposed a rule for “Investigational Tobacco Product
12 Applications and General Information Regarding Submission of Information to Support Legal
13 Marketing” and set a goal for issuing a Notice of Proposed Rulemaking by August 2014. *See* Ofc.
14 of Info. And Reg. Affairs (“OIRA”), Unified Agenda and Reg. Plan Search Results (RIN 0910-
15 AH06) (last visited Mar. 4, 2024). The FDA then engaged in a protracted series of missed goals,
16 new goal-setting, a re-categorization of certain goals, more missed goals, and a repeated process
17 of more goal-setting followed by yet more missed goals. To date, no such rule is in place.

18 145. In short, even when Congress has set a specific statutory deadline, the FDA has
19 failed to rise to the challenge.

20 146. The FDA is furthermore slow to act, even when the public health is being
21 harmed. Menthol in cigarettes—the focus of this lawsuit and Plaintiffs’ earlier 2020 lawsuit—is a
22 prime example. FDA’s slow action on e-cigarettes is another example, as is the agency’s delayed
23 response to the opioid epidemic. *See* Megan Thielking, STAT, *FDA ‘should have acted sooner’ on e-*
24 *cigarettes, agency head tells Congress* (Sept. 25, 2019)⁵³; Andrew Kolodny, M.D., *How FDA Failures*
25 *Contributed to the Opioid Crisis*, AMA Journal of Ethics (Aug. 2020) (“In 2017, the President’s
26 Commission on Combatting Drug Addiction and the Opioid Crisis found that the opioid crisis was
27

28 ⁵³ Available at <https://www.statnews.com/2019/09/25/fda-e-cigarettes-congress/>.

1 caused in part by ‘inadequate oversight by the Food and Drug Administration’⁵⁴. Similarly, when
 2 a 2021 House of Representatives’ subcommittee report found that many popular infant foods
 3 were tainted with dangerous levels of arsenic, lead, cadmium, and mercury,⁵⁵ many wondered
 4 with good reason, “Where was the FDA?”

5 147. Indeed, shortly after FDA Commissioner Robert Califf’s appointment in 2022, he
 6 announced that the FDA’s food safety and tobacco regulatory divisions would be subject to an
 7 external review by the Reagan-Udall Foundation. Disturbingly, the Foundation’s review found
 8 that the FDA’s food division lacked clear leadership, avoided bold policy or enforcement actions,
 9 and fostered a culture that did not adequately protect the public health. The FDA’s tobacco
 10 division similarly “struggled to function as a regulator in part due to some of its own policy
 11 choices.” See Regan-Udall Foundation, *FDA Operational Evaluations of FDA’s Human Foods Program*
 12 *and FDA’s Tobacco Program* (2022).⁵⁶

13 **2. This Court directs Defendants to issue a rulemaking notice.**

14 148. Given Defendants’ track record, the Defendants’ unwillingness to set a specific
 15 date for issuing a Notice of Proposed Rulemaking to ban menthol cigarettes was disconcerting.
 16 Defendants, nonetheless, moved to dismiss Plaintiffs’ case as moot. Plaintiffs opposed.

17 149. After receiving briefing and arguments from the parties, this Court then issued an
 18 order holding Defendants’ second motion to dismiss in abeyance until May 2022, explaining its
 19 reasoning as follows:

20 The FDA has stated that it intends to issue a notice of rulemaking
 21 by April 2022, or in approximately five months. **If the FDA does**

22
 23 ⁵⁴ Available at <https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08>.

24 ⁵⁵ See U.S. House of Rep., Comm. on Oversight and Reform, Subcomm. on Econ. And
 25 Consumer Policy, *Staff Report: Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium,*
 26 *and Mercury* (Feb. 4, 2021). Available at
 27 <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

28 ⁵⁶ Available at <https://reaganudall.org/programs/operational-evaluation-fdas-human-foods-tobacco-programs>.

1 **not issue the Notice of Rulemaking, the Court may find**
 2 **that the delay is unreasonable** under the factors set forth in
 3 *Telecommunications Research and Action Center v. FCC* (“*TRAC*”) for
 4 determining unreasonable delay.

5
 6 The Court finds *In re a Community Voice* [878 F.3d 779 (9th Cir. 2017)]
 7 most instructive. There, [the Ninth Circuit recognized] ... that
 8 **delays of months or a few years is generally not an**
 9 **unreasonable delay unless there is something more, e.g.,**
 10 **a threat to human welfare. Such a threat could be found**
 11 **here, based on the significant threat to human health**
 12 **posed by menthol cigarettes.** Should the FDA not issue a notice
 13 of rulemaking in the year since granting Plaintiff’s citizen petition, a
 14 delay of more than one year could very well be unreasonable
 15 (particularly as that delay continues). Further, as Plaintiffs observe,
 16 **other *TRAC* factors could support a finding of undue**
 17 **delay, as the FDA has described a final rule banning**
 18 **menthol as “one of the Agency’s highest priorities.”**

19 *African Am. Tobacco Control Leadership Council v. United States HHS*, 571 F. Supp. 3d 1144, 1146 (N.D.
 20 Cal. 2021) (emphasis added).

21 **3. The Defendants comply with this Court’s strong suggestion**
 22 **and issue a Notice of Proposed Rulemaking.**

23 150. Following this Court’s order and strong suggestion, the Defendants issued a
 24 Notice of Rulemaking on May 4, 2022. *See* FDA Proposed Menthol Rule, 87 Fed. Reg. 26454.

25 151. This new proposed tobacco product standard—i.e., the “Menthol Rule”—would
 26 amend the Code of Federal Regulations to add a new part 1162 (to chapter I of title 21) and
 27 provide for the following:

28 § 1162.1 **Scope**

1 ...

2 (b) No person may manufacture, distribute, sell, or offer for
3 distribution or sale, within the United States a cigarette or any of
4 its components or parts that is not in compliance with this part.

5
6 § 1162.3 **Definitions**

7 ...

8
9 § 1162.5 **Prohibition on use of menthol as a**
10 **characterizing flavor in cigarettes.**

11 A cigarette or any of its components or parts (including the
12 tobacco, filter, wrapper, or paper, as applicable) shall not contain,
13 as a constituent (including a smoke constituent) or additive,
14 menthol that is a characterizing flavor of the tobacco product or
15 tobacco smoke.

16 *Id.* at 26501–02.

17 152. The Notice acknowledged that each year, roughly 480,000 people die
18 prematurely from a smoking-attributable disease, making tobacco use the leading cause of
19 preventable death and disease in the United States; that the Tobacco Control Act banned all
20 flavored cigarettes (except for tobacco and menthol) based on their appeal to youth; and that as a
21 result, the only cigarettes marketed with a characterizing flavor in the United States were
22 menthol cigarettes. *See id.* at 25455.

23 **i. The Defendants’ Notice identifies numerous benefits to**
24 **public health by finalizing the Menthol Rule.**

25 153. The Notice further acknowledged Plaintiffs’ initial lawsuit brought against the
26 Defendants, *Menthol Lit. I*; this Court’s Order directing the FDA to make a determination (i.e., as
27 to whether menthol should be banned as a characterizing flavor); as well as Defendants’
28 determination that menthol should be banned to protect the public health. *See id.* at 26460–61.

1 That determination was based in part on the many benefits that would flow from such a final
2 rule, including the following:

- 3 a. Reduced appeal of cigarettes, “particularly to youth and young adults, who are
4 more likely to try a menthol cigarette as their first cigarette than a non-menthol
5 cigarette”;
- 6 b. Decreased likelihood that “nonusers who would otherwise experiment with
7 menthol cigarettes would progress to regular smoking”—in other words, “a
8 significant reduction in the likelihood of youth and young adult initiation and
9 progression to regular cigarette smoking, which is expected to prevent future
10 cigarette-related disease and death”;
- 11 c. Improved health and reduced mortality risk of current menthol cigarette smokers
12 “by substantially decreasing cigarette consumption and increasing the likelihood
13 of cessation”;
- 14 d. Reduced smoking prevalence over the next 40 years by over 15%;
- 15 e. Avoiding 324,000 to 654,000 lives lost to smoking, including approximately
16 92,000 to 238,000 lives lost among African Americans;
- 17 f. A “substantial” decrease of tobacco-related health disparities;
- 18 g. The advancement of health equity;
- 19 h. Decreased illness and associated reductions in medical costs (both publicly and
20 privately funded);
- 21 i. Decreased productivity loss, and improved health-related quality of life for
22 menthol smokers and non-smokers;
- 23 j. Reductions in smoking-related fires, cigarette butt litter, and associated harms to
24 the environment; and
- 25 k. Diminished exposure to second-hand smoke among non-smokers; and
- 26 l. Decreased potential years of life lost, decreased disability, and an improved
27 quality of life among former smokers.

28 *Id.* at 25455, 26458, 26489.

1 154. The FDA further anticipated that removing menthol cigarettes from the market
2 would provide between \$102 billion and \$353 billion in annualized benefits (as measured over a
3 40-year time period)—an amount magnitudes larger than the rule’s anticipated costs. *See id.* at
4 26456.

5 155. The final rule would also apply only to “manufacturers, distributors, wholesalers,
6 importers, and retailers,” and would not be enforced against individual consumers for possession
7 or use of menthol cigarettes. *Id.* at 26456. And state and local law enforcement agencies would
8 not be authorized to enforce the new rule, much less the Tobacco Control Act. *See id.*

9 156. As a result, the FDA found (again) that the proposed tobacco product standard
10 would be appropriate for the protection of public health. *See id.* at 26455, 26458, 26461–62,
11 26469–85.

12 **ii. The Defendants’ proposed Menthol Rule is reviewed by**
13 **OIRA pursuant to Executive Order 12866.**

14 157. Finally, the FDA’s Notice provided that the proposed Menthol Rule qualified as
15 “an economically significant regulatory action as defined by E.O. 12866 [i.e., Executive Order
16 12866]. As such it has been reviewed by the Office of Information and Regulatory Affairs
17 [“OIRA”].” FDA Proposed Menthol Rule, 87 Fed. Reg. at 26489.

18 158. On information and belief, before the Defendants published their Notice of
19 Proposed Rulemaking on May 4, 2022—

- 20 a. the Defendants sent OIRA the proposed Menthol Rule;
- 21 b. OIRA “reviewed” the Menthol Rule pursuant to Executive Order 12866;
- 22 c. OIRA completed its review without any request to Defendants for further
23 consideration;
- 24 d. there were no disagreements or conflicts among the Defendants, other agency
25 heads, OMB, or OIRA that might necessitate a resolution by the Vice President
26 or President of the United States, pursuant to section 7 of the Executive Order;
- 27 e. the Vice President and President of the United States approved the above-
28 identified Menthol Rule; and

1 f. OIRA approved the above-identified Menthol Rule for Defendants’ inclusion and
2 publication in the Defendants’ May 2022 Notice of Proposed Rulemaking.

3 **4. Plaintiffs voluntary dismiss their lawsuit.**

4 159. Accordingly, based on the Defendants’ publication of the formal Menthol Rule,
5 OIRA’s review and approval of the Rule, as well as Defendants’ promise to make the enactment
6 of the final rule “one of the Agency’s highest priorities,” Plaintiffs voluntarily dismissed their
7 lawsuit on June 1, 2022.

8 **III. The Court’s intervention is once again required.**

9 160. But because Defendants have continued to delay the promulgation and
10 publication of a final rule, much less conclude the critical public health issue of menthol in
11 cigarettes, the Plaintiffs now bring this instant suit.

12 161. And because Defendants’ delay harms the public health and violates both the
13 Tobacco Control Act and Administrative Procedure Act, this Court’s help is once again
14 required.

15 **A. The Tobacco Control Act mandates the Defendants’ promulgation**
16 **and publication of a final rule.**

17 162. The Tobacco Control Act provides that “the Secretary shall ... promulgate a
18 regulation establishing a tobacco product standard and publish in the Federal Register findings
19 on the matters referred to in subsection (c) [i.e., 21 U.S.C. § 387g(c) (Proposed Standards)]” if
20 certain pre-conditions are met, *id.* § 387g(d)(1), namely:

- 21 a. the Secretary has published a Notice of Proposed Rulemaking in the Federal
22 Register and the comment period has closed, *see id.* § 387g(d)(1);
- 23 b. the Secretary has considered the comments submitted under subsections (b) and
24 (c) [21 U.S.C. § 387g(b), (c)], *see id.* § 387g(d)(1), in other words—
- 25 i. comments submitted in response to the Notice of Proposed Rulemaking,
26 *see id.* § 387g(c);
- 27 ii. comments concerning the “technical achievability of compliance with such
28 standard,” *id.* § 387g(b)(1);

1 iii. “all other information submitted in connection with a proposed standard,
2 including information concerning the countervailing effects of the tobacco
3 product standard on the health of adolescent tobacco users, adult tobacco
4 users, or nontobacco users, such as the creation of a significant demand for
5 contraband or other tobacco products that do not meet the requirements
6 of this subchapter and the significance of such demand,” *id.* § 387g(b)(2);

7 c. The Secretary has considered any report from the Tobacco Products Scientific
8 Advisory Committee, *id.*; and

9 d. The Secretary “determines that the standard would be appropriate for the
10 protection of public health,” *id.* § 387g(d)(1)(A).

11 **1. By January 4, 2023, each precondition to publishing and**
12 **promulgating the final Menthol Rule exists.**

13 163. Each precondition required by the Tobacco Control Act to finalize the Menthol
14 Rule exists here:

15 164. On May 4, 2022, the Defendants published a Notice of Rulemaking in the
16 Federal Register. *See* HHS /FDA, Proposed Menthol Rule.

17 165. On August 2, 2022, the comment period then closed. *See* FDA, *Comment Period*
18 *Closed for FDA Proposed Rules Prohibiting Menthol Cigarettes and Flavored Cigars* (Aug. 10, 2022).

19 166. On information and belief, Defendants have previously considered—

20 a. the 2011 Menthol Report, issued by their Tobacco Products Scientific Advisory
21 Committee, sometime in 2011 when that Report was initially released;

22 b. the comments submitted under subsections (b) and (c) (i.e., 21 U.S.C. § 387g(b),
23 (c)), as required by Subsection (d)(1), when the Defendants received such
24 comments as part of the fact-gathering process and review of the scientific
25 evidence conducted by the FDA’s Advisory Committee (2010–11), the FDA’s own
26 research (peer-reviewed and published in 2013), the FDA’s review of the Plaintiffs’
27 2013 Citizen Petition, and the FDA’s repeated calls for comments and scientific
28 data in 2013, 2018, and 2022.

1 167. By late-September 2022, the Defendants completed their review of comments
2 submitted during the May 2022 through August 2022 comment period. Because many of the
3 received comments were similar to those previously submitted to the Defendants in 2013 and
4 2018 as part of Defendants’ Advanced Notice of Proposed Rulemaking, the Defendants were
5 able to quickly complete their review. Around this same time, Defendant CTP Director King
6 also spoke at a panel presentation at the Third National Menthol Conference, in Washington
7 D.C., entitled “Where is the FDA on the Menthol Rule Making Process?”

8 168. On January 4, 2023, the Defendants and the White House then published their
9 Fall 2022 Unified Regulatory Agenda and Regulatory Plan. *See* White House, OMB, 2022
10 Unified Regulatory Agenda and Regulatory Plan (Jan. 4, 2022). That Agenda identified
11 “08/00/2023” as the date by when Defendants expected to promulgate and publish the final
12 Menthol Rule. Fall 2022 Agenda (identifying August 2023 as when a final rule would be
13 issued)⁵⁷; Spring 2023 Agenda (same)⁵⁸.

14 169. On information and belief, the decision by the White House’s Office of
15 Management and Budget (“OMB”) to set a date (i.e., “08/00/2023”) for the promulgation and
16 publication of a final Menthol Rule meant that the Defendants—including the Defendant HHS
17 Secretary—had necessarily determined that the proposed Menthol Rule was appropriate for the
18 protection of public health.

19 170. Accordingly, by January 4, 2023 (if not earlier), each necessary element to
20 promulgating and publishing the Menthol Rule existed. And as Defendants May 2022 Notice
21 acknowledged, the draft Menthol Rule had already been reviewed by the Office of Information
22 and Regulatory Affairs (“OIRA”) pursuant to Executive Order 12866.

25 ⁵⁷ Available at
<https://web.archive.org/web/20230201022111/https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0910-AI60>.

27 ⁵⁸ Available at
<https://web.archive.org/web/20230922194307/https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI60>.

1 171. On January 31, 2023, however, Defendant CTP Director King issued a slightly
 2 more ambiguous timeline for the Defendants’ finalization of the Menthol Rule. Acknowledging
 3 the Defendants’ recent publication of the Fall 2022 Unified Agenda (which had included the
 4 same “08/00/2023” date for the promulgation of a finalized Menthol Rule), Defendant CTP
 5 Director King noted that Defendants were “currently drafting the final rules and are committed
 6 to completing the rulemaking process in 2023. These product standards remain a top priority for
 7 FDA, and we will continue to provide updates on the status of these rules as they become
 8 available.” Brian King, Dir. of FDA’s Center for Tobacco Products, *Looking Back, Looking Ahead:
 9 FDA’s Progress on Tobacco Product Regulation in 2022* (Jan. 31, 2023).⁵⁹

10 172. Defendant CTP Director King went on to note that when finalized, “these
 11 product standards are expected to significantly reduce initiation and increase cessation. These
 12 proposed rules will also help address longstanding health disparities related to menthol cigarettes
 13 and flavored cigars, including among African Americans, who use these products at higher rates
 14 than other racial and ethnic groups.” *Id.*

15 173. Finally, on February 22, 2023, the Defendants’ Fall 2022 Regulatory Agenda was
 16 published in the Federal Register. *See* Reg. Info. Service Center, *Introduction to the Unified Agenda of
 17 Federal Regulatory and Deregulatory Actions – Fall 2022*, 88 Fed. Reg. 10966 (Feb. 22, 2023),
 18 [https://www.federalregister.gov/documents/2023/02/22/2023-02113/introduction-to-the-
 19 unified-agenda-of-federal-regulatory-and-deregulatory-actions-fall-2022](https://www.federalregister.gov/documents/2023/02/22/2023-02113/introduction-to-the-unified-agenda-of-federal-regulatory-and-deregulatory-actions-fall-2022).

20 174. As before, the Defendants identified “08/00/23” as the date by which a Final
 21 Rule would be promulgated and published. *Id.* at 11036. The Defendants also noted that the
 22 finalization of Menthol Rule would—

- 23 • “significantly reduce disease and death from combusted tobacco product use, the
 24 leading cause of preventable death in the United States”;

25
 26
 27
 28
⁵⁹ Available at [https://www.fda.gov/tobacco-products/ctp-newsroom/looking-back-looking-ahead-fdas-progress-tobacco-product-regulation-2022#:~:text=In%20April%202022%2C%20FDA%20announced,than%20tobacco%20flavor\)%20in%20cigars](https://www.fda.gov/tobacco-products/ctp-newsroom/looking-back-looking-ahead-fdas-progress-tobacco-product-regulation-2022#:~:text=In%20April%202022%2C%20FDA%20announced,than%20tobacco%20flavor)%20in%20cigars).

- 1 • “promote better health outcomes across population groups”; and
- 2 • “benefit the population as a whole, ... [and] substantially decrease tobacco-
- 3 related health disparities”;
- 4 • “reduce the appeal of cigarettes, particularly to youth and young adults, and
- 5 thereby decrease the likelihood that nonusers who would otherwise experiment
- 6 with menthol cigarettes would progress to regular cigarette smoking”;
- 7 • “improve the health and reduce the mortality risk of current menthol cigarette
- 8 smokers by decreasing cigarette consumption and increasing the likelihood among
- 9 current menthol cigarette smokers ... of cessation”; and
- 10 • “reduce[] illness for smokers and non-smokers.”

11 *Id.* at 11023, 11036.

12 175. The Defendants further acknowledged that the “[e]vidence shows that tobacco is

13 disproportionately marketed to underserved communities and vulnerable populations—such as

14 disproportionate storefront and outdoor marketing, as well as point-of-sale marketing, in Black,

15 Hispanic, and low-income communities. The disparities in tobacco marketing and use shape

16 disparities in tobacco-related disease and death.” *Id.* at 11036.

17 **2. Defendants’ improperly allow politics to prevent the**

18 **promulgation and publication of the Menthol Rule.**

19 176. By August 2023, however, the Defendants had failed to publish, much less

20 explain, why a final Menthol Rule had yet to be promulgated or published.

21 177. Following that missed deadline, Defendants CTP Director King publicly

22 suggested that the Defendants had intended all along to publish the final Menthol Rule by

23 December 2023.

24 178. But by early December 2023, the Defendants had issued a new Fall 2023

25 Regulatory Agenda and moved the goal posts (yet again)—this time setting “Final Rule”

26 promulgation date of March 2024.

27 179. White House officials “later signaled to public health groups that they hoped to

28 finish them by January [2024],” but at the same time, four officials with knowledge of “internal

1 White House deliberations” anonymously relayed that the finalization of a menthol ban would
2 possibly be subject to further delays because of considerations related to the upcoming election.
3 *See* Dan Diamond and David Ovalle, *Biden ban on menthol cigarettes to be delayed amid political concerns,*
4 *officials say*, The Washington Post (Dec. 5, 2023). According to these officials, the Biden
5 administration would delay the ban on menthol cigarettes to avoid angering some Black smokers
6 who might hurt President Biden’s reelection prospects. *See id.*

7 180. In other words, even though the Defendants (including the Defendant HHS
8 Secretary) had already determined that the Menthol Rule was appropriate for the protection of
9 public health, (a) President Biden, the Vice President, OMB, OIRA or other White House
10 officials asked, directed, communicated to, or else pressured the Defendants to improperly,
11 arbitrarily, and capriciously delay the promulgation and publication of the Menthol Rule in
12 order to improve President Biden’s chances of winning re-election in November 2024; and (b) the
13 Defendants improperly, arbitrarily, capriciously, and unlawfully acceded to that request and
14 political pressure. (That same pressure on Defendants continues with respect to Vice President
15 Harris’ chances of winning the November 2024 presidential election.⁶⁰)

16 181. As a result, the Defendants missed their December 2023 internal deadline, as well
17 as their January 2024 internal deadline.

18 182. By February 2024, Defendant FDA Commissioner Robert Califf had reportedly
19 spoken to White House aides and had taken the unusual step of asking personal and professional
20 contacts to press the White House regarding the advancement of the menthol ban. Regarding
21 the current context of FDA policymaking, Califf said “In the last year of this administration, so
22 many things happen with a lot of pressure to get things finished, and sometimes **political**
23 **pressure comes into play.**” Adam Cancryn and David Lim, *A top official fears Biden might let*
24 *politics interfere with public health*, Politico (Feb. 15, 2024) (emphasis added).⁶¹

25 ⁶⁰ Lia DeGroot, *Presidential contenders stay mum, for now, on menthol ban*, Roll Call (Sept. 12, 2024),
26 available at <https://rollcall.com/2024/09/12/presidential-contenders-stay-mum-for-now-on-menthol-ban/>.

27 ⁶¹ Available at <https://www.politico.com/news/2024/02/15/robert-califf-fda-chief-biden-menthol-cigarette-ban-00141549>.

B. Plaintiffs’ filed this lawsuit to address Defendants’ ongoing delay.

183. To address the Defendants’ ongoing delay, the Plaintiffs AATCLC, ASH, and NMA filed this instant lawsuit on April 4, 2024. *See* Compl. ECF No. 1.

184. Shortly thereafter, former CTP Director Mitch Zeller observed that “at this point, **the only holdup could be the politics.**” Lauren Clason, *Decades of dallying led to current delay on menthol ban* (Apr. 24, 2024) (emphasis added) (noting further that when “[former FDA Commissioner Scott] Gottlieb resigned in 2019 [that] was the end of FDA advancing menthol nicotine reduction,” Zeller said. ‘I was told by political appointees at FDA to stop talking about menthol and nicotine publicly in my speeches.’”).

1. Defendant HHS Secretary Becerra’s stated reasons for the delay.

185. On April 26, 2024, the American Medical Association then joined as a co-Plaintiff, and that same afternoon, Defendant HHS Secretary Becerra issued a statement on the status of the proposed Menthol Rule:

This rule has garnered historic attention and the public comment period has yielded an immense amount of feedback, including from various elements of the civil rights and criminal justice movement.

It’s clear that there are still more conversations to have, and that will take significantly more time.⁶²

186. Notably, no indication was given as to when a final rule might be issued. But according to an unnamed senior administration official, more time was needed “to hear from outside groups, especially on the civil rights side.”⁶³

⁶² Available at <https://www.hhs.gov/about/news/2024/04/26/secretary-becerra-statement-proposed-menthol-cigarette-rule.html#:~:text=HHS%20Press%20Office-,Secretary%20Becerra%20Statement%20on%20the%20Proposed%20Menthol%20Cigarette%20Rule,rights%20and%20criminal%20justice%20movement..>

⁶³ Alexander Tin, CBS News, *Menthol Cigarette Ban Delayed Due To “Immense” Feedback, Biden Administration Says* (Apr. 26, 2024), <https://www.cbsnews.com/news/menthol-cigarette-ban-delay-fda-feedback-biden-administration/>.

1 **2. Defendants’ reasons for the delay are pretextual.**

2 187. That reason for Defendants’ delay, however, appears to be a pretext. Per the Wall
3 Street Journal, **“Political considerations have swayed the Biden administration’s**
4 **thinking on this public-health issue**, said Mitch Zeller, who served as director of the FDA’s
5 Center for Tobacco Products until 2022. **‘The science is clear that there will be a**
6 **massive health benefit from removing menthol cigarettes,**’ he said.” Jennifer Maloney
7 et al., *Biden Administration Shelves Plan to Ban Menthol Cigarettes*, Wall Street Journal (Apr. 26, 2024)
8 (emphasis added).

9 188. Indeed, following Defendant Secretary Becerra’s April 26, 2024 announcement,
10 the Defendants completed only five additional meetings—i.e., with an unaffiliated individual,
11 Michael O’Conner; the Indiana Wholesale Distributors Association; the Indiana Grocery and
12 Convenience Store Association; the Florida Retail Federation; and the New Jersey Gasoline,
13 Convenience, Automotive Association. *See* Exec. Order 12866 Meetings Search Results (last
14 visited Sept. 16, 2024) (applying search criteria RIN 0910-AI60), *available at*
15 <https://www.reginfo.gov/public/do/eom12866SearchResults>.

16 189. None of those five meetings appeared to be with a civil rights or criminal justice
17 group. *See id.* The last meeting was held on May 15, 2024—over four months ago—and no other
18 meetings are currently scheduled.

19 190. In sum, the Defendants’ stated reasons for delaying the final Menthol Rule have
20 been a pretext, and politics have improperly prevailed over public health.

21 **C. Defendants’ ongoing delay is harming Plaintiffs and the public**
22 **health.**

23 191. At bottom, the Defendants’ mission is to “promote the public health by promptly
24 and efficiently reviewing clinical research and taking appropriate action on the marketing of
25 regulated products in a timely manner,” 21 U.S.C. § 393(b)(1). This mission extends to
26 “regulating the manufacturing, marketing, and distribution of tobacco products to protect the
27 public health and reduce tobacco use by minors,” FDA, *What We Do* (last updated Nov. 21,
28

2023),⁶⁴ as well as “[p]rotecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products,” FDA, *Reg. Procedures Manual*, Intro., at 3 (Aug. 2018).⁶⁵

192. But because of Defendants’ inaction, tobacco companies have predictably continued to use menthol cigarettes to target youth, women, and the Black community⁶⁶—all to the detriment of Plaintiffs and the public health.

193. Given Defendants’ unjustified refusal to act on this issue without prompting from this Court, the Plaintiffs respectfully request this Court’s intervention yet again.

1. Plaintiffs have suffered—and will likely continue to suffer—an imminent concrete injury from the Defendants’ delay.

194. Each Plaintiff has suffered a concrete injury from Defendants’ inaction, and is likely to suffer an imminent, concrete injury from Defendants’ inaction. Plaintiffs’ injuries (and imminent injuries) are fairly traceable to Defendants’ inaction, and the predictable actions of the tobacco companies advertising, marketing, and promotion of menthol cigarettes to them. A favorable decision from this Court—e.g., directing Defendants to promulgate and publish the Menthol Rule—will likely redress Plaintiffs’ injuries.

⁶⁴ Available at <https://www.fda.gov/about-fda/what-we-do>.

⁶⁵ Available at <https://www.fda.gov/media/71923/download>. The Regulatory Procedures Manual “is a reference manual that provides internal procedures and related information to be used by FDA employees who process certain regulatory and enforcement matters in support of the agency’s public health mission.” FDA Reg. Procedures Manual at 1. This Manual further identifies some of the FDA’s values, including the following: “We demonstrate our commitment to safeguarding the public health in our actions.” *Id.* at 3.

⁶⁶ See Robert K. Jackler et al., *Advertising Created & Continues to Drive the Menthol Tobacco Market: Methods Used by The Industry to Target Youth, Women, & Black Americans* (Oct. 3, 2022). Accessible at <https://tobacco-img.stanford.edu/wp-content/uploads/2022/10/02234723/SRITA-AHA-MentholAdvertising.pdf>.

i. Individual Plaintiffs have a personal and concrete interest in protecting their own health.

195. As detailed further below, each individual Plaintiff retains a personal and concrete interest in protecting their health. Each individual Plaintiff is an African American adult addicted to menthol cigarettes, or else formerly addicted to menthol cigarettes.

196. Each individual Plaintiff—and the African American community to which they belong—was targeted, and continues to be targeted today, by the tobacco companies that manufacture, sell, distribute, advertise, market, and promote menthol cigarettes.

197. And each individual Plaintiff furthermore suffers from the health effects of their addiction to menthol cigarettes, even years after breaking their addiction.

(a) Plaintiff Lisa Mitchell

198. Plaintiff Lisa Mitchell is an African American resident of Madison, Wisconsin, and a daily menthol cigarette smoker. Ms. Mitchell began smoking menthol cigarettes when she was 10 years old, in part because she thought it was cool. Indeed, her first menthol cigarette was a Kool menthol cigarette. Growing up—first in Chicago, Illinois and then later in Madison, Wisconsin—nearly everyone in her community of family and friends smoked menthol cigarettes, including her mother, her mother’s eight sisters, her uncles, two brothers, and two younger sisters.

199. Plaintiff Mitchell’s extended family, like Plaintiff Mitchell, is African American and lives in Madison, Wisconsin. Ms. Mitchell regularly spends time with her family, and has plans to continue seeing, talking with, and enjoying the shared company of her family on a regular basis.

200. For as long as Plaintiff Mitchell can remember, her mother Emma Mims smoked menthol cigarettes. Her mother was so addicted to menthol cigarettes that on at least one occasion, when money and food was scarce in their home, Ms. Mitchell’s mother would go out into the street in her wheelchair, to beg for money that she could use to buy menthol cigarettes.

201. During her lifetime, Ms. Mitchell’s mother suffered from clogged arteries in her legs, that her doctors identified as having been caused by Ms. Mims’ addiction to menthol

1 cigarettes. Ms. Mims tried to end her addiction to menthol cigarettes, but failed. Eventually, the
2 arteries in Ms. Mims’ legs became so clogged that her doctors were forced to amputate one of her
3 legs. Because the symptoms related to Ms. Mims’ menthol cigarette addiction required constant
4 care, Plaintiff Mitchell took care of her mother during the last five years of her life.

5 202. At all relevant times, the Defendants have known that smoking cigarettes can clog
6 arteries, causing pain, decreasing circulation, and leaving no other option but amputation.

7 203. Ms. Mims was unfortunately unable to break her addiction to menthol cigarettes
8 until the day she died in 2018.

9 204. Notably, Defendants already knew at this time and at all relevant times that—

10 a. removing menthol cigarettes from the market would improve the public health,

11 b. the tobacco companies—which Defendants directly regulate—were engaged in
12 the following:

13 i. targeting the Black community and smokers like Ms. Mims, e.g., through
14 advertising, marketing, and promotional discounts and rebates, and

15 ii. manipulating the levels of menthol in cigarettes to maintain smokers’
16 addiction, and that

17 c. a menthol ban would motivate many menthol cigarette smokers to quit, *see, e.g.,*
18 Jennifer Pearson et al., *A Ban on Menthol Cigarettes: Impact on Public Opinion and*
19 *Smokers’ Intention to Quit*, Am. J. Public Health 102(11): e107–e144 (Nov. 2012).

20 205. Plaintiff Mitchell also lost her older brother Timothy Mims to menthol cigarettes.
21 For as long as Ms. Mitchell can remember, her brother smoked Newport menthol cigarettes.

22 206. During his lifetime, Mr. Mims developed diabetes—a condition caused by
23 smoking cigarettes. Mr. Mims’ doctors informed Mr. Mims repeatedly that his menthol cigarette
24 addiction would only make his diabetes worse, and that he needed to stop smoking menthol
25 cigarettes. And yet, Mr. Mims was unable to break his menthol cigarette addiction until his death
26 in 2023. At the time of his death, Mr. Mims was just 51 years old.

1 207. At all relevant times, the Defendants have known that cigarette smoking is a cause
2 of diabetes, that smoking makes managing diabetes more difficult, and that an estimated 9,000
3 people in the United States “die each year from diabetes caused by cigarette smoking.”

4 208. Plaintiff Mitchell also lost her younger sister Barbara Mims to menthol cigarettes.
5 Ms. Barbara Mims was an African American resident of Madison, Wisconsin. For decades, Ms.
6 Barbara Mims smoked menthol cigarettes. During her lifetime, she developed and suffered from
7 diabetes, fell into a coma—during which time her organs shut down and she was placed on life
8 support—and then died at the age of 39.

9 209. At all relevant times, Plaintiff Mitchell was close to her sister Ms. Barbara Mims,
10 would regularly enjoy her company, conversation, and shared history together. Plaintiff Mitchell
11 is also close to Ms. Barbara Mims’ children who also live in Madison, Wisconsin, one of whom
12 she sees regularly and who smokes menthol cigarettes. Because Plaintiff Mitchell is concerned for
13 her niece’s health, Plaintiff Mitchell has encouraged her to quit, but to no avail.

14 210. Plaintiff Mitchell’s remaining sister, Tawanda Mims, is also a menthol cigarette
15 smoker. Ms. Tawanda Mims has smoked menthol cigarettes for decades and has recently
16 suffered two strokes. For years, Ms. Tawanda Mims’ doctors have pushed her to stop smoking
17 menthol cigarettes, but Ms. Tawanda Mims has been unable to break her addiction. Today, Ms.
18 Tawanda Mims resides in an assisted care facility, and has continued smoking menthol cigarettes,
19 despite the warnings from her doctors. Plaintiff Mitchell enjoys her sister’s company,
20 conversation, and shared history together, and plans to regularly see her sister in the future.

21 211. At all relevant times, the Defendants have known that smoking cigarettes can
22 cause “many types of cancer as well as heart disease, stroke, lung disease, type two diabetes, and
23 other health problems.” FDA, Minority Health and Health Equity Resources, Tobacco Use (last
24 visited Sept. 7, 2024). Defendants have also known that tobacco products like menthol cigarettes
25 “are often marketed toward racial and ethnic minority communities, which tend to have a higher
26 density of tobacco retailers” *Id.* In addition, Defendants have known that “African Americans
27 who smoke are less successful at quitting ... and are more likely to die from a smoking-related
28 disease.” *Id.*

1 212. Despite her loss and grief to losing her family members to menthol cigarettes—as
2 well as her ongoing concerns for her family members who still smoke menthol cigarettes today—
3 Plaintiff Mitchell remains addicted to menthol cigarettes, typically smoking over half a pack of
4 menthol cigarettes each day.

5 213. Plaintiff Mitchell has attempted to break her menthol cigarette addiction several
6 times. Most recently, Plaintiff Mitchell encountered a smoker in her residential building earlier
7 this year that was smoking a cigarette through a surgically created hole in his neck (i.e., a stoma).
8 Seeing him smoke a cigarette through his neck frightened Plaintiff Mitchell into trying to quit
9 once again. But as before, she was unsuccessful at breaking her menthol cigarette addiction.

10 214. Growing up, Ms. Mitchell remembers the tobacco companies' efforts to target the
11 Black community with menthol cigarettes. These advertising, marketing, and promotional efforts
12 by the manufacturers of Kool and Newport menthol cigarettes, included water bottles, fanny
13 packs, billboards, promotions, discounts in the form of coupons, and direct mailings.

14 215. These targeted efforts by menthol cigarette manufacturers continue to this day in
15 the form of direct mailings, promotions, coupons, and discounts for menthol cigarettes, both
16 online and in Plaintiff Mitchell's community and local convenience store that sells, advertises,
17 markets, and promotes menthol cigarettes in partnership with the tobacco menthol cigarette
18 manufacturers.

19 216. Plaintiff Mitchell's addiction to menthol cigarettes has caused a variety of health
20 problems to her over the years. These health problems include a degenerating spinal disc, trouble
21 breathing, and tightness and pressure (i.e., possibly clogged arteries) in her legs. And because
22 Plaintiff Mitchell is a trans woman taking estrogen hormone therapy, her addiction to menthol
23 cigarettes significantly increases her risk of suffering blood clots, strokes, and heart attacks.

24 217. Nonetheless, when President Biden and the Defendants announced that they
25 would be banning menthol cigarettes from the market, Plaintiff Mitchell had hope that she might
26 then be able to break her addiction. And if Defendants were to finalize the Menthol Rule
27 (effectively ending the manufacture, sale, and distribution of menthol cigarettes), Plaintiff
28

1 Mitchell believes she would have a substantially increased likelihood of being able to quit. In her
2 own words, she would have “hope”—not only for herself, but also for others in her family.

3 **(b) Plaintiff Daryl Thomas**

4 218. Plaintiff Daryl Thomas is an African American resident of Pasadena California
5 and a daily menthol cigarette smoker.

6 219. Plaintiff Thomas began smoking menthol cigarettes in elementary school and has
7 been addicted to menthol cigarettes now for over 50 years.

8 220. Growing up, many members of Plaintiff Thomas’ family smoked menthol
9 cigarettes, including his father, three brothers, and sister. In addition, many if not most of
10 Plaintiff Thomas’ friends also grew up smoking menthol cigarettes. All of Plaintiffs’ described
11 family members and friends are African American.

12 221. In 1990s, Plaintiffs’ father began suffering from health issues caused by his
13 addiction to menthol cigarettes. Plaintiff’s father was later diagnosed with throat cancer, and
14 underwent an operation on his neck. After that surgery, however, Plaintiff Thomas’ father was
15 never quite the same—his father could no longer swallow oatmeal or toast, and eventually, in
16 1996, he passed away.

17 222. Over time, Plaintiff Thomas’ friends also began suffering from health problems
18 caused by their addiction to menthol cigarettes. And eventually, several of Plaintiff Thomas’
19 friends died from their addiction—one from pancreatic cancer, another from lung cancer, and
20 yet another friend from throat cancer. Plaintiff Thomas himself also developed lung disease,
21 trouble breathing, and a persistent cough.

22 223. Concerned with his own health (as well as his family members’) and seeing his
23 father and friends suffer as they did, Plaintiff Thomas sought to try and break his own addiction
24 to menthol cigarettes. Plaintiff was successful once, but later relapsed. Numerous other attempts
25 at quitting were unsuccessful.

26 224. At all relevant times, the Defendants have known that cigarette smoking is a
27 leading cause of pancreatic cancer, lung cancer, throat cancer, lung disease, trouble breathing
28

1 and a persistent cough; and that menthol cigarette smokers are more likely to relapse into their
2 addiction.

3 225. Today, Plaintiff Thomas has 11 children, 20 grandchildren, and 10 great-
4 grandchildren that range in age from 1 to 13 years old. Plaintiff Thomas is close to, and spends
5 regular time, with his family. Many of Plaintiff Thomas' family members live nearby in Southern
6 California or else in Las Vegas, Nevada. And Plaintiff Thomas makes regular plans to see and
7 enjoy the company of his family for the weekends, during the week, and for holidays, birthdays,
8 and other life events, both large and small.

9 226. Plaintiff Thomas has other family members that continue to smoke, and are
10 addicted to, menthol cigarettes. Plaintiff Thomas is furthermore concerned for such family
11 members' health. And similarly, Plaintiff Thomas is concerned for the health of his great-
12 grandchildren, and does not want them to become addicted to menthol cigarettes.

13 227. If a menthol ban were to go into effect, Plaintiff Thomas might be encouraged to
14 try and break his menthol cigarette addiction once again. Plaintiff Thomas believes that menthol
15 cigarettes are killing people. He further believes that menthol cigarettes should be removed from
16 the market, and are hurting people's health, including his own, and should be stopped.

17 **(c) Plaintiff Lila June**

18 228. Plaintiff Lila June is an African American resident of Brooklyn, New York, and a
19 regular, if not daily, menthol cigarette smoker.

20 229. Plaintiff June began smoking menthol cigarettes when she was in her late 20s,
21 stopped smoking when she became pregnant with her first child, and relapsed into her menthol
22 cigarette addiction at the age of 40.

23 230. Today, Plaintiff June and her husband Kelvin June's family includes seven adult
24 children and 10 grandchildren. Her oldest grandchild is 16 years old, and her youngest is in
25 utero (due October 16, 2024).

26 231. Plaintiff June's three youngest children—one of whom is pregnant and carrying
27 Plaintiff June's youngest grandchild—live with Plaintiff June and her husband. Plaintiff June's
28 older children live nearby in the New York tri-state area.

1 239. Growing up in New Jersey, Plaintiff Ullie lived in an urban neighborhood that
2 was predominately African American. Much of the advertising for menthol cigarette was aimed
3 at the Black community. These advertisements and promotions (e.g., coupons and discounts)
4 often appeared at grocery stores, convenience stores, and on the street. The marketing was so
5 prevalent and effective—with so many adults in Plaintiff Ullie’s community smoking—that
6 menthol cigarettes simply looked cool and calming. Smoking and buying menthol cigarettes
7 seemed hardly any different than buying bread or milk at the store, and the health risks seemed
8 almost no different.

9 240. Perhaps unsurprisingly then, as the years passed, Plaintiff Ullie also saw many of
10 his family members struggle with and suffer from their addiction to menthol cigarettes. For
11 example, Plaintiff Ullie’s father Maurice Lashelle Thomas struggled to break his addiction to
12 menthol cigarettes after decades of smoking. Similarly, Plaintiff Ullie’s uncle Reginald Thomas—
13 a daily menthol cigarette smoker for decades—later developed diabetes and suffered a smoking-
14 related stroke.

15 241. Plaintiff Ullie’s aunt began smoking menthol cigarettes in her 20s (Newport 100s),
16 before suffering severe respiratory issues that made moving around difficult. By that point, she
17 had been smoking for roughly 30 years. She was only able to break her addiction to care for her
18 ailing mother. Unfortunately, however, her body still suffered from the harms caused by her
19 menthol cigarette addiction. This past December, for example, Plaintiff’s aunt—in an effort to
20 treat her cardiovascular issues—underwent open heart surgery. Her respiratory problems then
21 soon returned, making it difficult for her to breathe and walk. More recently, Plaintiff Ullie’s aunt
22 contracted bronchitis, and suffered through extended and painful bouts of coughing.

23 242. Today, Plaintiff Ullie is most concerned for his younger sister, who continues to
24 smoke menthol cigarettes despite suffering from cystic fibrosis. Plaintiff’s sister has two young
25 boys (ages 10 and 16) that live with her, who are growing up in the same urban environment that
26 Plaintiff Ullie did, and who are regularly exposed to their mother’s menthol cigarette addiction
27 and second-hand smoke.
28

1 243. Plaintiff Ullie cares deeply for the health and well-being of his two young
2 nephews. He wants to protect his nephews from becoming addicted to menthol cigarettes, like so
3 many of their shared family members (e.g., Plaintiff Ullie’s father, uncle, aunt, cousin, and
4 younger siblings). Similarly, Plaintiff wants to protect his nephews from his sister’s menthol
5 cigarette addiction. Plaintiff is committed to being an involved uncle and father-figure to his
6 sister’s children—e.g., by doling out life advice (both asked for, and unsolicited), listening
7 thoughtfully to his nephew’s concerns and questions, keeping tabs on how his nephews are doing
8 and growing into becoming young Black men, visiting whenever Plaintiff Ullie can, and taking
9 care of his nephews when they visit him. Indeed, Plaintiff’s nephews were the impetus for Plaintiff
10 Ullie’s sobriety, and Plaintiff never smokes in their presence.

11 244. Plaintiff Ullie—who does not have children of his own—has gone so far as to ask
12 his sister to stop smoking around her children. Plaintiff’s sister, however, has ignored his pleas,
13 which has been challenging for Plaintiff Ullie and a source of tension with his sister. That said,
14 Plaintiff remains close to his sister, close to his extended family, and wants to continue being a
15 strong and present adult, male figure for his nephews.

16 245. For Plaintiff Ullie, his menthol cigarette addiction began in his early 20s. At the
17 time, he considered his smoking habit to be a social one, something fun to do when going out,
18 and a habit that he could easily stop. Over time, however, Plaintiff Ullie realized that he had
19 become addicted to menthol cigarettes.

20 246. In 2009, Plaintiff Ullie moved to Los Angeles, and a few years later, was able to
21 quit drinking and using recreational drugs. Despite several attempts to quit his menthol cigarette
22 addiction, however, Plaintiff Ullie has remained unsuccessful. His addiction has turned into a
23 crutch for him to relax, to start work, to feel open, and to fall asleep. In other words, Plaintiff’s
24 menthol cigarette addiction has deeply and negatively impacted his mental health, and depressed
25 his energy. Plaintiff is concerned that his health will continue to suffer even more so, unless he is
26 able to quit.

27 247. Accordingly, Plaintiff Ullie would appreciate the opportunity to break his menthol
28 cigarette addiction. And if the Defendants promulgated a final Menthol Rule, Plaintiff Ullie

1 would be encouraged to break his cigarette addiction, and to live a healthier life. Plaintiff wants
2 to remain present in his nephews' and family members' lives, and hopes that such a ban would
3 also encourage them in a similar way.

4 **(e) Plaintiff Ben Smith**

5 248. Plaintiff Ben Smith is an African American resident of Buffalo, New York. Plaintiff
6 Smith began smoking in the early 1970s and has smoked menthol cigarettes for over 40 years.

7 249. At the time, the tobacco companies were targeting the Black community with
8 menthol cigarettes everywhere—e.g., on billboards, in magazine advertisements, on television
9 shows, and through promotional discounts and coupons. As a result of the tobacco companies'
10 efforts, nearly everyone in Plaintiff Smith's community of family and friends (also African
11 American) smoked menthol cigarettes, including Plaintiff Smith's brother and older sister. These
12 sorts of efforts by the tobacco companies further enticed Plaintiff Smith to begin smoking
13 menthol cigarettes, and to be "cool." Indeed, the first cigarette Plaintiff Smith tried was a Kool
14 menthol cigarette.

15 250. Eventually, Plaintiff Smith's addiction to menthol cigarettes caused or contributed
16 to him developing stomach cancer, asthma, pneumonia (twice), COVID, and chronic obstructive
17 pulmonary disease ("COPD"). Plaintiff Smith furthermore used to cough all the time, and he
18 found that only by smoking menthol cigarettes would he find temporary relief.

19 251. Plaintiff Smith tried various cessation products over the years (e.g., gum and the
20 patch), but was unable to break his addiction at the time to menthol cigarettes.

21 252. In 2016, Plaintiff Smith was hospitalized over 25 times for these smoking related
22 health issues.

23 253. Eventually, however, Plaintiff Smith was able to break his addiction to menthol
24 cigarettes. That said, Plaintiff Smith still suffers from the effects of his menthol cigarette
25 addiction, including being recently diagnosed with prostate cancer.

26 254. Today, Plaintiff Smith has a son who currently smokes menthol cigarettes.
27 Plaintiff Smith's son began smoking several years ago while in California, and since moving back
28

1 to Buffalo, New York, has continued to remain addicted to menthol cigarettes. Plaintiff Smith
2 has tried several times to encourage his son to break his addiction, but to no avail.

3 255. Plaintiff Smith cares deeply about his son, his son's health, and does not want his
4 son to suffer from the same health problems that Plaintiff Smith has suffered. Plaintiff sees his son
5 each week, and enjoys his company, conversation, and their shared history together.

6 256. Plaintiff Smith believes that the Black community is among the most vulnerable to
7 menthol cigarette smoking, and targeting by the tobacco companies; that the tobacco companies'
8 efforts in fear-mongering (e.g., creating an illicit menthol cigarette market, increase policing in
9 the Black community) is wrong; and that a menthol cigarette ban would help to protect the next
10 generation, the Black community, and encourage his family members and others within his
11 community addicted to menthol cigarettes, to quit.

12 **ii. Members of Plaintiff public health associations have a**
13 **strong personal interest in their family and close friends.**

14 257. Each individual Plaintiff and public health organization Plaintiff member has a
15 personal, aesthetic, and recreational interest in their family and close friends, and has concrete
16 plans to see, visit, and enjoy spending time with them. These interests are furthermore germane
17 to the mission of each public health organization Plaintiff.

18 **(a) Plaintiff AATCLC member Valerie Yerger**

19 258. African American Tobacco Control Leadership Council ("AATCLC") member
20 and co-founder Dr. Valerie Yerger is a resident of Hercules, California.

21 259. Dr. Yerger and her extended community of family—i.e., parents, grandparents,
22 aunts, uncles, siblings, children, and grandchildren—are all African American. Growing up, Dr.
23 Yerger's family was a close one—regularly seeing each other on weekends, for holidays,
24 vacations, and special events. At the time, each of Dr. Yerger's children were still in their teens or
25 younger, and five generations lived within a 10-mile radius of one another.

26 260. Early in her professional career, Dr. Yerger became one of the first naturopathic
27 doctors, and the first non-nurse midwife to be licensed in the State of California. Dr. Yerger
28

1 planned to open a private practice based on her naturopathic and midwifery training, with a
2 specific focus on pre-conception health for child-bearing women.

3 261. But in 2000, Dr. Yerger worked on a project at U.C. San Francisco involving
4 previously secret tobacco company documents. As Dr. Yerger began to learn more about the
5 tobacco industry's predatory marketing of menthol cigarettes to low-income Black
6 neighborhoods, she felt compelled to put her clinical practice on hold for a little while—at least
7 that was her plan.

8 262. Dr. Yerger has suffered a deeply personal and concrete injury from the tobacco
9 companies, as well as from the Defendants who have unduly delayed issuing a final Menthol
10 Rule. In the span of 10 years—i.e., the same period of time that the Defendants have delayed
11 promulgating a final Menthol Rule—Dr. Yerger lost her father, brother, and aunt to menthol
12 cigarettes.

13 263. For as long as Dr. Yerger remembers, her father Dr. Benjamin Yerger smoked
14 Kool cigarettes, which were aimed at Black men like Dr. Yerger's father. Magazines in Dr.
15 Yerger's family households—e.g., *Ebony*, *Jet*, and *The Crisis*—all contained menthol cigarette
16 advertisements aimed at the Black community. In addition, nearly everyone in Dr. Yerger's
17 community of family, close friends, and local activists smoked menthol cigarettes. Dr. Benjamin
18 Yerger tried to quit his menthol cigarette addiction numerous times. But despite his success in
19 many other areas of his life⁶⁷, Dr. Benjamin Yerger was unable to break his menthol cigarette
20 addiction. All told, he smoked menthol cigarettes for over 50 years.

21 264. Towards the end of his life, Dr. Yerger's father began suffering from a series of
22 mini-strokes and transient ischemic attacks. He eventually died in 2014.

23 265. At all relevant times, Defendants have known that cigarette smoking can cause
24 mini-strokes and transient ischemic attacks.

25 266. Dr. Yerger also lost her brother Benjamin Yerger Jr. to menthol cigarettes in
26 2018. Mr. Yerger Jr. smoked Newport menthol cigarettes every day for over 45 years, starting

27 ⁶⁷ See Remembering Ben Yerger, educational servant, pioneer, Berkeleyside (Feb. 28, 2014).
28 Available at <https://www.berkeleyside.org/2014/02/28/remembering-benjamin-james-yerger>.

1 from when he was roughly 12 years old. Over time, he developed trouble breathing and walking.
2 He also developed diabetes, and was later diagnosed with pulmonary fibrosis—i.e., a chronic
3 lung disease often caused by smoking that causes scarring and thickening of the lung tissue,
4 making it harder to breathe. Mr. Yerger’s doctor at the Oakland Veterans Administration told
5 him it was as though he had “cement in his lungs.” And despite his several attempts to break his
6 menthol cigarette addiction, Dr. Yerger’s younger brother was unsuccessful.

7 267. Towards the end of his life his health had deteriorated so far that he could not
8 care for himself. As a result, Dr. Yerger was compelled to assist with the care of her younger
9 brother, managing his finances, and the care of his home—all while raising four children of her
10 own and witnessing the further deterioration of her brother’s health.

11 268. At all relevant times, Defendants have known that smoking cigarettes is a cause
12 for pulmonary fibrosis. Defendants furthermore know that a ban on the manufacture and sale of
13 menthol cigarettes promotes smoking cessation among menthol cigarette smokers. *See Sarah D*
14 *Mills, et al., The Impact of Menthol Cigarette Bans: A Systematic Review and Meta-Analysis*, Nicotine &
15 *Tobacco Research* (Feb. 21, 2024).

16 269. Dr. Yerger similarly lost her aunt Juan Williams to menthol cigarettes. Ms.
17 Williams was a daily menthol cigarette smoker for over 50 years, until her death in January 2024.
18 In that time, Mrs. Williams developed emphysema and was put on oxygen, which severely
19 impacted her quality of life. Although Mrs. Williams tried to break her menthol cigarette
20 addiction several times, Ms. Williams was ultimately unsuccessful until she witnessed her sister’s
21 (Dr. Yerger’s mother) slow death from a smoking-related disease.

22 270. In addition to losing her father, brother, and aunt to menthol cigarettes, Dr.
23 Yerger also lost her mother, grandmother, and fiancée to cigarettes.

24 271. Dr. Yerger’s grandmother Hattie “Bea” Walker smoked cigarettes for over 40
25 years, beginning in the mid-1950s. Mrs. Walker worked as a nurse for many years, was the
26 family’s matriarch (often dressed in a matching hat, purse, and gloves), and hated her own
27 addiction to cigarettes. Towards the end of her life, Mrs. Walker developed trouble breathing
28 and walking, and was later prescribed oxygen therapy (i.e., put on oxygen). She suffered from

1 painful circulatory problems in her feet that eventually led to the amputation of part of her toe
2 and severe disfiguration of that foot. Because these amputations greatly reduced her ability to
3 move about, Dr. Yerger's grandmother was at times reduced to begging her family members to
4 bring her cigarettes, while attached to her oxygen tank. Mrs. Walker later died in 1996 from
5 emphysema.

6 272. Dr. Yerger also lost her fiancée Isidoro Quinones to cigarette smoking. Mr.
7 Quinones grew up in the same neighborhood as Dr. Yerger and for years had been addicted to
8 cigarettes. Although he had tried to break his addiction numerous times, Mr. Quinones was
9 unsuccessful. Shortly after his diagnosis of stomach cancer on November 4, 2009, Mr. Quinones
10 passed away the following month.

11 273. The loss of Dr. Yerger's fiancée was only compounded by the loss of her mother
12 less than six months later in 2010.

13 274. Dr. Yerger's mother Bobbey Walker smoked cigarettes for over 50 years.
14 Although she tried multiple times to quit (and was successful for a handful of years), Dr. Yerger's
15 mother for decades was unable to break her cigarette addiction. Eventually, Dr. Yerger's mother
16 developed cardiovascular and pulmonary health issues, and during the last ten years of her life,
17 could only walk for a few feet at a time, while struggling to breathe. During this time, Dr. Yerger
18 took care of her mother until she was admitted to an intensive care unit in January 2010 where
19 she stayed for five weeks. She then returned home where she died four months later.

20 275. Given this personal history of loss caused by cigarettes, the targeting of the Black
21 community by the tobacco companies, and Defendants' inaction with respect to removing
22 menthol cigarettes from the marketplace, Dr. Yerger has a strong personal, aesthetic, and
23 recreational interest in her four grandchildren who are four, five, nine, and 15 years old, and
24 who are African American—i.e., two groups (youth and the Black community) that the tobacco
25 companies have targeted, and continue to target, with menthol cigarettes.

26 276. Dr. Yerger has concrete plans to see her grandchildren this Thanksgiving and
27 Christmas. Dr. Yerger also regularly checks in with her grandkids, and plans to see them for
28 other holidays, graduations, birthdays, summer vacations, and other family events. Dr. Yerger

1 enjoys each of her grandchildren, and plans on seeing and talking with them regularly, whether
 2 in-person at home, over video chat, or while traveling together. Indeed, because two of Dr.
 3 Yerger’s children are single parents, Dr. Yerger regularly helps to “co-parent” and take care of
 4 two of her four grandchildren.

5 277. Growing up in Berkeley, Oakland, and Richmond, California, Dr. Yerger had a
 6 strong appreciation for the presence, help, joy, and wisdom of her family elders, parents,
 7 grandparents, aunts, and uncles. And as her family’s only granddaughter, Dr. Yerger was
 8 particularly close to her grandmother Bea, great-grandmother “Mama Prim,” and aunt Juan.
 9 Dr. Yerger also grew up with a strong appreciation for improving the lives of those within her
 10 community. In her youth, the Black Power movement was ascendant. And, Dr. Yerger’s father
 11 had created the first African Studies course at Merritt College⁶⁸ and was planning events with
 12 local Black leaders including the Rev. Booker T. Anderson and Ronald Dellums. These
 13 experiences brought home and emphasized to Dr. Yerger the importance of protecting Black
 14 lives, the Black community, and Black families.

15 278. In a similar vein, Dr. Yerger—as the matriarch of her family—expects and plans
 16 on playing a significant role in, and taking a strong personal interest in, the lives of her
 17 grandchildren, nieces, and nephews.

18 **(b) Plaintiff AATCLC member Carol McGruder**

19 279. African American Tobacco Control Leadership Council (“AATCLC”) co-
 20 Chairperson and co-founder Carol McGruder is an African American resident of San Francisco,
 21 California.

22 280. Ms. McGruder is a seasoned veteran of California’s tobacco prevention
 23 experience, a senior project director, an activist, a researcher, and a writer. She has worked in
 24

25 ⁶⁸ Jed Riffe Films, *Africana Interactive Studies Center* (noting that “Merritt College offered the first
 26 African Studies course in the country in 1964. Bobby Seale and Huey P. Newton were students
 27 at Merritt and took the courses. They organized the Black Panther Party at Merritt in 1966 in
 28 response to the murder of Malcolm X and police brutality in Oakland.”), available at
<https://jedriffefilms.com/africana/#:~:text=Merritt%20College%20offered%20the%20first,an d%20police%20brutality%20in%20Oakland.>

1 tobacco prevention since 1994. Ms. McGruder has served in many roles, including as the
2 NAACP Branch President for Berkeley, California (2010–2014).

3 281. As high school student in San Francisco, Ms. McGruder took the public bus by
4 herself from Bayview-Hunters Point (a predominately African American neighborhood) all the
5 way across the city to the Sunset district in order to attend a better high school. The trip took one
6 and a half hours each way. And each school day, she rode past Bayview and Fillmore—two
7 historically Black neighborhoods with lots of menthol cigarette advertising, and a high density of
8 liquor and tobacco retailers. From that experience, she repeatedly witnessed the tobacco industry
9 targeting of the neighborhood she lived in—particularly, when comparing her high school’s
10 neighborhood, where there were very few menthol cigarette advertisements or liquor retailers.

11 282. Ms. McGruder has suffered a deep and personal injury from Defendants’ failure
12 to regulate the menthol cigarette companies that have targeted her family, including her aunt,
13 niece, brother, and cousin, all of whom are also African American.

14 283. Ms. McGruder’s favorite aunt, Barbara Lois Oldham, smoked menthol cigarettes.
15 Ms. McGruder lived in Los Angeles with her aunt for several years when she was in her mid-
16 twenties. She was one of the smartest and most dynamic women Ms. McGruder has ever known.
17 And, she helped Ms. McGruder to see the world differently, encouraged her to travel, and helped
18 to shape Ms. McGruder into the person she is today. Ms. Oldham would regularly throw parties
19 and hold gatherings in her home, consistently bringing family and friends together. United by the
20 bonds of affection between Barbara, Ms. McGruder’s mother, and others, Ms. Oldham would
21 spoil Ms. McGruder and the other members of their family. They were the vital linchpins of their
22 families, the people who kept the family united in both good and bad times.

23 284. A few years later in 1984, Ms. Oldham had emergency surgery for an intestinal
24 blockage. The stress it put on her body led to her lung function decreasing dramatically and
25 permanently. She underwent surgery, was then placed on a respirator for a while, and then put
26 on oxygen for the rest of her life. She died at the age of 58, before Ms. McGruder had even
27 begun her work in tobacco control. Later, after years of working in tobacco control and learning
28 about how the tobacco industry targeted African Americans, Ms. McGruder saw Ms. Oldham’s

1 suffering and death in a new light. And when Ms. McGruder turned 58 herself, she realized just
2 how young that was and how Ms. Oldham's life was cut short.

3 285. Ms. Oldham was terribly ashamed that she could not break her menthol cigarette
4 addiction. And she would at times sneak into her bathroom to smoke—even after she was on
5 oxygen. She suffered like that for five years before her passing in 1990.

6 286. On Ms. McGruder's last visit to Ms. Oldham at her nursing home (just before she
7 died), Ms. McGruder brought her mother and young daughter as well. Ms. Oldham asked Ms.
8 McGruder to come into the bathroom with her because she was afraid the strain would put too
9 much stress on her heart, and she felt comforted having Ms. McGruder beside her.

10 287. Her two sons, one of whom was a menthol smoker, are now deceased as well.
11 When Ms. McGruder lived in Los Angeles, they were always taking her out to social events, such
12 as movies, plays, and restaurants.

13 288. Ms. McGruder has experienced what it means when a family loses a leader, a key
14 person. It causes immense intergenerational harm. Ms. Oldham was the glue in her family, she
15 was the person who caught people, who would help others with their mortgage, and who would
16 convene the family. When those bonds stretch over time, a family is never the same, the family
17 never quite heals, and that person and their wisdom is gone forever. And when many family
18 members from multiple generations are lost at a young age, the effect on the family to that loss
19 compounds.

20 289. To combat this, Ms. McGruder remains close to her family, even those who
21 smoke menthol cigarettes—e.g., her oldest brother Jack McGruder Jr., her cousins Anthony
22 Johnson and Francesca Johnson.

23 290. Ms. McGruder's brother Jack lives in Tulsa, Oklahoma, and smokes roughly half
24 a pack of menthol cigarettes each day. He has high blood pressure and once suffered from a
25 nosebleed that required an emergency room visit. Ms. McGruder, having seen this pattern of
26 symptoms before, has anticipatory grief in knowing that her brother is at an extremely high risk
27 for stroke. Ms. McGruder has shared with her brother, that his wife and son will likely need to
28 take care of him in the near future.

1 291. Ms. McGruder and her brother talk or text each week. She jokes with him, by
2 telling him all her anti-menthol efforts are for him (which is not inaccurate). And each time Ms.
3 McGruder tries to encourage her brother to try quitting, he pushes back. A few years ago Ms.
4 McGruder paid for Mr. McGruder Jr. to visit the family in California.

5 292. Ms. McGruder's cousin Anthony Johnson lives in Japan, and started smoking
6 menthol cigarettes in his late teens. He now smokes non-mentholated cigarettes, and asks for
7 family and friends (except Ms. McGruder of course) to bring him Newports when they visit, as
8 menthol cigarettes are prohibited in Japan.

9 293. As a younger man, he did not take Ms. McGruder's anti-menthol advocacy
10 particularly seriously. But now, after a serious bladder cancer scare, he's grown to respect her
11 work—in part, because he's now seen many smokers suffering and dying from menthol-related
12 conditions.

13 294. Ms. McGruder's cousin Ms. Francesca Johnson is a heavy menthol smoker, 70
14 years old, in poor health, and constant pain. She has breathing difficulties, neuropathy, and is
15 very frail. Holding her, Ms. McGruder can feel her bones under her skin when they embrace.
16 She has been smoking for decades, at least since her twenties.

17 295. Another of Ms. McGruder's cousins, a longtime Newport smoker and veteran, is
18 currently fighting pancreatic cancer. Her daughter is a smoker as well.

19 296. Ms. McGruder cares about her family, and has plans to visit, talk with, and check
20 in with them, including Mr. McGruder Jr. and Mr. Johnson, on a regular basis.

21 **(c) Plaintiff AATCLC member Minou Jones**

22 297. African American Tobacco Control Leadership Council (“AATCLC”) member
23 Minou Jones is an African American resident of Detroit, Michigan who currently serves as
24 Director of the Detroit Wayne Oakland Tobacco Free Coalition. Ms. Jones is also a former
25 Executive Director of the Black Caucus Foundation of Michigan.

26 298. Ms. Jones has suffered a deep and personal injury from Defendants' failure to
27 regulate the menthol cigarette companies that have targeted her family and close friends. Ms.
28

1 Jones has lost her father, grandmother, aunt, best friend, brother-in-law, and cousin to menthol
2 cigarettes.

3 299. Both of Ms. Jones' parents were menthol smokers. They smoked menthol
4 cigarettes like almost everybody else that she knew at the time. Ms. Jones grew up in the urban
5 center of Detroit at a time when it was roughly 90% Black and Newport had achieved market
6 dominance.

7 300. Ms. Jones recently went through her family's photo album and was reminded that
8 growing up, people used to smoke inside and outside of church, in school, at work, and in
9 airplanes. She remembers waiting in the exam room for the doctor to finish their cigarette. Even
10 when the Michigan clean indoor ordinance passed in 2010, in the Michigan health department,
11 where Ms. Jones was employed in 2010, so many health workers were incensed that they would
12 no longer be able to smoke in their offices anymore.

13 301. Ms. Jones recalls that tobacco companies used to come to the Black
14 neighborhoods in the Detroit metro area to promote their menthol cigarettes. Ms. Jones' mother
15 used to work for an advertising agency that was hired by the Lorillard Tobacco Company, which
16 produced, advertised, and sold Newport, among other brands, to give away free menthol
17 cigarettes at the African World Festival. The number of cigarettes Lorillard was giving away was
18 enormous—Ms. Jones recalls an entire warehouse full of pallets on which cigarette cartons were
19 stacked.

20 302. Ms. Jones' aunt, Ms. Constance Griffin, was one of the workers hired to pack and
21 unpack the cigarettes, and received free cigarettes as compensation, which Ms. Jones remembers
22 her packing up by the carload. She ultimately smoked herself to death, dying of lung cancer.

23 303. Ms. Jones' entire family—who are also African American—lives in Detroit and
24 are very close. As a child, Ms. Jones was very close with her immediate family and extended
25 family of cousins, aunts, and uncles. Ms. Jones saw her aunt roughly every other day until her
26 death. Her cousins were like siblings and grew up constantly spending the night at each other's
27 homes. Even as an adult, Ms. Jones lived two houses down from her father.
28

1 304. Ms. Jones' father, Mr. Reginald Trent, was an elder in the church and
2 community, whom she saw every day. Ms. Jones watched menthol slowly suffocate her father to
3 death in 2022. At 40, Mr. Trent was diagnosed with emphysema, and then was able to quit.
4 However, Ms. Jones' mother did not quit, and as a result his already sensitive pulmonary system
5 was continuously exposed to secondhand smoke until his passing.

6 305. Mr. Trent's death certificate shows that he died of acute young failure. The day
7 before he passed, he had texted Ms. Jones in crisis, and then when she arrived at her parent's
8 house, he was in bed saying everything was fine. Ms. Jones would pay their rent online for them,
9 and he said he needed to write her the check for rent, and that he would. Then the next morning
10 Ms. Jones' husband got the call. She wasn't expecting it at all. Ms. Jones can't get the image of
11 her father dead on the floor out of her mind.

12 306. Ms. Jones is a mother of six. All of Plaintiff Jones' children were incredibly close to
13 her father, as their father was not a constant presence in their lives. Her father was theirs as well
14 in many respects. He loved to fish and passed on the activity and lifestyle to Ms. Jones' sons,
15 fishing with them in Belle Isle, Michigan, Kensington Park, Michigan, and even Canada until he
16 was unable to do so due to shortness of breath.

17 307. Ms. Jones' cousin Mr. Daryle McCallum began smoking menthol cigarettes when
18 he was young, around 9 or 10. Later in life he tried to quit with the encouragement of his wife,
19 but has been unable to break his addiction. Ms. Jones states that as she and her family grew up
20 with gangs, drive-by shootings, drug dealers, were in the murder capital, they didn't think
21 tobacco would be their biggest enemy.

22 308. In 2016, Mr. McCallum died of squamous cell carcinoma, which attacked his
23 throat at 38, leaving his wife widowed without income and with three children to care for.

24 309. Ms. Jones' niece's father, Mr. Kevin Green died in a house fire because he was on
25 oxygen as a result of smoking-related lung disease and lit a cigarette. The resulting fire killed him
26 and burned down their house.

27 310. Ms. Jones' best friend, Ms. Audrey Boone Anthony, who was a person in
28 recovery, died from menthol-related cancer at 46. Her daughter, whom Ms. Jones has known

1 since infancy, is one of Ms. Jones' son's godmothers. She was able to become sober from crack,
2 heroin, and alcohol, but was unable to kick her Newport smoking habit. Ms. Jones believes that
3 FDA's failure to include menthol in the ban on flavored cigarettes left her with a reason to
4 continue to smoke, as she (as well as many others), had been led to believe by tobacco marketing
5 that menthol was safer than non-menthol cigarettes. Ms. Anthony smoked until the day she died.

6 311. Ms. Anthony had purchased a new home that year after saving for years. Ms.
7 Jones took her to her last chemo session while her windows were being installed. That day, her
8 white cell count was too low to get chemo, the doctors told her the cancer had spread to her
9 brain, and she was sent to hospice. She never got to see the windows in her new home.

10 312. Ms. Anthony had a daughter who was 13 when she passed, Naomi. Without the
11 support of her mother, Naomi became involved in gangs, and at 25, was found murdered in a
12 park the day after Christmas 2020. Naomi's two children are now in foster care. Naomi's
13 grandfather and father had also previously died from menthol-cigarette related disease.

14 313. As evidenced by the stories of Ms. Jones' family members and friends above,
15 Detroit and many of its residents face many challenges, such as food insecurity, gun violence,
16 homelessness, and severe blight. In response to these issues, Ms. Jones dedicated her professional
17 efforts, including via the organizations she leads and has led, to increasing health equity for
18 African Americans.

19 314. Ms. Jones understands that there is no other legal product that is more
20 carcinogenic and deadly than menthol in the Black community, and as such she dedicates the
21 bulk of her time to ameliorating the effects of menthol in her community.

22 315. In addition to menthol-related efforts in Detroit, Ms. Jones has worked to
23 organize covid testing and vaccinations, canvassed neighborhoods to inform people about the
24 importance of being counted in the Census, distributed food boxes, conducted financial literacy
25 trainings, engaged in coalition-building, engaged in drug prevention efforts, and held life skills
26 trainings for middle and high school youth. All of this has taken a back seat to banning menthol
27 because of the amount of people Ms. Jones sees Detroit lose to tobacco, and the incredibly
28 damaging domino effect that that loss creates.

1 316. The initial decision made as a part of the Tobacco Control Act to not include
2 menthol cigarettes in the ban on flavored cigarettes has led to Ms. Jones spending much more
3 time educating family, youth through her nonprofit in Detroit, and local decision makers—who
4 are often relatively uninformed—as to why menthol was not included in the ban, and why it is
5 harmful. It also caused many of the youth Ms. Jones works with to continue to be exposed to
6 menthol cigarette smoking.

7 317. Additionally, when in August of 2023 following *Menthol Lit. I* the FDA announced
8 it would move forward with a ban on menthol cigarettes, Ms. Jones’ organization spent over
9 \$500,000 on a media education campaign to raise awareness about menthol and the harms
10 caused by tobacco industry targeting. The further delay has again left many victims of targeting
11 wondering if she is telling the truth, and as such the delay has hurt her credibility as a tobacco
12 control expert and shattered her confidence in FDA following the science.

13 318. So many people in Ms. Jones’ life have been lost to cancer, emphysema, stroke,
14 hypertension, asthma, and COPD. For the menthol smokers in Ms. Jones’ life who remain alive,
15 and for youth, she feels that the banning of menthol would lead to decreased uptake and relapse
16 rates, increased quit rates, and less death in her community.

17 319. Ms. Jones is a central figure in her family and regularly spends time with her
18 family members, especially her children, some of whom she speaks to daily and several others
19 weekly. Ms. Jones has concrete plans to see her family, including her children and extended
20 relations, in the future

21 320. As such, Plaintiff Jones has a strong personal, aesthetic, and recreational interest
22 in the health of her family and of the Black community of Detroit.

23 **(d) Plaintiff ASH member Kelsey Romeo-Stuppy**

24 321. Action on Smoking and Health (“ASH”) member and Managing Attorney Kelsey
25 Romeo-Stuppy is a resident of Clarksville, Maryland. As ASH’s Managing Attorney Ms. Romeo-
26 Stuppy is responsible for leading ASH’s human rights program, which aims to use the human
27 rights framework to strengthen tobacco control policies.
28

1 322. Today, Ms. Romeo-Stuppy and her husband have three young children that
2 range in age from two years old to seven years old.

3 323. Because of her strong interest in seeing her children grow up to become healthy
4 young adults, Ms. Romeo-Stuppy spends time with her children each day teaching them about
5 how best to take care of themselves in a rapidly changing world.

6 324. Part of that time is spent explaining, among other things, the work she does to
7 help prevent other's suffering from a lifetime of nicotine addiction and other harms caused by
8 menthol cigarettes. In 2022, for example, Ms. Romeo-Stuppy led an effort (through ASH) at the
9 international human rights body the Committee on the Elimination of Racial Discrimination to
10 call on the United States to act to protect all Americans from tobacco, particularly from menthol
11 products. Together with the AATCLC, Ms. Romeo-Stuppy was able to garner the support of
12 120 organizations. (The United States is a signatory to the International Convention on the
13 Elimination of All Forms of Racial Discrimination. The tobacco companies' ongoing targeting of
14 the Black community with menthol cigarettes—all the while, with Defendants' knowledge and
15 willful inaction to stop such efforts—constitutes a form of racial discrimination perpetuated by
16 the Defendants under the Convention.)

17 325. Closer to home, Ms. Romeo-Stuppy also spends time teaching her children about
18 the various tactics that tobacco companies have used, and continue to use today, to target
19 youth—e.g., through flavors, vapes, mixed messages of public harm and safety, messages that
20 appeal to youth, and other forms of advertising, marketing, and promotions. Some of those
21 lessons take place near Ms. Romeo-Stuppy's local Maryland gas station, which advertises,
22 markets, and promotes the sale of menthol cigarettes. Other lessons take place in nearby North
23 Carolina, which more heavily and publicly advertises, markets, and promotes menthol cigarettes.

24 326. And because Ms. Romeo-Stuppy's interest in her children extends to the
25 community of people in which they (and she) regularly see and enjoy, Ms. Romeo-Stuppy has
26 also developed and taken a strong interest in the youth and young adults in her local community,
27 regularly volunteering at her children's school, chaperoning field trips, field days, and other off-
28 site school events.

1 327. In sum, Ms. Romeo-Stuppy has plans to regularly see, take care of, and enjoy the
2 company of her children for many years, if not decades. Defendants' inaction on regulating the
3 predictable and ongoing efforts of the tobacco companies to target youth with menthol cigarettes,
4 constitutes an impending and imminent injury to Ms. Romeo-Stuppy's (and her husband's)
5 strong interest in her young children.

6 **(e) Plaintiff NMA and AMA member Mark Mitchell**

7 328. National Medical Association and American Medical Association member Mark
8 Mitchell is an African American physician and resident of Hartford, Connecticut.

9 329. Growing up in the 1960s in largely white suburb of St. Louis, Missouri, Dr.
10 Mitchell faced instances of racism on near daily basis (e.g., from the students in his schools,
11 people staring at the grocery store, neighbors yelling from their cars as they passed by, and the
12 institutions that he attended, or else wanted to attend). As a result, Dr. Mitchell decided at an
13 early age to excel in school (i.e., to show others that he belonged), to become a doctor (and help
14 others where he could), and to dedicate his life towards making a more just and equitable society.

15 330. That early decision directed Dr. Mitchell's career towards public health and a
16 lifelong effort to address inequity through the practice of medicine. It also led Dr. Mitchell to
17 advocate and work for tobacco control, particularly within the Black community. As has been
18 recognized for decades, one of the largest public health disparities in the United States exists
19 because of the tobacco industry's decades of advertising, marketing, and promotion of menthol
20 cigarettes—all aimed at the Black community, women, and youth. Accordingly, Dr. Mitchell has
21 applied his practice to, among other things, (a) addressing the tobacco companies' discriminatory
22 and harmful practices, (b) confronting the acquiescence, or willing participation, of institutions
23 that turn a blind eye towards the tobacco industry's practices; and (c) providing the tools that
24 addicted smokers need to break their addiction.

25 331. For example, while training at the Johns Hopkins Bloomberg School of Public
26 Health, Dr. Mitchell studied health policy and completed his residency specialty in preventive
27 medicine. This area focused much of his time on public education at the local and national level.
28 More specifically, Dr. Mitchell studied smoking education and advocacy, and because of his

1 background and interests, understood how to apply this knowledge to counter-messaging to the
2 African American community—e.g., how to educate the Black community about the tactics of
3 the tobacco industry, how to effectively talk about cessation programs, and how to best counter
4 the targeting of African Americans.

5 332. As part of his training, Dr. Mitchell spent six weeks with the Congressional Black
6 Caucus Foundation. Dr. Mitchell learned how the Foundation relied heavily on funding from the
7 tobacco industry. He also learned how at the Foundation's white linen gala (frequently attended
8 by the President and other high level, national politicians) attractive women would circulate
9 among guests and distribute free cigarettes to guests, and packs of cigarettes were placed with
10 each guest's table setting.

11 333. Upset at what he found, Dr. Mitchell wrote a letter to the Executive Director for
12 the Congressional Black Caucus Foundation, encouraging the Foundation to stop accepting
13 money from the tobacco industry, particularly given their hand in killing so many African
14 Americans. The Foundation then sent his letter to the tobacco industry, which replied to the
15 Foundation that the science was out on whether cigarette smoking caused cancer. This was in
16 1984—twenty years after the Surgeon General had issued their groundbreaking report in 1964,
17 finding that smoking caused lung cancer (among other health ailments) and premature death.

18 334. On a more personal level, much of Dr. Mitchell's work and interest in protecting
19 the Black community is driven by his direct experience with family members and patients that
20 were targeted by the tobacco industry and later became addicted to cigarettes, including menthol
21 cigarettes. Their experience—struggling with addiction, the lack of control over one's cravings,
22 the physical harms left by smoking, and the loss and grief experienced by their families left
23 behind—left an indelible mark on Dr. Mitchell's practice and work today with the NMA and
24 AMA.

25 335. Dr. Mitchell's childhood best friend and cousin Phillip Walton, for example,
26 smoked menthol cigarettes for years. Two years older than Dr. Mitchell, Mr. Walton lived in the
27 inner city of St. Louis in a building where Dr. Mitchell's grandparents also lived. Each weekend,
28 Dr. Mitchell and his father would travel from the suburbs of St. Louis to visit Mr. Walton, his

1 mother, and Dr. Mitchell's grandparents. Dr. Mitchell enjoyed spending this time together with
2 his best friend and family immensely. Each Sunday was a chicken dinner. And because Mr.
3 Walton's grandparents lived in a predominantly Black neighborhood (a different world from Dr.
4 Mitchell's experience growing up in a largely white suburb), visiting Mr. Walton was a special
5 experience to look forward to. That said, the advertising of menthol cigarettes in Mr. Walton's
6 inner-city neighborhood was ubiquitous, and clearly targeted towards the Black community.⁶⁹

7 336. Perhaps unsurprisingly then, Mr. Walton began smoking Kool menthol cigarettes
8 as a teenager. He then later joined the military, married, and moved to Oklahoma. He served for
9 20 years and then retired to become a bus driver in Las Vegas. But because he was unable to
10 break his addiction to menthol cigarettes, Mr. Walton, shortly after his military service,
11 developed lung cancer. At that time, such a diagnosis meant that a patient had 50-50 chance of
12 dying within the next six months, and there were few, if any, truly effective treatments.

13 337. For Mr. Walton, his diagnosis came too late for any treatment. Following his
14 cancer diagnosis, he moved back with his family to St. Louis, where he died a short time later at
15 the age of 42. The death of Mr. Walton was a heavy blow to his wife and stepchildren that he left
16 behind, Dr. Mitchell, and Mr. Walton's extended family.

17 338. Dr. Mitchell's cousin Ms. Sharon Dungy also smoked menthol cigarettes from a
18 young age, and died from smoking-related disease. Just a few years older than Dr. Mitchell, Ms.
19 Dungy grew up in St. Louis and regularly saw Dr. Mitchell and his family. Like Dr. Mitchell, Ms.
20 Dungy had a mother that was a daily smoker and who had smoked for decades. Ms. Dungy's
21 mother died of ovarian cancer in the mid-1990s.

22 339. As a music teacher and singer, Ms. Dungy would often try to hide her addiction
23 and tried quitting numerous times. But Ms. Dungy was only able to reduce the number of
24

25 ⁶⁹ Indeed, smoking was so normalized at the time that Dr. Mitchell's own high school had a
26 smoking lounge for students that were 18 years old. One of Dr. Mitchell's teachers regularly
27 smoked in the classroom while teaching. And Dr. Mitchell's mother—a medical record
28 librarian—smoked two packs a day for decades before quitting. As a consequence, Dr.
Mitchell—a lifelong non-smoker—became the first person in his family to develop asthma and
coronary artery disease while still at a relatively young age.

1 menthol cigarettes that she smoked and was ultimately unsuccessful in breaking her addiction. In
2 her later years, she was diagnosed with lung cancer, which then spread slowly throughout her
3 body. She suffered in this way for years before the cancer eventually spread to her brain, causing
4 metastatic brain tumors. She then passed away in 2021.

5 340. The loss of Ms. Dungy to her family was immense. Ms. Dungy was the Mitchell
6 family historian (e.g., visiting the family's historic homestead in Alabama), a key organizer of the
7 Mitchell family reunion (with over 300 family members attending, from all over the country), the
8 daughter who took care of her own mother (when her mother's health began to fail), the niece
9 who visited and took care of her aunt at a nursing home (and who later helped to plan her aunt's
10 funeral while her own health was failing), and the family member who thoughtfully kept in touch
11 with each branch of the family over the years. Some of the tributes to her life included the
12 following:

- 13
- 14 a. "I will forever love, love, love Sharon Ann Dungy-Peters. She was just simply the
15 best at sharing, advising, listening, and loving her family. I am glad her suffering is
16 over."
- 17 b. "The times were whenever we got to talk or go out to eat, we laughed so hard we
18 would just cry! I'll miss my Mother's Day cards you so graciously sent me every
19 year, you never forget me. I'll never forget you. I loved you as my biological sister
20 I never had."
- 21 c. "Sharon, our beloved cousin, the Walton family would like to thank you simply
22 for being YOU! We cherish your memory as a fun loving, hard working,
23 nurturing MATRIARCH, who has helped so many in our times of need. Our
24 lives are all better because of your loving touch!"
- 25 d. "We will forever love Cousin Sharon. She has been a beloved member of our
26 family and a loving and caring pillar of the family, who kept us all connected, for
27 our entire lives. She was especially caring to our Grandmother, her aunt, Myrtle
28 Dungy at her time of her illness and convalescence, before her passing, as well as
our Grandfather, her uncle, Harry Taylor, Sr. She was also the close cousin with

1 our father Harry Taylor, Jr. with whom she shared the common love of delving
2 into the family history and genealogy.”

- 3 e. “In many ways, you have been the **ROCK** of our family. You have been so kind
4 and diligent to keep us together, always valuing family. You and Robert were
5 always so faithful to visit us in CA and to open up your home at Christmas to your
6 lovely home and to allow us to gather. You kept us abreast of the goings-on of
7 everyone in the family. **FAMILY** meant everything to you and we all felt your
8 love and warmth that you and Robert exuded. You were more than that. You
9 were like my big sister. I loved our lively conversations that we all had. I will
10 never forget your laughter and your care.”

11 341. In short, Ms. Dungy was in many ways the glue that held the Mitchell family, and
12 so many other branches of Dr. Mitchell’s family, together. Her

13 342. Dr. Mitchell’s experience treating patients has also informed and directed his life’s
14 work. One of Dr. Mitchell’s patients was 39-year-old, white male smoker who had severe chronic
15 obstructive pulmonary disease (“COPD”)—a lung disease that causes breathing problems and
16 restricted airflow, and which is usually caused by smoking. This patient had trouble breathing
17 without the assistance of a respirator, had serious challenges trying to wean himself off. He
18 eventually succumbed to the harms caused by his menthol cigarette addiction, and left behind a
19 grief-stricken 24-year-old wife.

20 343. Based on these personal and professional experiences, Dr. Mitchell has used his
21 position within the NMA and AMA to help smokers (particularly within the Black community)
22 get the help they need to quit smoking and to make educated decisions about their own health.

23 344. Part of that work includes, not only delivering the right message, but just as
24 importantly, finding the right messenger. For smokers within the Black community, it is
25 important to appeal to family values, and one’s sense of community. Black smokers are more
26 receptive to quitting in an individual setting (versus group setting) and are more likely to try
27 quitting for family and trusted leaders within the community (e.g. doctors and ministers). Because
28 the Black community has long been targeted and taken advantage of by outside interests, finding

1 and being able to rely on trusted advocates who can connect with Black smokers is particularly
2 important.

3 345. So, it is particularly disturbing when the tobacco industry has used Black leaders
4 in the community to keep the African American community hooked on menthol cigarettes. As
5 reported by the Washington Post, “Reynolds American, which makes Newport, the nation’s top-
6 selling menthol brand, donated to the National Action Network [a group run by the Rev. Al
7 Sharpton] and to scholarships run by civil rights lawyer Ben Crump, and has contributed
8 hundreds of thousands of dollars to organizations representing Black law enforcement officials
9 and Black newspapers, according to the recipients. Representatives of those groups went on to
10 meet with Biden administration officials to oppose the menthol ban. Sharpton and Crump have
11 previously said the donations did not influence their position; neither responded to requests for
12 comment.” Fenit Nirappil, *How Black activists became defenders of Big Tobacco*, The Washington Post
13 (June 21, 2024).

14 346. The same article noted that “Gwen Carr, [Eric] Garner’s mother, said Reynolds
15 made a ‘small’ donation to the foundation she set up in her son’s memory,” and that in Detroit,
16 the Reverend Horace Sheffield “had turned down offers of up to \$250,000 from Reynolds
17 representatives to oppose a menthol ban.” As others have also reported, “for years, Philip Morris
18 gave heavily to the Congressional Black Caucus, with annual contributions sometimes exceeding
19 \$250,000. The organization’s dependence on tobacco money prompted many African American
20 legislators to oppose restrictions on menthol cigarettes. As the late Representative John
21 Lewis explained: ‘People are reluctant to criticize the giver, to bite the hand that feeds them.’”
22 Timothy Noah, *Don’t Let the Tobacco Industry Use George Floyd to Kill a Ban on Menthol Cigarettes*, The
23 New Republic (Apr. 29, 2022).

24 347. Indeed, the Washington Post’s referenced-meeting⁷⁰ between the Biden
25 administration officials and certain Black interest groups (e.g., Ben Crump, the National Action
26

27 ⁷⁰ See E.O. 12866 Mtg. (Nov. 20, 2023) (identifying additional participants between various Biden
28 administration officials, Black interest groups, and tobacco industry officials), *available at*

1 Network, Black law enforcement officials, and Black newspapers) **was also notable for the**
 2 **attendance of the tobacco industry**—i.e., **Philip Morris International**⁷¹ (using its own
 3 government relations contact and Stewart Strategies and Solutions⁷²), **Altria Group**⁷³ (using
 4 G.K. Butterfield of McGuire Woods Consulting LLC⁷⁴) which was previously known for decades
 5 as Philip Morris⁷⁵, and **Reynolds American** (using Peter Damon Group⁷⁶).

6 348. To help Black smokers receive the help they need, Dr. Mitchell chairs the NMA’s
 7 Council on Environmental Health and Climate Change, which encompasses addressing health
 8 disparities and their contributors, such as menthol cigarettes and tobacco. Dr. Mitchell also
 9 currently serves on the Steering Committee for the NMA’s Black Quit and Screen Smoking
 10 Cessation Project, an effort by the NMA to train its member doctors to advise and refer African
 11 American and Black smokers who are interested in quitting smoking, including quitting smoking
 12 menthol cigarettes, to smoking cessation programs and lung cancer screening programs in their
 13 local community.

14
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 16 [https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910-
 17 AI60&meetingId=244023&acronym=0910-HHS/FDA](https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910-AI60&meetingId=244023&acronym=0910-HHS/FDA).

18 ⁷¹ A 2020 report noted that “Leaked Philip Morris International (PMI) documents reveal that it
 19 opposes flavour bans, and our monitoring of industry activity indicates that tobacco companies
 20 have been exploiting loopholes in the menthol ban and related legislation in the UK, particularly
 21 in the months leading up to the ban.” Rosemary Hiscock, et al., *Tobacco industry tactics to circumvent
 22 and undermine the menthol cigarette ban in the UK*, Tobacco Control 2020;29: e138-e142 (2020).

23 ⁷² See Open Secrets, Groups that have retained Stewart Strategies & Solutions Year 2023 (last
 24 visited Sept. 16, 2024), available at [https://www.opensecrets.org/federal-
 25 lobbying/firms/summary?cycle=2023&id=D000075194](https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2023&id=D000075194).

26 ⁷³ In 2003, Philip Morris

27 ⁷⁴ See Open Secrets, Groups that have retained McGuire Woods Consulting LLC Year 2023 (last
 28 visited Sept. 16, 2023), available at [https://www.opensecrets.org/federal-
 lobbying/firms/summary?cycle=2023&id=D000022103](https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2023&id=D000022103).

⁷⁵ John Schwartz, *Philip Morris to change name to Altria*, The New York Times (Nov. 16, 2001).

⁷⁶ See Open Secrets, Groups that have retained Peter Damon Group (last visited Sept. 16, 2024),
 available at [https://www.opensecrets.org/federal-
 lobbying/firms/summary?cycle=2023&id=D000082155&year=2023](https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2023&id=D000082155&year=2023).

1 349. Dr. Mitchell also works through the AMA to help achieve their goal (shared with
2 the NMA) of health equity. The AMA Center for Health Equity works to embed health equity
3 across the AMA, and to imbue the practice of each physician with the precepts of health equity.
4 *See* AMA Center for Health Equity (last visited Sept. 16, 2024). This means addressing the root
5 causes and drivers of health inequities, confronting both historical and contemporary injustices in
6 the health care system, and improving health outcomes to reduce those health disparities.⁷⁷

7 350. For Dr. Mitchell specifically, this has meant working within the AMA to help
8 educate the public about the tobacco industry’s tactics, the steps Black smokers can take in
9 response, and what resources may be available for smokers that want to quit. One such project,
10 for example, involved Dr. Mitchell traveling with the (now former) Chair of the AMA Board of
11 Trustees Willie Underwood III to jointly address the attendees at a Black church in upstate New
12 York.

13 351. Other groups that reflect Dr. Mitchell’s passion and work to protect the health of
14 the Black community also include the Connecticut Equity and Environmental Justice Advisory
15 Council, where Dr. Mitchell serves as Co-Chair; the Connecticut Coalition for Economic and
16 Environmental Justice, which Dr. Mitchell founded and serves as a Senior Policy Advisor; and
17 the Coalition for a Safe and Healthy Connecticut, where Dr. Mitchell serves as a Senior Policy
18 Advisor.

19 352. Dr. Mitchell furthermore lives today (and he has for many years) in Hartford,
20 Connecticut—a city that is 85% Black and Latino. After serving as Hartford’s Health Director in
21 the 1990s, Dr. Mitchell chose to remain in Hartford to continue serving the community he has
22 become close to. That work and commitment to his community has blossomed into several
23 friendships for Dr. Mitchell, including one that he shares with Carlos Caez, a close friend who
24 smokes roughly half a pack of menthol cigarettes each day. Mr. Caez is Black and Latino, and
25 someone that Dr. Mitchell has known for roughly 20 years. Notably, although Mr. Caez was able
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27 ⁷⁷ *See* AMA, 2024–2025 AMA health equity strategic plan: Reaffirming AMA’s commitment to
28 equity. Available at <https://www.ama-assn.org/system/files/ama-equity-strategic-plan-2024-2025.pdf>.

1 to break his addiction to crack cocaine, Mr. Caez has been unable to break his addiction to
2 menthol cigarettes, despite numerous attempts.

3 353. Dr. Mitchell values his friendship with Mr. Caez, and makes regular plans to see
4 and enjoy Mr. Caez’s company and conversation. They often enjoy, and make plans to enjoy, a
5 meal or drink together, catching up on friends and family. Dr. Mitchell remains concerned,
6 however, for Mr. Caez’s health, how his loss may be felt among his friends, family, and Dr.
7 Mitchell, and how the tobacco companies continue to target Mr. Caez through the relentless
8 advertising, marketing, and promotion of menthol cigarettes, and the use of Black “leaders” who
9 are more interested in serving the tobacco industry, than the vulnerable populations like Mr.
10 Caez who remain unable to break their addiction to menthol cigarettes.

11 **2. Plaintiffs’ injuries are fairly traceable to Defendants’ inaction**
12 **on addressing menthol in cigarettes.**

13 354. Plaintiffs’ concrete injuries, and likely impending injuries, are furthermore fairly
14 traceable to the Defendants’ inaction.

15 **i. Defendants directly regulate the tobacco companies—**
16 **i.e., the manufacturers of menthol cigarettes, who**
17 **deliberately target Plaintiffs and their members.**

18 355. Since at least 2009, the Defendants have been responsible for enforcing the
19 Tobacco Control Act—specifically (a) regulating the tobacco companies that manufacture, sell,
20 and distribute menthol cigarettes; and (b) promulgating and publishing final rules that are
21 appropriate for the protection of the public health.

22 356. Despite such responsibilities, the Defendants have for decades allowed the tobacco
23 companies to target African Americans, women, and youth with menthol cigarettes. This
24 abdication of responsibility harms (and will likely imminently harm) each individual Plaintiff;
25 each Plaintiff organization and their members; each person that the tobacco companies’ have
26 aimed, and continue to aim, their menthol cigarette advertising, marketing, and promotional
27 efforts towards (e.g., the African American community, women, and youth), and each person
28 who maintains a strong or close connection to such targeted persons.

1 357. This is because the manufacturers of menthol cigarettes (e.g., R.J. Reynolds
2 Tobacco Company) will predictably continue to manufacture, distribute, sell, advertise, market,
3 and promote such cigarettes to current menthol cigarette smokers (e.g., Plaintiff Lisa Mitchell),
4 the Black community (e.g., Plaintiff Ben Smith, a former menthol cigarette smoker, and his son, a
5 current menthol smoker), women (e.g., Plaintiff Lila June, who is also Black), and youth (e.g.,
6 Plaintiff AATCLC member Val Yerger’s grandchildren, who are also Black).

7 358. For years, Defendants have long been aware of the targeting of the Black
8 community and youth by the tobacco companies that manufacture, sell, and distribute menthol
9 cigarettes. Despite declarations to the contrary, on the whole Defendants have failed to act in
10 accordance with their own research and the broader scholarship of which they indicate
11 awareness.

12 359. For over a decade, Defendants have clearly been aware of the negative public
13 health impact of the targeting of the Black community and youth via the marketing,
14 manufacture, distribution, and sale of menthol cigarettes.

15 360. In 2011, as required by the Family Smoking Prevention and Tobacco Control
16 Act, FDA’s Tobacco Products Scientific Advisory Committee (TPSAC), released its report, based
17 on the available scientific evidence at the time, regarding the impact of menthol cigarettes on the
18 public health. Their recommendation was conclusive: “removal of menthol cigarettes from the
19 marketplace would benefit public health in the United States.” 2011 TPSAC Menthol Rept. at
20 225.

21 361. Part of the evidence reviewed by TPSAC in reaching this conclusion focused on
22 the history of tobacco companies targeting the Black community and youth via menthol
23 cigarettes.

24 362. With respect to targeting of the Black community, TPSAC’s overall conclusion
25 was that “[t]he tobacco industry’s internal documents illustrate sustained efforts to target African
26 Americans through the development and advertising of menthol products and through corporate
27 involvement in community-based organizations.” *Id.* at 21.

1 363. This included targeting via Black print media (e.g. Jet, Essence, Ebony, and key
2 newspapers), music promotions (e.g., Kool Jazz concerts, Kool mobile music tour), using vans to
3 distribute large quantities of free cigarettes in Black communities, deploying specialized
4 promotion campaigns in inner cities, billboard advertising in Black neighborhoods, and
5 specialized branding. *Id.*

6 364. Studies reviewed by TPSAC concluded that a magazine targeted at African
7 Americans was 9.8 times more likely to contain a menthol ad than a magazine targeted at white
8 Americans. *Id.* at 24.

9 365. Evidence from the TPSAC report suggests that tobacco companies targeted Black
10 people in urban areas on account of their vulnerability due to pressing concerns as a result of
11 widespread poverty and other issues threatening their communities:

12 In a “Black Opportunity Analysis” conducted by R. J. Reynolds in
13 1985, the company’s research observed that an “underclass” of
14 African American smokers would remain reliable customers in
15 spite of growing health concerns: “Blacks simply have more
16 pressing concerns than smoking issues.” (R.J. Reynolds 1985, cited
17 in Anderson 2011). A 1983 industry study of low-income African
18 American smokers observed that recall of advertising for specific
19 menthol brands had improved since 1979 and “the use of menthol
20 cigarettes among the 18–34 lower income Black segment is almost
21 universal.” *Id.* at 23.

22 366. Tobacco companies marketing and selling menthol undertook a similar campaign
23 with youth. The TPSAC report concluded that “the industry developed menthol marketing to
24 appeal to youth ... Marketing messages positioned menthol cigarettes as an attractive starter
25 product for new smokers who are unaccustomed to intense tobacco taste and/or high levels of
26 menthol. Empirical studies provide further evidence of targeting: youth pay attention to and are
27 attracted to menthol cigarette advertising. Cigarette advertising, including menthol cigarette
28

1 advertising, has a greater impact on the brand choice of adolescents than it does for adult
2 smokers.” *Id.* at 20.

3 367. Studies evaluated in the TPSAC report showed that youth brand preference was
4 driven primarily by brand-specific advertising expenditure, as opposed to total market share. *Id.*
5 at 19–20.

6 368. Of course, hooking kids on cigarettes early has long been a crucial part of the
7 tobacco industry’s business model.⁷⁸

8 369. Menthol has played a crucial role in that process. As articulated by R.J. Reynolds
9 in a 1982 marketing report cited in the TPSAC study, menthol smokers are “‘the (Coolness
10 Segment) ... the youngest, the most economically disadvantaged, and the most likely to be in
11 minority and ethnic groups,’ who ‘tend, more than average, to desire their brand of cigarettes to
12 symbolize personal qualities ...’” 2011 TPSAC Menthol Rept. at 14.

13 370. Thus, it is important to recognize, as the TPSAC report did, that tobacco
14 companies are targeting youth and the Black community as part of an overall effort, historically
15 crucial to the business model of tobacco companies, to target vulnerable and marginalized youth,
16 addict them early, establish brand preference, and profit off of the ensuing public health harm.

17 371. In 2011, in the remarks of Lawrence R. Deyton, Director of the CTP, regarding
18 the TPSAC report on menthol, the FDA stated that “a top priority for FDA is to protect the
19 public health from the harmful effects of tobacco use by preventing youth from starting to use
20 tobacco products and encouraging current users to stop.”⁷⁹

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25 ⁷⁸ See Glantz and Ling, *Why and How the Tobacco Industry Sells Cigarettes to Young Adults: Evidence From*
26 *Industry Documents*, American Journal of Public Health (June 2002). Available at:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447481/>.

27 ⁷⁹ Available at:
28 [https://web.archive.org/web/20110403020313/http://www.fda.gov/AdvisoryCommittees/Co
mmitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm](https://web.archive.org/web/20110403020313/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm).

1 372. As previously noted, in response to the TPSAC report the FDA underwent a
2 multiyear independent evaluation of the scientific evidence regarding menthol, released to the
3 public in 2013. *See* 2013 FDA Findings.⁸⁰

4 373. Their conclusions regarding targeting mirror those of the TPSAC report. The
5 FDA wrote that “[r]esearch indicates tobacco companies with menthol brands use a marketing
6 mix and concepts that target African Americans,” including via advertising in magazines with
7 primarily African American readership, comparatively high placement of outdoor menthol
8 advertisements in African American neighborhoods, free sampling, mobile vans, event
9 sponsorships, and inner-city sales programs. *Id.* at 68. Additionally, the FDA’s report
10 summarized reviews of “industry documents that suggest players in the tobacco industry formed
11 strategic partnerships with national and community African American organizations to gain
12 support for their menthol brands.” *Id.* at 69.

13 374. The FDA also noted the overlap between menthol marketing to African
14 Americans and youth, reporting the results of an observational study which examined the
15 number of ads in and around retail establishments and finding correlation between ad quantity
16 and use by middle schoolers—Kool, the brand with the most ads, was also the most commonly
17 used. Themes in these ads, “reflect[ing] an urban, “cool” lifestyle have been used in advertising
18 campaigns and product names to promote menthol cigarettes to the African American
19 community.” *Id.* at 68.

20 375. Similarly, the FDA reported that “Menthol advertisements were particularly
21 common in areas with higher proportions of African Americans and youth 10-17 years old. The
22 proportion of stores that advertised promotions for Newport (menthol), Marlboro Menthol, and
23 Marlboro (nonmenthol) were 27 percent, 51.4 percent, and 75 percent, respectively. When
24 analyzed further, researchers found that for every 10 percent increase in the proportion of
25 African American students in the neighborhood, the odds of a store advertising promotions for
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28 ⁸⁰ *Available at:* <https://www.fda.gov/media/86497/download>.

1 Newport were 1.5 times greater.”. And for each 10 percent point increase in African American
2 students, the price of Newports decreased by \$0.12. *Id.* at 70

3 376. The report concluded that the evidence “indicate[d] tobacco industry knowledge
4 and acceptance that menthol provides a mechanism through which new smokers are able to
5 more successfully initiate smoking.” *Id.* at 95.

6 377. The FDA has continued to note the consistent targeting of menthol to vulnerable
7 populations. In FDA Commissioner Scott Gottlieb’s March 14, 2018 statement “on efforts to
8 reduce tobacco use, especially among youth, by exploring options to address the role of flavors –
9 including menthol – in tobacco products,” he stated that “for years we have recognized that
10 flavors in these products appeal to kids and promote youth initiation,” and “we know that youth
11 who initiate smoking with menthol cigarettes may be at a greater risk of progression from
12 experimentation to established smoking and nicotine dependence.”⁸¹

13 378. In the 2022 FDA Proposed Menthol Rule, 87 Fed. Reg. 26454, the FDA
14 explained the following:

15 “[R]esearch indicates that in the 1960s and 1970s, the tobacco
16 industry’s menthol cigarette advertising and promotion heavily
17 targeted the African American community by use of darker-
18 skinned models, tailored messaging and language, and reliance on
19 media such as magazines with a high Black readership (Refs. 168,
20 90, and 92). Industry research identified the cultural values,
21 geographic location, and taste preferences of Black smokers, which
22 was then used to inform tobacco product branding (e.g., “Kool”
23 cigarettes), culturally-tailored imagery in advertisements, and
24 locations to reach and appeal to Black menthol smokers.”

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27 ⁸¹ Available at: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking>.

1 379. The FDA’s proposed rule also noted that tobacco companies producing,
2 marketing, and selling menthol cigarettes have targeted vulnerable populations, including
3 African Americans and youth, with discounts, distribution of free samples, advertising in
4 nightclubs, bars, and special events, and smaller package quantities to provide a lower price
5 point. *Id* at 50.

6 380. In addition to analyzing historical examples of tobacco companies using menthol
7 to target vulnerable populations, the FDA also concluded that these actions remained ongoing,
8 citing data that showed that menthol marketing remains more prevalent in neighborhoods with
9 Black and low-income residents, and data showing that tobacco retailers are still more likely to
10 advertise and sell menthols at lower prices and/or discounts in Black neighborhoods. *Id*.

11 381. As consistently emphasized over the last decade of research by the FDA and
12 associated parties, the FDA again found that higher exposure to menthol retailing and
13 advertisements was directly associated with disparities in tobacco use among youth. *Id*. at 51.

14 382. In this final rule, appropriately given the preponderance of the evidence, the FDA
15 did not mince words:

16 “Taken together, scientific evidence indicates that menthol
17 cigarettes have historically and continue to be disproportionately
18 marketed in underserved communities and contribute to the
19 longstanding disparities in menthol cigarette smoking and health
20 outcomes observed in vulnerable populations, particularly the
21 Black community. While targeted marketing is only one factor in
22 the development and perpetuation of menthol cigarette use and
23 related harms, this background helps to explain and provide
24 critical context for the outcomes and disparities that undermine
25 public health and are of concern to FDA. Addressing how these
26 products disproportionately affect vulnerable populations supports
27 the Agency’s mission of promoting public health.” *Id*.

1 383. Other research efforts have reached similar—or even more alarming—
2 conclusions regarding the extent of menthol targeting by tobacco companies in the present day.
3 A comprehensive analysis of the role advertising plays in driving the popularity of menthol
4 tobacco products conducted by Robert Jackler, principal investigator at Stanford Research into
5 the Impact of Tobacco Advertising (SRITA) concluded that “[t]he prodigious growth in
6 popularity of menthol cigarettes over recent decades did not arise spontaneously – it was
7 orchestrated by major tobacco companies,” and “[r]ecent menthol cigarette advertising has not
8 modulated from its excesses of the past.”⁸²

9 384. Jackler found that deception and targeting of vulnerable populations by tobacco
10 companies through menthol marketing was continuing “with unabated vigor and creativity,”
11 including through the greenwashing of menthol via representations such as “organic,” and “from
12 farm to pack,” the continued use of themes of youthfulness ,coolness, popular music and
13 partying, and entirely new innovations, such as menthol “crushers” that flood the senses with a
14 surge of menthol flavor.” *Id.* at 3.

15 385. In May 2024, the CDC published a study on its webpage under the “Preventing
16 Chronic Disease,” issue section, which emphasizes continued concerns as relating to the targeting
17 Black communities by tobacco companies via menthol.⁸³

18 386. Echoing decades of research, the authors concluded that “tobacco companies
19 have aggressively marketed menthol tobacco products in Black communities,” including via a
20 higher number of tobacco retailers and more marketing of menthol products. *Id.*

21 387. Tobacco company targeting of vulnerable communities, including targeting of
22 low-income Black youth, has previously been proven in court, including in *Evans v. Lorillard*, a
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25 ⁸² Jackler et al, *Advertising Created & Continues to Drive the Menthol Tobacco Market: Methods Used by the*
26 *Industry to Target Youth, Women and Black Americans*, SRITA (October 3, 2022). Available at
<https://stanfordmedicine.app.box.com/s/0dydu6qzbsumpdwoarbzkzbi7q62no98b>.

27 ⁸³ *It's Not Just: Evaluation of a Media Campaign to Motivate Action Around Targeting of Menthol Tobacco in*
28 *Black Communities* (April 11, 2024). Available at
https://www.cdc.gov/pcd/issues/2024/23_0237.htm.

1 case in which Lorillard was found liable for their targeting of plaintiff Marie Evans.⁸⁴ Starting at
2 the age of nine, Lorillard dispensed free cigarettes to Evans at the playground, and contributed to
3 misinformation which obscured the health risk of Evans' smoking from her throughout her life.
4 After trying to quit numerous times, Ms. Evans contracted lung cancer, as her father had, and
5 passed away at 54.⁸⁵

6 388. Ms. Evans' son, Will Evans, sued Lorillard, documenting their targeting actions
7 with testimony, industry documents proving that "sampling" events had occurred, and evidence
8 showing that as late as 1990, Lorillard continued to study its marketing impact on children in the
9 12–17 year age demographic. The judge called the evidence for targeting "overwhelming." *Id.*

10 389. More broadly, the CDC's message is clear: "Menthol Tobacco Products Are A
11 Public Health Problem" is the title of one of their webpages, in which they state that aggressive
12 marketing tactics to vulnerable populations are a crucial element of the overall public health
13 harm of menthol cigarettes, along with the fact that menthols make it easier to start and harder
14 to quit.⁸⁶

15 390. From the profit-maximizing perspective of tobacco companies, there is substantial
16 reason for this intensive and continuous marketing effort. A 2021 effort to quantify the total harm
17 caused by menthol smoking to the African American population concluded that in the period
18 between 1980-2018, menthol cigarettes were responsible for 10 million new smokers, along with
19 the corresponding massive health impact: for African Americans, menthol cigarettes specifically
20 were responsible for 157,000 smoking-related premature deaths and some 1.5 million life years
21 lost, 41% and 50% of smoking-related harm quantified by those means, respectively.⁸⁷

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⁸⁴ *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997 (Mass. 2013).

23 ⁸⁵ *Evans v. Lorillard: A Bittersweet Victory Against the Tobacco Industry*, Tobacco Control Legal
24 Consortium (August 2016). Available at
25 <https://publichealthlawcenter.org/sites/default/files/resources/tclc-Evans-v-Lorillard-case-study-2016.pdf>.

26 ⁸⁶ Available at <https://www.cdc.gov/tobacco/menthol-tobacco/public-health-problem.html>.

27 ⁸⁷ Mendez and Le, *Consequences of a match made in hell: the harm caused by menthol smoking to the African*
28 *American population over 1980-2018*, Tobacco Control, at 3 (Sep. 16, 2021). Available at
<https://pubmed.ncbi.nlm.nih.gov/34535507/>.

1 391. Throughout this period, tobacco companies have reaped massive profits partially
2 and in some cases, such as Lorillard (which previously owned Newport), almost entirely on the
3 basis of increased market penetration, revenues, and profits from menthol cigarettes. As the FTC
4 noted in their 2021 Cigarette Report, (“2021 Cigarette Rept.”) “[t]he market share for menthol
5 cigarettes has more than doubled over the years.”⁸⁸

6 392. As shareholder-owned, publicly traded corporations, tobacco companies are
7 primarily motivated by this profit incentive and the necessity for continuous growth, which
8 typically drives increases in stock price as well.

9 393. Overall, menthol cigarettes represent roughly 37% of cigarette market share, up
10 from 26% in 2000.⁸⁹

11 394. The size of the American cigarette market is \$82.6 billion dollars, so menthol
12 represents roughly \$30 billion of those sales figures.⁹⁰

13 395. As relayed in a 2022 study, “smoking is declining, except among current menthol
14 smokers.”⁹¹ The proportion of menthol cigarettes in the market is rising. In 1963, menthol
15 represented just 16% of the cigarette market share, rising to 20% in 1967. It then took over forty
16 years, until 2009, for menthol to represent 30% of overall market share. In 2021, just 12 years
17 later, menthol represented 37% of the overall cigarette market. 2021 Cigarette Rept.

18 396. Researchers further found that increases in menthol smoking from 2003-2019
19 were observed in targeted groups: non-Hispanic Black people (76.8% in 2018–2019 from 73.0%
20 in 2003), young adults, (37.7% in 2018–2019 from 31.7% in 2003), and women (39.6% in 2018–
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22 ⁸⁸ Available at https://www.ftc.gov/system/files/ftc_gov/pdf/pl14508cigarettereport2021.pdf.

23 ⁸⁹ *Menthol: facts, stats and regulations*, Truth Initiative (Jan. 23, 2024). Available at
24 <https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations>.

25 ⁹⁰ *United States Cigarette Market Report by Type (Light, Medium, and Others), Distribution Channel (Tobacco
26 Shops, Supermarkets and Hypermarkets, Convenience Stores, Online Stores, and Others), and Region 2024-2032*,
IMARC Group (2023). Available at <https://www.imarcgroup.com/united-states-cigarette-market>.

27 ⁹¹ Seaman et al., *Menthol Cigarette Smoking Trends Among United States Adults, 2003-2019*, *Cancer
28 Epidemiol Biomarkers Prev.* (Oct. 4, 2022). Available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9532352/>.

1 2019 from 32.1% in 2003). Targeting of vulnerable groups works, as does promoting a product
2 that is easier to pick up and harder to quit than a typical cigarette.

3 397. Reynolds American Inc., which owns the Newport, Camel, Pall Mall, Lucky
4 Strike, Misty, and American Spirit cigarette brands, among others, had 48% of the total 2019
5 menthol market share.⁹²

6 398. Philip Morris USA / Altria Group, the other major player in American menthol,
7 which owns the Marlboro, Parliament, Virginia Slims, L & M, and Basic cigarette brands, had
8 32% of the 2019 menthol market share. *Id.*

9 399. For the two companies which dominate menthol and cigarette sales in America
10 generally, as well as for manufacturers, distributors, marketers, and sellers of menthol cigarettes
11 more broadly, menthol is crucial to meeting—and exceeding—the bottom line due to its
12 increasing centrality in the market.

13 400. Historically, tobacco companies have placed profit first, being generally willing to
14 engage in costly efforts to preserve market share and size regardless of the legality or morality of
15 the project. These efforts include, but are not limited to, knowingly promoting false claims about
16 the lack of health risk—and health benefits—of cigarettes, funding research presenting favorable
17 views of tobacco products, extensive lobbying efforts (despite the illegality of tobacco lobbying),
18 engaging in disingenuous claims about the natural and sustainable nature of their products,
19 bribery, intimidation, claiming a public health role, the creation of fake pro-tobacco third party
20 groups, involvement in illicit smuggling and trade, and of course, targeted marketing efforts and
21 price promotions.⁹³

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24 ⁹² Miller et al., *Trends in Overall and Menthol Market Shares of Leading Cigarette Brands in the USA: 2014-*
25 *2019*, International Journal of Environmental Research and Public Health (Feb, 17, 2022).
26 Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8871779/>

27 ⁹³ See, e.g., *Tobacco Industry Tactics*, Tobacco Tactics (last edited Mar. 20, 2024), available at
28 <https://tobaccotactics.org/article/tobacco-industry-tactics/>; Gannon et al., *Big tobacco's dirty tricks:*
Seven key tactics of the tobacco industry, Tobacco Prevention and Cessation (Dec. 20, 2023), available at
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10731746/#:~:text=Members%20of%20the%20Tobacco%20Control,2\)%20Front%20groups%2C%203](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10731746/#:~:text=Members%20of%20the%20Tobacco%20Control,2)%20Front%20groups%2C%203).

1 401. With regard to menthol, tobacco companies are telling us how important these
2 products are to their business model with their efforts and their pocketbooks. Reynolds American
3 and Philip Morris pumped more than \$20 million dollars into the campaign to block SB 793, a
4 bill that ultimately blocked the sale of menthol cigarettes in California, and paid protestors \$80
5 each to organize against the bill. They have sponsored dinners for Black legislators in which
6 prominent Black leaders speak against banning menthol cigarettes across the country.⁹⁴

7 402. As established, menthol continues to be marketed disproportionately to the Black
8 community, youth, and other vulnerable groups. This tactic has inflated the overall market share
9 of tobacco companies beyond what it would be otherwise, bolstering profits for RJ Reynolds,
10 Philip Morris, and others. The campaign to promote, distribute, and sell menthol cigarettes to
11 vulnerable groups through targeted marketing and price promotions has proven one of the
12 central business strategies for tobacco companies in the contemporary period. As it becomes
13 more and more essential for tobacco companies to retain this source of profit, given the
14 overwhelming evidence that tobacco companies chase profits even when doing so causes them to
15 shirk legal obligations and act immorally, what will occur if the FDA allows menthol cigarettes to
16 remain on the market is eminently predictable.

17 403. Tobacco companies will proceed with their plan to preserve their profits, using the
18 combination of their past successes in addicting vulnerable communities and the increased
19 addictiveness of menthol to continue to target the Black community, youth, and other
20 demographic groups which exhibit higher rates of menthol usage.

21 404. As such, plaintiffs in this lawsuit can reasonably expect further harms to
22 themselves and their communities via the continued presence of menthol on the market and
23 continued tobacco company targeting if the FDA does not act and add menthol to the flavor ban.
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26 ⁹⁴ Stockton et al, *Paid Protesters, Free Lunches and Backroom Chats: Inside the Menthol Lobbying Machine*,
27 The Bureau of Investigative Journalism (April 25, 2022). Available at
28 <https://www.thebureauinvestigates.com/stories/2022-04-25/inside-the-menthol-cigarette-lobbying-machine/>.

ii. Executive Order 12866 does not absolve Defendants of their unlawful and unreasonable inaction.

405. The Defendants’ inaction and harm to Plaintiffs and the public health is not absolved by Executive Order 12866, or else Defendants’ erroneous suggestion that the Menthol Rule is “presently with the White House.”⁹⁵ This is true for at least two reasons:

406. First, the Executive Order 12866 provides that “[n]othing in this order shall be construed as displacing the agencies’ authority or responsibilities, as authorized by law.” E.O. 12866, § 9 (Sept. 30, 1993).

407. In other words, Executive Order 12866 does not override or displace the Defendants’ existing responsibilities under the Tobacco Control Act and Administrative Procedure Act, including the following:

- a. Promulgating rules and regulations that are appropriate for the protection of the public health, 21 U.S.C. § 387g(d);
- b. Concluding each matter presented to an agency “within a reasonable time,” 5 U.S.C. § 555(b); and
- c. Ensuring that the agency’s actions are not “unlawfully withheld or unreasonably delayed,” *id.* § 706(1), or else “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” *id.* § 706(2)(A).

408. Stated somewhat differently, the Executive Order “is intended only to improve the internal management of the Federal Government,” E.O. 12866 § 10.

409. Second, even assuming arguendo that Executive Order 12898’s guidelines applied here, the time for OIRA’s review has passed and the responsibility for promulgating and publishing the Menthol Rule has since returned to the Defendants.

⁹⁵ On September 10, 2024, Defendant CTP Director Brian King testified (erroneously) before Congress that the Menthol Rule product standard is “presently with the White House.” Health Comm. On Energy and Commerce Hr’g, “Evaluating Human Foods and Tobacco Programs.” Available at: <https://www.youtube.com/watch?v=yK8y5bO-2ik&t=7243s>.

1 410. By its own terms, the Executive Order provides that OIRA “shall maintain a
2 publicly available log that shall contain, at a minimum, the following information pertinent to
3 regulatory actions under review (i) The status of all regulatory actions, including if (and if so,
4 when and by whom) Vice Presidential and Presidential consideration was requested; (ii) A
5 notation of all written communications forwarded to an issuing agency ...; and (iii) The dates and
6 names of individuals involved in all substantive oral communications, including meetings and
7 telephone conversations, between OIRA personnel and any person not employed by the
8 executive branch of the Federal Government, and the subject matter discussed during such
9 communications.” E.O. 12866, § 6(b)(4)(C).

10 411. Per Section 6(b) of the Executive Order, OIRA “shall waive review or notify the
11 agency in writing of the results of its review ... within 90 calendar days after the date of
12 submission of the information,” E.O. 12866 § 6(b)(2)(B). That time for review “may be extended
13 (1) once by no more than 30 calendar days upon the written approval of the [OIRA] Director
14 and (2) at the request of the agency head.” *Id.* § 6(b)(2)(C).

15 412. And per Section 8 of the Executive Order, if “(1) the Administrator of OIRA
16 notifies the agency that OIRA has waived its review of the proposed action or has completed its
17 review without any request for further consideration, or (2) the applicable time period in section
18 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action
19 for further consideration under section 6(b)(3), whichever occurs first,” E.O. 12866 § 8, the
20 agency is then free under the guidelines of the Executive Order to publish the regulatory action
21 in the Federal Register.

22 413. Here, a review of OIRA’s publicly available record concerning the Menthol
23 Rule’s status shows that despite the Executive Order’s directive to share “the status of all
24 regulatory actions,” including “if (and if so, when and by whom) Vice Presidential and
25 Presidential consideration was requested,” the publicly available record—

- 26 a. lacks any record that OIRA returned the proposed Menthol Rule for further
27 consideration under Section 6(b)(3) of the Executive Order; or else
28

1 b. lacks any record that OIRA, OMB, an agency head, or the Defendants had
2 requested consideration of the Menthol Rule by the Vice President or President of
3 the United States (e.g., to resolve any conflict between the Defendants, OMB, or
4 OIRA, *see* E.O. 12866 § 7).

5 *See* OIRA Pending EO 12866 Regulatory Review (RIN 0910-AI60) (last visited Sept. 16, 2024),
6 available at <https://www.reginfo.gov/public/do/eoDetails?rrid=341268>.

7 414. In other words, none of the events that might trigger a further review of the
8 Menthol Rule appears to have occurred. Accordingly, Section 8 provides that when “the
9 applicable time period in section 6(b)(2) expires,” then the Defendants are free to publish the
10 regulatory action (i.e., the Menthol Rule) in the Federal Register.

11 415. And here, because the applicable time period provided by section 6(b)(2) has
12 expired—i.e., over 120 days have passed since October 13, 2023, when OIRA received the draft
13 Menthol Rule from the Defendants—Executive Order 12866 does not pose a bar to Defendants’
14 promulgation and publication of the final Menthol Rule.

15 **3. A favorable decision from this Court will likely redress**
16 **Plaintiffs’ injuries.**

17 416. A favorable decision from this Court—e.g., directing Defendants to promulgate
18 and publish the Menthol Rule—will likely redress Plaintiffs’ injuries and imminent injuries.

19 417. If the Defendants are directed to promulgate and publish the Menthol Rule, the
20 tobacco companies will be barred from manufacturing—much less distributing, selling,
21 advertising, marketing, or promoting—any cigarette in the United States that has menthol as a
22 characterizing flavor. Defendants will be unable to target (as they have for so long) Plaintiffs and
23 other vulnerable populations with menthol cigarettes.

24 418. In all likelihood, a favorable decision from this Court would encourage Plaintiffs
25 and other menthol smokers to quit, and one of this nation’s largest public health disparities
26 (costing billions on medical care costs, and an untold number of lives lost to nicotine addiction)
27 would begin to close.

1 419. In light of the foregoing, Plaintiffs allege the following claims and seek the
2 following relief.

3 **CLAIMS FOR RELIEF**

4 **Count I: Violation of the Administrative Procedure Act**

5 **(5 U.S.C. §§ 555(b) & 706(1))**

6 420. Plaintiffs incorporate by reference each of the foregoing allegations, above.

7 421. Section 555(b) of the Administrative Procedure Act requires each agency “to
8 conclude a matter presented to it” “within a reasonable time,” 5 U.S.C. § 555(b). Section 706(1)
9 provides that a reviewing court “shall compel agency action unlawfully withheld or unreasonably
10 delayed,” *Id.* § 706(1).

11 422. Together, Sections 555(b) and 706(1) “indicate a congressional view that agencies
12 should act within reasonable time frames and that courts designated by statute to review agency
13 actions may play an important role in compelling agency action that has been improperly
14 withheld or unreasonably delayed.” *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70,
15 76–77 (D.C. Cir. 1984). Accordingly, “delays that might be altogether reasonable in the sphere of
16 economic regulation are less tolerable when human lives are at stake.” *Cutler v. Hayes*, 818 F.2d
17 879, 898 (D.C. Cir. 1987) (footnotes omitted).⁹⁶ “This is particularly true when the very purpose
18 of the governing Act is to protect those lives.” *Public Citizen Health Research Group v. Aughter*, 702
19 F.2d 1150, 1157–58 (D.C. Cir. 1983).

20 423. The Defendants have unlawfully withheld or unreasonably delayed promulgating
21 a final rule banning menthol as a characterizing flavor in combustible cigarettes.

22 424. The Tobacco Control Act provides that “[a]fter the expiration of the period for
23 comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco
24 product standard and after consideration of comments submitted under subsections (b) and (c)
25 and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall ...
26 if the Secretary determines that the standard would be appropriate for the protection of the

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28 ⁹⁶ *See also Cutler*, 818 F.2d at 898 n.162 (noting further that “the risk to human life need not be a
certainty to justify expedition”).

1 public health, promulgate a regulation establishing a tobacco product standard and publish in
2 the Federal Register findings on the matters referred to in subsection (c) [i.e., 21 U.S.C. §
3 387g(c).]” 21 U.S.C. § 387g(d)(1)(A).

4 425. Here, each pre-condition to the Defendants’ promulgation and publication of a
5 final rule has been met. First, the comment period to the proposed Menthol Rule has closed. *See*
6 *FDA, Comment Period Closed for FDA Proposed Rules Prohibiting Menthol Cigarettes and Flavored Cigars*
7 (Aug. 10, 2022).⁹⁷ Second, the Defendants have already considered the Tobacco Products
8 Scientific Advisory Committee’s 2011 Menthol Report; as well as the comments and information
9 submitted pursuant to subsections (b) and (c), *see* 21 U.S.C. § 387g(b), (c). And third, the Secretary
10 has already determined that the proposed Menthol Rule is appropriate for the protection of the
11 public health.

12 426. Given that each element to promulgating and publishing a final rule is present,
13 the Tobacco Control Act mandates that the Secretary “shall ... promulgate” such regulation
14 “and publish in the Federal Register findings on the matters” Defendants’ failure to do so
15 here, constitutes a violation of the Tobacco Control Act.

16 427. And given that Defendants’ inaction is harming the public health (i.e., by causing
17 youth smoking and decreasing smoking cessation among smokers), Defendants’ failure here
18 constitutes agency action “unlawfully withheld or unreasonably delayed,” 5 U.S.C. § 706(1), and
19 a failure to “conclude a matter” within a reasonable time, *id.* § 555(b).

20 428. Given this ongoing harm, the FDA’s unreasonable delay and inaction violates
21 both the Tobacco Control Act and Administrative Procedure Act. *See Cutler*, 818 F.2d at 897
22 n.156 (“There comes a point when relegating issues to proceedings that go on without conclusion
23 in any kind of reasonable time frame is tantamount to refusing to address the issues at all—and
24 the result is a denial of justice.”).

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28 ⁹⁷ Available at <https://www.fda.gov/tobacco-products/ctp-newsroom/comment-period-closed-fda-proposed-rules-prohibiting-menthol-cigarettes-and-flavored-cigars>.

Count II: Violation of the Administrative Procedure Act
(5 U.S.C. § 706(2)—Arbitrary and Capricious)

429. Plaintiffs incorporate by reference each of the foregoing allegations, above.

430. Despite the overwhelming evidence that removing menthol cigarettes from the marketplace would benefit public health and Defendant FDA’s own stated intention to ban menthol in combustible cigarettes for these reasons, Defendants have declined to add menthol to the flavor ban list, 21 U.S.C. § 387g(a)(1)(A).

431. Defendants have failed to provide any coherent explanation for this decision, failed to engage in any reasoned decision-making in reaching this determination, and reached a conclusion that contradicts the underlying record and expert evidence.

432. At most, Defendants have been pressured—and remain pressured—by President Biden, Vice President Harris, OMB, OIRA, and other White House officials to delay the promulgation and publication of the Menthol Rule due to its perceived negative impact on the Democratic presidential nominee’s chances in the November 2024 election. The Defendants have improperly and unlawfully acceded to such pressure at a great cost to the public health and the rule of law.

433. Defendants’ improper consideration of politics—e.g., President Biden’s or else Vice President Kamala Harris’ likelihood of winning the November 2024 election—as part of its decision to refrain from promulgating and publishing the final Menthol Rule constitutes “agency action” subject to judicial review, and is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, *see* 5 U.S.C. § 706(2).

REQUESTED RELIEF

WHEREFORE, Plaintiffs request that this Court enter the following:

1. Pursuant to 28 U.S.C. § 2201, an Order declaring Defendants to be in violation of the Administrative Procedure Act;

2. Pursuant to 28 U.S.C. § 2201, an Order declaring Defendants to be in violation of the Tobacco Control Act;

1 3. Pursuant to the Administrative Procedure Act, Tobacco Control Act, 28 U.S.C.
2 §§ 1361 and 1651, an Order directing Defendants to—

3 a. Promulgate the Menthol Rule—i.e., the proposed regulation establishing a
4 tobacco product standard to ban menthol as a characterizing flavor for
5 combustible cigarettes, *see* 21 U.S.C. § 387g(d)(1)(A);

6 b. Publish in the Federal Register the Secretary’s “findings,” *id.* § 387g(d)(1)(A), and
7 “supporting justification” as to why the establishment of this new tobacco product
8 standard “is appropriate for the protection of public health,” *id.* § 387g(c)(1); and

9 c. Complete such actions within a reasonable timeframe.

10 4. Pursuant to 28 U.S.C. § 2412 and 5 U.S.C. § 504, an Order awarding Plaintiffs
11 their reasonable costs and attorneys’ fees; and

12 5. Pursuant to 28 U.S.C. § 2202, an Order granting all other necessary or proper
13 relief as necessary.

14
15 Date: September 16, 2024
16 Brooklyn, NY

Respectfully submitted,

/s/ Christopher K. Leung

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