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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, ACTION ON SMOKING AND HEALTH, NATIONAL MEDICAL ASSOCIATION, and AMERICAN MEDICAL ASSOCIATION, Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; U.S. FOOD AND DRUG ADMINISTRATION; 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 **FIRST AMENDED COMPLAINT (Administrative Procedure Act Case)**

1. Plaintiffs African American Tobacco Control Leadership Council ("AATCLC"), Action on Smoking on Health ("ASH"), National Medical Association ("NMA"), and American Medical Association ("AMA") allege upon knowledge as to themselves, and upon information and belief as to all other matters, as follows:

INTRODUCTION

2. This case involves (a) Defendants' continuing failure to conclude the critical public health issue of menthol in cigarettes—an issue that Congress directed the Defendants to address in 2009; and (b) Defendants' unreasonable delay in promulgating and publishing a final rule that bans menthol as a characterizing flavor in cigarettes, consistent with the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified, in relevant part, at 15 U.S.C. §§ 1333–34 and 21 U.S.C. § 301 *et seq.*) (2009) ("Tobacco Control Act").

3. In 2009, Congress enacted the Tobacco Control Act and handed the critical public health issue of menthol in cigarettes to the Defendants—i.e., the U.S. Department of Health and Human Services ("HHS") and its Secretary, the U.S. Food and Drug Administration ("FDA") and its Commissioner, as well as the Center for Tobacco Products ("CTP") and its Director. This Act, among other things, established the FDA's authority to regulate tobacco products, 21 U.S.C. § 387a, and banned all characterizing flavors in cigarettes, save for tobacco and menthol (i.e., the "flavor ban"), *id.* § 387g(a)(1). This flavor ban was intended to protect the public health, by banning the manufacture and sale of cigarettes "that appeal to youth."[1]

4. Although it did not ban menthol at that time, Congress recognized that menthol cigarettes might "pose unique health risks to those who smoke them."[2] Congress was "especially concerned about proportionately higher rates of menthol cigarette use among African American smokers"; "the historic targeting of African Americans for menthol cigarette use by tobacco companies"; "the high rates of [menthol cigarette] use among … African American youth"; as

[1] H. Rept. 111-58, Part 1, Tobacco Control Act, 111th Congress (2009–10), 37 (Energy and Commerce Comm.) ("H. Rept., Part 1"). *Available at* https://www.congress.gov/111/crpt/hrpt58/CRPT-111hrpt58-pt1.pdf.

[2] *Id.* at 38.

well as the "higher rates of lung cancer documented among African American smokers as compared to non-African American smokers[.]"[3]

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

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

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

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

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[3] *Id.*

[4] Cong. Rec.—House, H4318, H4339 (Vol. 155, No. 55) (Apr. 1, 2009); Cong. Rec.—House, 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.

[5] *See* Fed. Trade Comm., Cigarette Rept. for 2017, Table 7B (issued 2019). *Available at* 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.

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

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

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

9. To address Defendants' inaction, the Plaintiffs sued the Defendants in 2020. *See African American Tobacco Control Leadership Council et al. v. U.S. Dep't of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.) ("*Menthol Lit. I*"). In that lawsuit, Plaintiffs alleged the Defendants' violation of the Tobacco Control Act and Administrative Procedure Act, Pub. L. No. 404, 60 Stat. 237, ch. 324, §§ 1–12 (1946), and sought to compel (a) Defendants' formal determination on menthol, consistent with 21 U.S.C. § 387g(a)(5) (i.e., to determine whether menthol should be added to the list of banned characterizing flavors, based on the available medical, scientific, and technological data), and (b) Defendants' substantive response to Plaintiffs'

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[6] *See* FDA, Menthol and Other Flavors in Tobacco Products. *Available at* https://web.archive.org/web/20200617110626/https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products (noting that "[m]ore than 19.5 million people are current smokers of menthol cigarettes"); Centers for Disease Control and Prevention, Smoking & Tobacco Use, Current Cigarette Smoking Among 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/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).

Citizen Petition, which requested the FDA's promulgation of a final rule banning menthol as a characterizing flavor.

10. Through Plaintiffs' litigation, the Defendants formally responded to Plaintiffs' Citizen Petition, and determined—for the first time, nearly 12 years after Congress' initial direction—that menthol should be added to the list of banned characterizing flavors. At this Court's strong urging, the Defendants later issued a May 2022 Notice of Proposed Rulemaking that proposed banning menthol cigarettes. *See* HHS / the FDA, *Tobacco Product Standard for Menthol in Cigarettes*, Dkt. No. FDA-2021-N-1349, 87 Fed. Reg. 26454 (May 4, 2022) (RIN 0910-AI60, adding part 1162 to subchapter K) ("Proposed Menthol Rule" or "Notice").[8] If implemented, this "landmark policy"[9] would, *inter alia*, save hundreds of thousands of people from a premature smoking-related death, save millions of lives from a lifetime of nicotine addiction, and result in medical cost savings of between $100 billion and $300 billion annually.

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

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

a. The Secretary has published a Notice of Proposed Rulemaking in the Federal Register and the comment period has closed, *see id.*;

b. The Secretary has considered (i) comments submitted in response to the Notice, (ii) comments concerning the "technical achievability of compliance with such standard," (iii) "all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the

[8] *Available at* https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes.

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

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 subchapter and the significance of such demand," and (iv) any report from the Tobacco Products Scientific Advisory Committee ("TPSAC"); and

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

13. As detailed further below, each pre-condition to finalizing the Proposed Menthol rule exists here. The Defendants have published a Notice of Proposed Rulemaking in the Federal Register and the comment period has closed (as of August 2022). Through their many years of study and repeated calls for public comments, the Defendants have already considered the necessary comments and information identified by Subsection (d)(1). Finally, the Secretary has already determined since at least April 29, 2021 that the Menthol Rule (banning menthol cigarettes in the marketplace) is "appropriate for the protection of public health[.]"

14. Under such facts, this Court's help is needed. Defendants' inaction continues to harm the public health. And the Defendants have repeatedly shown that they are unable to act on the issue of menthol in cigarettes without judicial intervention. Thus, Plaintiffs respectfully request this Court's assistance to once again direct Defendants to fulfill their duty to protect the public health—in this case, by promulgating and publishing the proposed Menthol Rule.

JURISDICTION & VENUE

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

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

17. Intradistrict Assignment: Pursuant to Civil L.R. 3-2(c), intradistrict assignment is proper in the San Francisco or Oakland Division. This is because Plaintiff African American

Tobacco Control Leadership Council maintains its principal place of business in the County of San Francisco, and because this action arises from, and touches on issues raised in, litigation previously assigned to the Oakland Division, *see African American Tobacco Control Leadership Council et al. v. U.S. Dep't of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.).

PARTIES

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

19. The AATCLC's mission is to save lives by partnering with community stakeholders, elected officials, and public health agencies from across the nation (e.g., Boston, Washington, D.C., Columbus, Chicago, Minneapolis, Denver, Berkeley, Oakland, Sacramento, and Los Angeles), to inform and affect the direction of tobacco policy, practices, and priorities, particularly as they affect the lives of Black Americans and African immigrant populations.

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

21. Such work includes providing testimony at FDA hearings held in 2010 and 2011, when the agency was first considering removing menthol cigarettes from the marketplace. The AATCLC also played a crucial part in the Chicago fight to establish 500-foot barriers around schools that banned the sale of menthol and flavored tobacco products—the first menthol restriction in the nation. These efforts further led to the Delta Sigma Theta Sorority, Inc. and the NAACP adopting resolutions, supporting a ban on all menthol products and other flavored

tobacco products. The AATCLC's efforts also led to the City and County of San Francisco enacting the first comprehensive, city-wide flavor ban that ended the sale of menthol cigarettes and all other flavored tobacco products.

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

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

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

25. Plaintiff Action on Smoking and Health ("ASH") is a non-profit organization headquartered in Washington, D.C. Founded in 1967, ASH has spent the last 50 years protecting society against the harms caused by the tobacco industry and its products. Its mission

is to advocate for innovative legal and policy measures to end the global tobacco epidemic. ASH's past accomplishments include helping to achieve restrictions on tobacco advertising and smoking bans in workplaces and various forms of public transit.

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

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

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

29. ASH led a submission, signed by 97 organizations, to the United Nations' Committee on the Elimination of all forms of Racial Discrimination ("CERD").[10] This letter

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

asked CERD to encourage the United States to protect African Americans' right to health against the tobacco industry's malfeasance—a step that would further social justice. ASH also led an additional 207 signatories from 61 countries to call on CERD to maintain and strengthen its call to country Parties in the Draft General Recommendation n°37 on Racial Discrimination in the enjoyment of the right to health to reduce or prevent the harms of tobacco.

30. The Defendants' unlawful refusal to ban menthol in combustible cigarettes, makes ASH's work more difficult, and forces ASH to continue devoting resources and efforts to educating the public about the dangers of menthol cigarettes. But for Defendants' actions, ASH could instead be directing its resources and efforts to advancing ASH's other organizational goals, such as helping to reduce the harms of tobacco on society (e.g., by eliminating the sale of cigarettes altogether).

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

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

33. As the nation's only organization devoted to the needs of African American physicians, health professionals, and their patients, the NMA serves as the conscience of the

medical profession in the ongoing fight to eliminate health disparities in the nation's health care delivery system. The NMA has been an unwavering advocate for health policies that improve the quality and availability of health care for African Americans and other underserved populations. For instance, the NMA was the force behind such landmark reforms as Medicare and Medicaid.

34. Today, the NMA continues to provide leadership in shaping the national health policy agenda through continued involvement in a variety of critical policy matters, including with respect to smoking. For example, the NMA passed a resolution on August 3, 2017, during their Annual Meeting of the House of Delegates, supporting a ban on the sale of flavored tobacco products, including menthol cigarettes. As noted on the NMA's website, African Americans have the highest surveyed rate of desire to quit smoking but are less successful in quit attempts than white and Hispanic smokers. This is due in part to the anesthetic effects of menthol in mentholated cigarettes and the high rate of mentholated cigarette use among African Americans. This is precisely the type of health disparity the NMA seeks to eliminate.

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

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

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

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

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

40. Defendant Xavier Becerra is sued in his official capacity as the Secretary of the U.S. Department of Health and Human Services. As Secretary, Mr. Becerra is responsible for HHS's activities and policies and for implementing the Tobacco Control Act. Although the Secretary has delegated many responsibilities under the Act to the FDA Commissioner[11], the

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

Secretary has nonetheless reserved the authority to (a) establish procedural rules applicable to tobacco products, such as menthol cigarettes; and (b) present highly significant public issues involving the availability and marketability of tobacco products, including menthol cigarettes.

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

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

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

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

FACTUAL & LEGAL BACKGROUND

I. Defendants are unlawfully delaying acting on menthol cigarettes.

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

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

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

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

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

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

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

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

51. The Committee would then specifically review and address the considerations that the FDA would need to address in adopting a new tobacco product standard (e.g., to ban menthol as a characterizing flavor in cigarettes), *see id.* § 387g(e)(1), including the "scientific evidence" concerning the risks and benefits of a proposed standard, *see id.* § 387g(a)(3)(B)(i)[12]; "the technical achievability of compliance with such standard," *id.* § 387g(b)(1); and all "other information submitted in connection with a proposed standard," *id.* § 387g(b)(2)[13].

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

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

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

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[12] "In making a finding described in subparagraph (A), the Secretary [i.e., FDA] shall consider scientific evidence concerning (I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased 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).

[13] "The Secretary [i.e., FDA] shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard." 21 U.S.C. § 387g(b)(1). "The Secretary [i.e., FDA] shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing 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).

a. The Secretary has published a Notice of Proposed Rulemaking in the Federal Register and the comment period has closed, *see id.*;

b. The Secretary has considered—

i. Comments submitted in response to the Notice, *id.* (referring to 21 U.S.C. § 387g(c));

ii. Comments concerning the "technical achievability of compliance with such standard," *id.* (referring to 21 U.S.C. § 387g(b)(1));

iii. "[A]ll other information submitted in connection with a proposed standard, including information concerning the countervailing 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 subchapter and the significance of such demand," *id.* (referring to 21 U.S.C. § 387g(b)(2)); and

iv. Any report from the Tobacco Products Scientific Advisory Committee ("TPSAC"), *id.*; and

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

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

2. Congress directed the Defendants to address the issue of menthol in cigarettes "quickly."

56. Beyond providing such tools to Defendants, however, Congress also emphasized the speed by which it expected the Defendants to act—i.e., "quickly."

57. The Tobacco Control Act's primary sponsor and committee member in charge Rep. Henry A. Waxman, made clear that Congress considered menthol to be an urgent public health concern and intended the FDA to move "quickly" to address it. Per the Tobacco Control Act's accompanying Committee Report:

> *Section 907. Tobacco product standards* Consistent with the overall intent of the bill to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes, section 907(a)(1) is intended to prohibit the manufacture and sale of cigarettes with certain "characterizing flavors" that appeal to youth. …
>
> **The Committee recognizes the unique issues surrounding menthol cigarettes and urges the Secretary to address these issues as quickly as practicable.** The Committee is especially concerned about proportionately higher rates of menthol cigarette use among African American smokers, as well as the historic targeting of African Americans for menthol cigarette use by tobacco companies. … [T]he Committee recognizes that menthol cigarettes may pose unique health risks to those who smoke them. Given the high rates of use among African American smokers, including African American youth, as well as higher rates of lung cancer documented among African American smokers as compared to non-African American smokers, the Committee believes that **it is critical for the Secretary to move quickly to address the unique public health issues posed by menthol cigarettes.**

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

58. Rep. Waxman's floor statements further emphasized his efforts "with members of the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus" of attention by the FDA.[14]

[14] Cong. Rec.—House, H4318, H4339 (Vol. 155, No. 55) (Apr. 1, 2009 floor statement), *available at* 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),

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

59. At the time, the Defendants acknowledged Congress' urgency in addressing the critical health problem of menthol in cigarettes. On September 22, 2009, the FDA announced that it would be "examining options" for regulating menthol cigarettes:

> The FDA's ban on candy and fruit-flavored cigarettes … highlights the importance of reducing the number of children who start to smoke, and who become addicted to dangerous tobacco products. The FDA is also examining options for regulating both menthol cigarettes and flavored tobacco products other than cigarettes.[15]

60. And in response to questions from journalists, Dr. Lawrence Deyton—the Center for Tobacco Products' Director at the time—noted that the Center would be "studying" and "discussing" the issue of menthol cigarettes with the agency's Advisory Committee:

> Jennifer Corbett: The question I have is—and you mentioned in your press release—that you're looking at menthol cigarettes, because my understanding (about) is the—that's the biggest flavor out there that …
>
> Lawrence Deyton: Yes, the menthol issue is also specifically addressed in the Family Smoking Prevention

available at https://www.congress.gov/congressional-record/2009/06/12/house-section/article/H6630-1.

[15] FDA, News & Events, *Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law* (Sept. 22, 2009) (noting that "[a]lmost 90 percent of adult smokers start smoking as teenagers. These flavored cigarettes are a gateway for many children and young adults to become regular smokers," said FDA Commissioner Margaret A. Hamburg, M.D. …. Flavors make cigarettes and other tobacco products more appealing to youth. Studies have shown that 17 year old smokers are three times as likely to use flavored cigarettes as smokers over the age of 25. … "FDA's ban on these cigarettes will break that cycle for the more than 3,600 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.

> and Tobacco Control Act, and that is an issue again which we will be discussing with our Scientific Advisory Committee and studying. **We've been asked specifically by the [A]ct to study that.**

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

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

> Miriam Falco: … I got to say I'm a little confused. Your answers are all very government-speak, if I may say so. If you know that young people prefer menthol cigarettes, then why aren't they included in this? ….
>
> Lawrence Deyton: **In terms of the question of menthol, the law specifically asks us to look at menthol separately. And we will be doing that.**

Id. at 15 (emphasis added).

C. Since 2011, Defendants have known that removing menthol cigarettes from the market would benefit public health.

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

63. That Committee was comprised of "a panel of leading public health, scientific experts and representatives of various parts of the tobacco industry," and was charged with "providing advice, information, and recommendations to the FDA on health issues related to

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

tobacco products and other issues relating to the regulation of tobacco products." FDA, Dr. Lawrence R. Deyton, CTP Director, *FDA Remarks on the Report and Recommendation on the Public Health Impact of Menthol Cigarettes* (Mar. 18, 2011) ("2011 FDA Remarks on Menthol Cigarettes Rept.").[17]

64. The full Committee first met in March 2010, and 11 more times thereafter. *See* FDA Rept. to Congress, *Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act*, at 15 (2013). There were also two meetings of the Tobacco Products Constituents Subcommittee of the TPSAC and two meetings of the Menthol Report Subcommittee. *See id*. Each Committee and Subcommittee meeting covered a broad range of materials, presentations, and public submissions. *See* FDA 2010 TPSAC Mtg. Materials and Info.;[18] *see also* FDA 2011 TPSAC Mtg. Materials and Info.[19]

1. The Committee's 2011 report and findings.

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

i. Menthol masks nicotine's irritating effects.

66. Among other things, the Report found that menthol is a flavor additive that possesses a minty taste and aroma. *See* 2011 TPSAC Menthol Rept. at 16. While regulated as a

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

[18] *Available at* https://wayback.archive-it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm.

[19] *Available at* https://wayback.archive-it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm.

[20] *Available at* https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.

drug in certain medicinal products (e.g., cough drops), menthol was not regulated in tobacco products. *See id.* Menthol was also present in 90% of tobacco products, including cigarettes not marketed as menthol cigarettes. *See id.*

67. The Report further found that menthol produced a variety of sensory effects, including cooling, soothing, and anesthetic effects. *See id.* at 23. For example, "[i]n cigarettes with low levels of tar and nicotine, the addition of menthol can enhance the 'bite' or 'throat grab' of the smoke, making such cigarettes more acceptable to consumers. Conversely, the addition of menthol to cigarettes high in tar and nicotine can reduce the irritating effect of nicotine … making these cigarettes more palatable." *Id.* at 24.

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

ii. The tobacco companies targeted youth and minorities with menthol cigarettes.

69. The Report also found that the tobacco industry spent "as much or more on magazine advertising for menthol [cigarette brands] as for non-menthol brands, even though menthol brands represent a much smaller share of the market." 2011 TPSAC Menthol Rept. at 61. In addition, the Committee found that menthol cigarettes "are marketed disproportionately to younger people," *id.* at 92; menthol use is higher among youth and young adult smokers, *see id.*; women "have been targets of tailored menthol marketing efforts," *id.;* and menthol cigarettes are "disproportionately marketed per capita to African Americans. African Americans have been the subjects of specifically tailored menthol marketing strategies and messages. … Consistent with these targeted marketing efforts, menthol cigarettes are disproportionately smoked by African American smokers," *id.*

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

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

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

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

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

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

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

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

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

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

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

iv. *Recommendation*: Remove menthol cigarettes from the marketplace.

77. As a result of the Committee's findings and conclusions, the Committee then made the following "overall recommendation" to the FDA: "**Removal of menthol cigarettes from the marketplace would benefit public health in the United States**." 2011 TPSAC Menthol Rept. at 225 (emphasis in original).

78. Per the Committee, the tobacco companies' marketing of menthol cigarettes "has been successful":

> Menthol cigarettes are now smoked by most African American smokers and there is a concerning rise of menthol cigarette smoking among youth. Menthol cannot be considered merely a flavoring additive to tobacco. Its pharmacological actions reduce the harshness of smoke and the irritation from nicotine, and may increase the likelihood of nicotine addiction in adolescents and young adults who experiment with smoking. Furthermore, the distinct sensory characteristics of menthol may enhance the addictiveness of menthol cigarettes, which appears to be the case among youth. **[The Committee] has found that the availability of menthol cigarettes has an adverse impact**

on public health by increasing the numbers of smokers with resulting premature death and avoidable morbidity.

Id. at 225 (emphasis added).

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

D. Since 2011, Defendants have engaged in a series of half-measures, doublespeak, and foot-dragging.

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

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

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

1. Despite statements to the contrary, Defendants delay any regulation of menthol in cigarettes.

83. Following the release of the Advisory Committee's March 2011 findings and report, the FDA announced that it would conduct a "thorough review" of the TPSAC report with the agency's own experts. *See* 2011 FDA Remarks on Menthol Cigarettes Rept.

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

85. The FDA then reiterated that "a top priority for FDA is to protect the public health from the harmful effects of tobacco use[.]" *Id.* As explained by the Center of Tobacco

Products' Director, "Tobacco is the leading cause of preventable disease, disability, and death in the United States. Tobacco products are responsible for approximately 443,000 deaths and $193 billion on medical expenditures and lost productivity each year in the United States." *Id.*[21]

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

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

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

89. The FDA did not immediately respond to Plaintiff AATLC's call to action.

90. 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

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

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

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]

91. 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.

92. 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.*

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

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;

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[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.

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.

94. 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 United States are caused by tobacco use. Consistent patterns have emerged as a result of FDA's evaluation of the scientific evidence relevant to the impact of menthol tobacco products on public health. … [A]dequate data suggest that menthol use is likely associated with increased smoking

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[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.

> initiation by youth and young adults. Further, the data indicate that menthol in cigarettes is likely associated with greater addiction. Menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking. These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.

Id. at 6.

95. Given these findings, the Center for Tobacco Products Director Mitch Zeller restated what was by that time, obvious: "Menthol cigarettes raise critical public health questions." Michael Felberbaum, *FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23, 2013).[30]

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

97. And while Director Zeller noted that there was "no holdup" by the FDA proposing restrictions on menthol, there were still (purportedly) "some important questions" that needed to be answered. *See FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23, 2013).[31] Thus, the FDA would be funding three menthol-related studies looking at (a) whether genetic differences explained whether certain racial and ethnic populations were more likely to use menthol cigarettes; (b) menthol cigarettes' smoke-related toxins and carcinogens as compared

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[30] *Available at* https://www.usatoday.com/story/news/nation/2013/07/23/fda-menthol-cigarettes-health-risk/2578331/.

[31] *Available at* https://www.usatoday.com/story/news/nation/2013/07/23/fda-menthol-cigarettes-health-risk/2578331/.

to nonmenthol cigarettes; and (c) the effects of menthol and nonmenthol compounds in various tobacco products, with respect to both tobacco addiction and the toxicants of tobacco smoke. *See FDA Invites Public Input on Menthol in Cigarettes*, The ASCO Post, Vol. 4, Issue 13, at 21 (Aug. 13, 2013).[32]

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

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

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

> FDA has been unable to reach a decision on your petition because it raises significant, complex issues requiring extensive review and analysis by Agency officials. As you may know, FDA issued an advance notice of proposed rulemaking on July 24, 2013, seeking comments, including comments on FDA's preliminary scientific evaluation of public health issues related to the use of menthol in cigarettes, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes (78 FR 44484). … We will respond to your petition as soon as we have reached a decision on your request.

[32] *Available at* https://issuu.com/ascopost/docs/tap_vol_4_issue_13.

101. For the remainder of 2013, however, Defendants made no visible progress or any public announcements concerning their plans to regulate menthol in cigarettes. Defendants also did not respond to or otherwise supplement their response to Plaintiffs' Citizen Petition.

102. Defendants' silence and inaction continued for all of 2014, 2015, 2016, and the first half of 2017. Around this same time, however, many other countries had already banned menthol flavored cigarettes.[33]

2. Defendants' "accelerate[d]" rulemaking stalls.

103. In July 2017, Defendants announced the FDA's intention to, among other things, issue yet another Advance Notice of Proposed Rulemaking[34] to "seek public comment on the role that flavors (including menthol) in tobacco products play in attracting youth[.]" *See* FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease Death (July 27, 2017).[35]

104. Then, in March 2018, Defendants announced that they were seeking yet even more comments "on the role that flavors—including menthol—play in initiation, use and cessation of tobacco products." FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D.* (Mar. 14, 2018).[36]

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[33] For example, in 2012, Brazil approved a ban on all flavors, including menthol, in all tobacco products. In 2016, the European Union banned all flavored cigarettes including menthol (effective 2020). And in 2017, Canada banned the sale of menthol cigarettes. *See* Campaign for Tobacco-Free Kids, *Brazil's Highest Court Upholds Ban on Flavored Tobacco Products* (Feb. 1, 2018). *Available at* 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 Tobacco Products*, 49–50 (2016). *Available at* https://apps.who.int/iris/bitstream/handle/10665/205928/9789241510332_eng.pdf;jsessionid=6D55886EDA1A8FDA032CA2B42F4409FC?sequence=1.

[34] *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.'").

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

[36] Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels (Mar. 14, 2018). *Available at* https://www.fda.gov/news-events/press-

105. The FDA's call for additional study, of course, covered many of the same areas previously covered by the FDA's 2011 Tobacco Products Scientific Advisory Committee report, the Plaintiffs' 2013 Citizen Petition, as well as the FDA's 2013 "preliminary" findings. The FDA Commissioner noted, for example, that "youth consistently report product flavoring as a leading reason for using tobacco products. Flavors may disguise the taste of tobacco. But flavored cigarettes … are every bit as addictive as any other tobacco products, have the same harmful health effects and may even make it harder to quit. … Additionally, youth and young adult smokers are disproportionately more likely to smoke menthol than nonmenthol cigarettes. And we know that youth who initiate smoking with menthol cigarettes … may be at greater risk of progression from experimentation to established smoking and nicotine dependence." FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D.* (Mar. 19, 2018).[37]

106. Around this same time, the FDA also released a "Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard, and Request for Comments," Dkt. No. FDA-2018-N-0529, 83 Fed. Reg. 26,697 (Mar. 16, 2018).[38] Without mentioning menthol, the paper noted that "FDA is also considering

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announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking.

The three advance notices of proposed rulemaking were later published that same month: *See* FDA, *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*, Dkt. No. FDA-2017-N-6189, 83 Fed. Reg. 11818 (Mar. 16, 2018). *Available at* 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*, 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-tobacco-products; FDA, *Regulation of Premium Cigars*, Dkt. No. FDA-2017-N-6107, 83 Fed. Reg. 12901 (Mar. 26, 2018). *Available at* https://www.federalregister.gov/documents/2018/03/26/2018-06047/regulation-of-premium-cigars.

[37] 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.

[38] *Available at* 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.

establishing a product standard prohibiting the manufacture, sale, and distribution of tobacco products with certain characterizing flavors." FDA, *Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard*, at 4 (Mar. 15, 2018.)[39]

107. In October 2018, FDA Commissioner Gottlieb then announced that "he was revisiting [the FDA's consideration of] the use of menthol in certain products, which has been of particular concern in African-American communities targeted by makers of menthol cigarettes like Newport and Kools in years past. '**It was a mistake for the agency to back away on menthol**,' he said." Sheila Kaplan, *Altria to Stop Selling Some E-Cigarette Brands That Appeal to Youths*, The New York Times (Oct. 25, 2018) (emphasis added).[40]

108. The next month, the FDA Commissioner announced that the agency would "advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars, informed by the comments on our Advanced Notice of Proposed Rulemaking (ANPRM)." Statement from FDA Commissioner Scott Gottlieb, M.D. (Nov. 15, 2018).[41] Commissioner Gottlieb described his reasoning as follows:

> I'm deeply concerned about the availability of menthol-flavored cigarettes. I believe these menthol-flavored products represent one of the most common and pernicious routes by which kids initiate on

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

[40] *Available at* https://www.nytimes.com/2018/10/25/health/altria-vaping-ecigarettes.html?module=inline.

[41] 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-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=Eloqua.

> combustible cigarettes. The menthol serves to mask some of the unattractive features of smoking that might otherwise discourage a child from smoking. Moreover, I believe that menthol products disproportionately and adversely affect underserved communities. And as a matter of public health, they exacerbate troubling disparities in health related to race and socioeconomic status that are a major concern of mine.
>
> …
>
> I noted that the popularity of menthol cigarettes with youth is especially troubling. In fact, youth smokers are more likely to use menthol cigarettes than any other age group. More than half (54 percent) of youth smokers ages 12–17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older. Prevalence of menthol use is even higher among African-American youth, with data showing that seven out of 10 African-American youth smokers select menthol cigarettes.

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

109. Nonetheless, the FDA Commissioner expressed his agency's intention to "accelerate" the proposed rulemaking process to ensure that the FDA's policies on flavored tobacco products protected the public health. *Id.*

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

111. And by June 2019, without explanation, the FDA reversed course and decided not to initiate its previously announced rulemaking process. At that time, then-Acting FDA Commissioner Sharpless and Center for Tobacco Products Director Mitch Zeller announced the

FDA's Achievements in Tobacco Regulation Over the Past Decade and Beyond.[42] Among other things, that announcement noted the FDA's plan "to take action on flavored cigars and continue to explore other issues related to flavored tobacco products." *Id.* Absent from Defendants' announcement, however, was any plan to regulate menthol cigarettes.

112. Similarly, when HHS published its Spring 2019 Agenda (i.e., "the regulatory activities that the Department [i.e., Defendants HHS, the FDA and CTP] expects to undertake in the foreseeable future," HHS Regulatory Agenda, 84 Fed. Reg. 29623, 29624 (June 24, 2019)[43]), HHS and the Defendants omitted any mention of regulating menthol cigarettes. *See id.*, generally; HHS, Agency Rule List – Spring 2019.

113. Likewise, Defendants omitted including any plans to regulate menthol as part of HHS's Fall Regulatory Agenda. *See* HHS Regulatory Agenda, 84 Fed. Reg. 71129 (Dec. 26, 2019).[44]

114. The same was true of the 2019 Unified Agenda, which was compiled by the Regulatory Information Services Center for the Office of Information and Regulatory Affairs ("OIRA"). *See* Regulatory Info. Services Ctr., *Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions*, Dkt. No. 2019-12557, 84 Fed. Reg. 29591 (June 24, 2019)[45]; Regulatory

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

[43] *Available at* https://www.federalregister.gov/documents/2019/06/24/2019-12004/regulatory-agenda. *See also* HHS, Agency Rule List – Spring 2019. *Available at* https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPubId=201904&showStage=active&agencyCd=0900&csrf_token=AC9CA9308A92E9EACBFB612B667086E9017C80260FDDB0D9364F9F5F2137B6554EA1929687D28B0AFFBE211B4AB531B5D1F4.

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

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

Info. Services Ctr., *Intro. to the Fall 2019 Regulatory Plan*, Dkt. No. 2019-26533, 84 Fed. Reg. 71085 (Dec. 26, 2019)[46]. This Unified Agenda provides data on regulatory and deregulatory activities under development or review throughout the federal government—e.g., advance notices of proposed rulemaking, notices of proposed rulemaking, final rules, and long-term plans. *See* OIRA, About the Unified Agenda.[47]

115. And, it confirmed that Defendants had made no plans to undertake any regulatory action on menthol in cigarettes. *See id.* (identifying Defendants' regulatory actions at the pre-rule, proposed rule, and final rule stages of development and review). Indeed, HHS did not even list menthol regulation on its list of "Long-Term Actions," which identifies actions that the agency intends to pursue but does not anticipate taking action on in the following year. OIRA Long Term Actions, Agency Rule List – Spring 2019, HHS (identifying Defendants' long-term actions)[48], OIRA Long Term Actions, Agency Rule List – Fall 2019, HHS[49].

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

116. By 2020, it appeared that Defendants had abandoned regulating menthol in cigarettes. Contrary to Defendants prior statements—e.g., to "communicate . . . what future regulatory actions" the FDA might take with respect to menthol, to keep as a "top priority" the protection of the public health from the harmful effects of tobacco use, and to "accelerate" the

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[46] *Available at* https://www.federalregister.gov/documents/2019/12/26/2019-26533/introduction-to-the-fall-2019-regulatory-plan.

[47] *Available at* https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp.

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

[49] *Available at* https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPubId=201910&showStage=longterm&agencyCd=0900&csrf_token=243A419EF187585EFFD83CD9CFA7CB8F1D8F1155635D087656DF62F1D717959D8C6B90FE425F27A717CEC962B0EECE3D5800.

rulemaking process with respect to menthol—it seemed that Defendants were content to keep menthol cigarettes in the marketplace (thereby increasing the likelihood that youth would initiate smoking), and to allow the public health crisis caused by menthol cigarettes to worsen.

117. To address Defendants' inaction and these harms to public health, Plaintiffs filed suit against the Defendants on June 17, 2020. *See African American Tobacco Control Leadership Council et al. v. U.S. Dep't of Health and Human Servs. et al.*, Case No. 4:20-cv-04012-KAW (N.D. Cal.) ("*Menthol Lit. I*").

A. Plaintiffs' lawsuit sought to compel the FDA's formal determination on the issue of menthol.

118. Plaintiffs' complaint alleged three claims: (a) Defendants' undue delay (in violation of the Administrative Procedure Act and Tobacco Control Act) in determining whether menthol in cigarettes should be added to the list of banned characterizing flavors (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).

119. 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.

120. At the same time, Defendants also moved to dismiss Plaintiffs' Counts I (undue delay claim) and III (arbitrary and capricious claim, alleged in the alternative to Count I).

121. At bottom, 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.

122. Plaintiffs asserted that this Section required the FDA to make a specific determination concerning whether menthol should be added to the flavor ban established by Section § 387g(a)(1).

123. 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.

124. At oral argument, Defendants went even further, suggesting that the FDA could make an un-ending series of "tentative" decisions on menthol, and put off making a final determination indefinitely.

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

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

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

B. The FDA announces its intent to ban menthol cigarettes.

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

129. After considering the available scientific evidence, the FDA determined that "eliminating menthol as a characterizing flavor in cigarettes would benefit public health and, therefore, the Agency intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes." *Id.* at 10. The FDA's news release also announced the FDA's intention to ban menthol cigarettes.[50]

130. Unfortunately, the FDA's formal response and determination, as well as its news release, omitted identifying ***when*** the FDA would issue its proposed rule. At most, the FDA's news release indicated the following aspirational goal: "The FDA is **working toward issuing proposed product standards within the next year** to ban menthol as a characterizing flavor in cigarettes[.]" FDA, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021) (emphasis added).[51]

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

131. Given Defendants' earlier pronouncements of "accelerate[d]" rulemaking followed by years of inaction and broken promises, Plaintiffs had their concerns. Such concerns

[50] As explained by Acting FDA Commissioner Janet Woodcock, M.D.: "Banning menthol—the last allowable flavor—in cigarettes and banning all flavors in cigars will help save lives, particularly among those disproportionately affected by these deadly products. With these actions, the FDA will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products." 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.

[51] *Available at* https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

were based in part, on the FDA's long history of undue delay and missed deadlines—all at the expense of public health.

132. In *Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 724 F. Supp. 1013 (1989), for example, the court there found that the FDA's delay in promulgating a final rule standardizing tampon absorbency labeling reflected "an insensitivity to a long-existing and clearly identifiable problem [i.e., Toxic Shock Syndrome]. Its delay is particularly disturbing since the public health and human lives are at stake." *Id.* at 1022 (noting elsewhere that the FDA had "drag[ged] their feet" in promulgating this regulation, *id.* at 1021, and allowed women to "needlessly subject themselves to a risk of serious injury, and even death from Toxic Shock Syndrome," *id.* at 1019).[52]

133. Other instances of the FDA's pattern and practice of unlawful and undue delay abound: *See*, *e.g.*, *Tummino v. Torti*, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009) (holding that the FDA's repeated delays in issuing a decision concerning Plan B was suspect, and the likely result of improper political considerations)[53]; *NRDC v. United States the FDA*, 884 F. Supp. 2d 108, 119 (S.D.N.Y. 2012) (holding that the FDA's 30+ years of inaction constituted undue delay, where the FDA failed to initiate and complete the withdrawal of certain antibiotics being used for non-

[52] Noting the FDA's "history of delays and missed deadlines," the court found that a court-imposed schedule was necessary to protect the public health. *Id.* at 1020. Observing that "Defendants' justification for its continued delay in promulgating a regulation is lame at best and wholly irresponsible at worst," the court found it appropriate to note the following: "We have seen it happen time and time again, … action … for the protection of public health all too easily becomes hostage to bureaucratic recalcitrance, factional infighting, and special interest politics. At some point, we must lean forward from the bench to let an agency know, in no uncertain terms, that enough is enough." 724 F. Supp. at 1021 (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.

[53] "These political considerations, delays, and implausible justifications for decision-making [by the FDA] are not the only evidence of a lack of good faith and reasoned agency decision-making. Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures …." *Tummino*, 603 F. Supp. 2d at 523 (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.").

therapeutic purposes in livestock); *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin.*, No. 1:16-cv-11985, 330 F. Supp. 3d 657, 667 (D. Mass. 2018), Mem. and Order Granting Inj. Relief, (Mar. 5, 2019) (finding that the FDA had unreasonably delayed issuing the graphic warning label rule, and setting a deadline for the FDA to issue a final rule); *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin*, No. 8:18-cv-883, 399 F. Supp. 3d 479, 487 (D. Md. Mar. 27, 2018) (holding that the FDA's delay in reviewing new tobacco products was unreasonable, and imposing deadlines on the FDA's review in light of the important public health interests at stake).

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

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

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

137. Most recently in 2019, Congress directed the FDA to publish a final rule (i.e., conforming regulations to reflect the increased minimum age laws in effect) in the Federal

Register within 180 days (i.e., by June 17, 2020). The FDA then repeatedly listed this matter on several Unified Regulatory Agendas (*see* RIN 0910-AI51), submitted a proposed rule to OIRA in 2021, but then later withdrew that proposed rule, relisted the matter with a new timeline by which the agency believed such rule would be finalized, and then proceeded to miss the agency's June 2020 goal, miss the re-calendared November 2020 goal, and miss the re-calendared May 2021 date. To date, no such rule is in place.

138. In short, even when Congress has set a specific statutory deadline, the FDA is unable to rise to the challenge.

139. The FDA is furthermore slow to act, even when the public health is being harmed. Menthol in cigarettes—the focus of this lawsuit, and Plaintiffs' earlier 2020 lawsuit—is a prime example. FDA's slow action on e-cigarettes is another example, as is the agency's delayed response to the opioids epidemic. *See* Megan Thielking, STAT, *FDA 'should have acted sooner' on e-cigarettes, agency head tells Congress* (Sept. 25, 2019)[54]; Andrew Kolodny, M.D., *How FDA Failures Contributed to the Opioid Crisis*, AMA Journal of Ethics (Aug. 2020) ("In 2017, the President's Commission on Combatting Drug Addiction and the Opioid Crisis found that the opioid crisis was caused in part by 'inadequate oversight by the Food and Drug Administration'")[55]. Similarly, when a 2021 House of Representatives' subcommittee report found that many popular infant foods were tainted with dangerous levels of arsenic, lead, cadmium, and mercury[56], many wondered with good reason, "Where was the FDA?"

140. Indeed, shortly after FDA Commissioner Robert Califf's appointment in 2022, he announced that the FDA's food safety and tobacco regulatory divisions would be subject to an external review by the Reagan-Udall Foundation. Disturbingly, the Foundation's review found

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[54] *Available at* https://www.statnews.com/2019/09/25/fda-e-cigarettes-congress/.

[55] *Available at* https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08.

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

that the FDA's food division lacked clear leadership, avoided bold policy or enforcement actions, and fostered a culture that did not adequately protect the public health. The FDA's tobacco division similarly "struggled to function as a regulator in part due to some of its own policy choices." *See* Regan-Udall Foundation, *FDA Operational Evaluations of FDA's Human Foods Program and FDA's Tobacco Program* (2022).[57]

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

141. Given Defendants' track record, Defendants' unwillingness to set a specific date for issuing a Notice of Proposed Rulemaking to ban menthol cigarettes was disconcerting. Defendants, nonetheless, moved to dismiss Plaintiffs' case as moot. Plaintiffs opposed.

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

> The FDA has stated that it intends to issue a notice of rulemaking by April 2022, or in approximately five months. If the FDA does not issue the Notice of Rulemaking, the Court may find that the delay is unreasonable under the factors set forth in *Telecommunications Research and Action Center v. FCC* ("*TRAC*") for determining unreasonable delay.
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> The Court finds *In re a Community Voice* [878 F.3d 779 (9th Cir. 2017)] most instructive. There, [the Ninth Circuit recognized] … that delays of months or a few years is generally not an unreasonable delay unless there is something more, e.g., a threat to human welfare. **Such a threat could be found here, based on the significant threat to human health posed by menthol cigarettes.** Should the FDA not issue a notice of rulemaking in the

[57] *Available at* https://reaganudall.org/programs/operational-evaluation-fdas-human-foods-tobacco-programs.

> year since granting Plaintiff's citizen petition, a delay of more than one year could very well be unreasonable (particularly as that delay continues). Further, as Plaintiffs observe, **other *TRAC* factors could support a finding of undue delay, as the FDA has described a final rule banning menthol as "'one of the Agency's highest priorities.'"**

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

3. The Defendants comply with this Court's strong suggestion.

143. Following this Court's order, the Defendants issued a Notice of Rulemaking on May 4, 2022. *See* FDA Proposed Menthol Rule, 87 Fed. Reg. 26454.

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

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

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

a. Reduced appeal of cigarettes, "particularly to youth and young adults, who are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette";

b. Decreased likelihood that "nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking"—in other words, "a

significant reduction in the likelihood of youth and young adult initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death";

c. Improved health and reduced mortality risk of current menthol cigarette smokers "by substantially decreasing cigarette consumption and increasing the likelihood of cessation";

d. Reduced smoking prevalence over the next 40 years by over 15%;

e. Avoiding 324,000 to 654,000 lives lost to smoking, including approximately 92,000 to 238,000 lives lost among African Americans;

f. A "substantial" decrease of tobacco-related health disparities;

g. The advancement of health equity;

h. Decreased illness and associated reductions in medical costs (both publicly and privately funded);

i. Decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers;

j. Reductions in smoking-related fires, cigarette butt litter, and associated harms to the environment; and

k. Diminished exposure to second-hand smoke among non-smokers; and

l. Decreased potential years of life lost, decreased disability, and an improved quality of life among former smokers.

Id. at 25455, 26458, 26489.

147. The FDA further anticipated that this final rule would provide between $102 billion and $353 billion in annualized benefits (as measured over a 40-year time period)—an amount magnitudes larger than the rule's anticipated costs. *See id.* at 26456.

148. The final rule would also only apply to "manufacturers, distributors, wholesalers, importers, and retailers," and would not be enforced against individual consumers for possession or use of menthol cigarettes. *Id.* at 26456. State and local law enforcement agencies were furthermore not authorized to enforce the new rule. *See id.*

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

150. The FDA further ensured that the Office of Information and Regulatory Affairs ("OIRA") had reviewed the proposed rule. *See id.* at 26489.

C. Plaintiffs voluntary dismiss their lawsuit.

151. Accordingly, based on the Defendants' publication of the formal rule and promise that Defendants would make enactment of the final rule "one of the Agency's highest priorities," Plaintiffs voluntarily dismissed their lawsuit on June 1, 2022.

III. The Court's intervention is once again required.

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

153. And because Defendants' delay harms the public health and violates both the Tobacco Control Act and Administrative Procedure Act, this Court's help is once again required.

A. The Tobacco Control Act mandates the Defendants' promulgation of a final rule.

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

a. the Secretary has published a Notice of Proposed Rulemaking in the Federal Register and the comment period has closed, *see id.* § 387g(d)(1);

b. the Secretary has considered the comments submitted under subsections (b) and (c) [21 U.S.C. § 387g(b), (c)], *see id.* § 387g(d)(1), in other words—

   i. comments submitted in response to the Notice of Proposed Rulemaking, *see id.* § 387g(c);

ii. comments concerning the "technical achievability of compliance with such standard," *id.* § 387g(b)(1);

iii. "all other information submitted in connection with a proposed standard, including information concerning the countervailing 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 subchapter and the significance of such demand," *id.* § 387g(b)(2);

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

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

155. Each pre-condition exists here:

156. On May 4, 2022, the Defendants published a Notice of Rulemaking in the Federal Register. *See* HHS /FDA, Proposed Menthol Rule. The comment period for that Notice has since closed. *See* FDA, *Comment Period Closed for FDA Proposed Rules Prohibiting Menthol Cigarettes and Flavored Cigars* (Aug. 10, 2022).

157. On information and belief, Defendants have considered the 2011 Menthol Report, issued by their Tobacco Products Scientific Advisory Committee. The Defendants have also considered the comments submitted under subsections (b) and (c) (i.e., 21 U.S.C. § 387g(b), (c)), as required by Subsection (d)(1). These comments—e.g., concerning the technical achievability of compliance with such standard, information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, etc.—were received by Defendants as part of the fact-gathering process and review of the scientific evidence conducted by the FDA's Advisory Committee (2010–11), the FDA's own research (peer-reviewed and published in 2013), the FDA's review of the Plaintiffs' 2013 Citizen Petition, and the FDA's repeated calls for comments and scientific data in 2013, 2018, and 2022.

158. And because many of the 2022 comments echoed previously submitted comments in earlier years, the Defendants completed their review on or around February 1, 2023. By this time, the Defendants had identified August 2023 as the date by which a final rule would be issued. *See* Fall 2022 Agenda (identifying August 2023 as when a final rule would be issued)[58]; Spring 2023 Agenda (same)[59].

159. And by this same time (i.e., February 1, 2023), the Secretary had determined the proposed Menthol Rule (i.e., banning menthol as a characterizing flavor in cigarettes) was still appropriate for the protection of public health. Accordingly, each necessary element to promulgating and publishing the Menthol Rule existed.

160. But by August 2023, the Defendants had failed to publish, much less explain, why a final rule had yet to be promulgated or published.

161. In early September 2023, at the Third National Menthol Conference, CTP Director Brian King then explained that there was a delay in finalizing the rule and that such rule would likely be finalized by the end of December 2023.

162. By early December 2023, however, the Defendants had issued a new Fall 2023 Regulatory Agenda and moved the goal posts (yet again) for publicizing the final rule to March 2024.

163. Defendants then missed that internal rulemaking deadline as well. To date, no final rule is in place.

B. Defendants' ongoing delay hurts the public health.

164. At bottom, the Defendants' mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," 21 U.S.C. § 393(b)(1). This mission extends to

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[58] *Available at* https://web.archive.org/web/20230201022111/https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0910-AI60.

[59] *Available at* https://web.archive.org/web/20230922194307/https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI60.

"regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and reduce tobacco use by minors," FDA, *What We Do* (last updated Nov. 21, 29023),[60] 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).[61]

165. But because of Defendants' inaction, tobacco companies have continued to use menthol cigarettes to target youth, women, and the Black community[62]—all to the detriment of public health.

166. Given Defendants' seeming inability to act on this issue without prompting from this Court, the Plaintiffs respectfully request this Court's intervention yet again.

CLAIM FOR RELIEF

Count I: Violation of the Administrative Procedure Act

(5 U.S.C. §§ 555(b) & 706(1))

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

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

169. Together, Sections 555(b) and 706(1) "indicate a congressional view that agencies should act within reasonable time frames and that courts designated by statute to review agency actions may play an important role in compelling agency action that has been improperly

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[60] *Available at* https://www.fda.gov/about-fda/what-we-do.

[61] *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.

[62] *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).

withheld or unreasonably delayed." *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 76–77 (D.C. Cir. 1984). Accordingly, "delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake." *Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987) (footnotes omitted).[63] "This is particularly true when the very purpose of the governing Act is to protect those lives." *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157–58 (D.C. Cir. 1983).

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

171. The Tobacco Control Act provides that "[a]fter the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall … if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c) [i.e., 21 U.S.C. § 387g(c).]" 21 U.S.C. § 387g(d)(1)(A).

172. Here, each pre-condition to the Defendants' promulgation and publication of a final rule has been met. First, the comment period to the proposed Menthol Rule has closed. *See* FDA, *Comment Period Closed for FDA Proposed Rules Prohibiting Menthol Cigarettes and Flavored Cigars* (Aug. 10, 2022).[64] Second, the Defendants have already considered the Tobacco Products Scientific Advisory Committee's 2011 Menthol Report; as well as the comments and information submitted pursuant to subsections (b) and (c), *see* 21 U.S.C. § 387g(b), (c). And third, the Secretary has already determined that the proposed Menthol Rule is appropriate for the protection of the public health.

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[63] *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").

[64] *Available at* https://www.fda.gov/tobacco-products/ctp-newsroom/comment-period-closed-fda-proposed-rules-prohibiting-menthol-cigarettes-and-flavored-cigars.

173. Given that each element to promulgating and publishing a final rule is present, the Tobacco Control Act mandates that the Secretary "shall … promulgate" such regulation "and publish in the Federal Register findings on the matters …." Defendants' failure to do so here, constitutes a violation of the Tobacco Control Act.

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

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

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;

3. Pursuant to the Administrative Procedure Act and Tobacco Control Act, an Order directing Defendants to—

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

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

   c. Complete such actions within a reasonable timeframe.

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

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

Respectfully submitted,

Date: April 26, 2024
New York, NY

/s/ Christopher K. Leung

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