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9 *Control Leadership Council, Action on Smoking and*  
10 *Health, American Medical Association, and*  
11 *National Medical Association*

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

15 AFRICAN AMERICAN TOBACCO )  
16 CONTROL LEADERSHIP COUNCIL, )  
17 ACTION ON SMOKING AND HEALTH, )  
18 AMERICAN MEDICAL ASSOCIATION, )  
19 and NATIONAL MEDICAL )  
20 ASSOCIATION, )

21 Plaintiffs, )

22 vs. )

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

Defendants. )

Case No.: 4:20-cv-4012-KAW

**SECOND AMENDED COMPLAINT**  
**(FIRST SUPPLEMENT)**  
**(Administrative Procedure Act Case)**



1 Advisory Committee (“TPSAC” or “Committee”); (2) refer “[i]mmediately” to this Committee  
2 the issue of menthol in cigarettes and its effect on public health;<sup>4</sup> and (3) reevaluate periodically  
3 the flavor ban (which had omitted menthol) “to determine whether such standard[] should be  
4 changed to reflect new medical, scientific, or other technological data,” including with respect  
5 to menthol. *See* 21 U.S.C. § 387g(a)(5).

6 5. Congress repeatedly highlighted the urgent nature of the menthol inquiry,  
7 “urg[ing] the Secretary [of the U.S. Department of Health and Human Services (“HHS”)] to  
8 address these issues ***as quickly as practicable.***” H. Rept., Part 1 at 38 (emphasis added).  
9 Indeed, Congress believed that it would be “***critical*** for the Secretary ***to move quickly*** to  
10 address the unique public health issues posed by menthol cigarettes.” *Id.* at 38–39 (emphasis  
11 added).

12 6. Following the Act’s passage, FDA formed the Tobacco Products Scientific  
13 Advisory Committee, which conducted an extensive survey assessing the scientific evidence  
14 concerning the public health impacts of menthol in cigarettes and concluded in a 2011 report  
15 that the “**Removal of menthol cigarettes from the marketplace would benefit**  
16 **public health in the United States.**” 2011 TPSAC Menthol Rept., at 225 (emphasis in  
17 original).

18 7. The Committee’s Report further concluded that if menthol cigarettes had been  
19 removed from the marketplace in 2010, then (a) by 2020, roughly 17,000 premature deaths  
20 would have been avoided, and about 2.3 million people would not have started smoking; and  
21 (b) by 2050, the cumulative gains would have resulted in over 327,000 premature deaths  
22 avoided, and over 9.1 million people that would not have started smoking.

23 8. For the African American community, this would have meant that (a) by 2020,  
24 roughly 4,700 premature deaths would have been avoided, and about 461,000 African  
25 Americans would not have started smoking; and (b) by 2050, over 66,000 premature deaths  
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27 <sup>4</sup> *See* 21 U.S.C. § 387q(a); *id.* § 387g(e)(1).  
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1 would have been avoided, and over 1.6 million African Americans would not have started  
2 smoking.

3 9. FDA then conducted a peer-reviewed investigation in 2013, which reached a  
4 similar conclusion: menthol cigarettes (a) were associated with youth smoking initiation and  
5 greater addiction, and (b) posed “a public health risk above that seen with nonmenthol  
6 cigarettes.”

7 10. And yet, despite the findings of the TPSAC Report and FDA’s own  
8 investigation, reflecting new medical and scientific data, FDA did nothing until five years later  
9 in 2018, when then-FDA Commissioner Scott Gottlieb finally announced that FDA would  
10 advance a “Notice of Proposed Rulemaking that would seek to ban menthol in combustible  
11 tobacco products, including cigarettes and cigars.” FDA, Statement from FDA Commissioner  
12 Scott Gottlieb, M.D. (Nov. 15, 2018).<sup>5</sup> “Now, armed with the additional years of data,  
13 comments from the public ... and the perspective of [the FDA’s] Comprehensive Plan and its  
14 implementation,” FDA stated its intent to “accelerate the proposed rulemaking process to  
15 ensure that our policies on flavored tobacco products protect public health[.]” *Id.*

16 11. But instead—without engaging in any reasoned decision-making or providing  
17 any coherent explanation for its decision—FDA reversed course in or around June 2019 and  
18 allowed menthol to remain on the market:

- 19 a. On June 24, 2019, the HHS published its Spring 2019 inventory of rulemaking  
20 actions under development. *See* Regulatory Agenda, Ofc. of the Secretary,

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23 <sup>5</sup> FDA, Statement from FDA Commission Scott Gottlieb, M.D., on proposed new steps to  
24 protect youth by preventing access to flavored tobacco products and banning menthol in  
25 cigarettes (Nov. 15, 2018). *Available at* [https://www.fda.gov/news-events/press-  
26 announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-  
27 youth-preventing-  
28 access?utm\\_campaign=111518+Statement+FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm\\_medium=email&utm\\_source=El+oqua](https://www.fda.gov/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=El+oqua).

1 HHS, 84 Fed. Reg. 29623 (June 24, 2019).<sup>6</sup> This Agenda presented “the  
2 regulatory activities that the Department [i.e., HHS, FDA, and the defendant  
3 Center for Tobacco Products] expect[ed] to undertake in the foreseeable  
4 future,” *id.* at 29624 (citing various proposed rules, final rules, and long-term  
5 actions). Absent from HHS’s Spring inventory, however, was any plan by  
6 defendants to address menthol in cigarettes, much less any explanation as to  
7 why defendants’ about-face reflected new medical, scientific, or other  
8 technological data. *See* HHS Regulatory Agenda, *generally*.

- 9 b. HHS’s Fall 2019 inventory of rulemaking actions also failed to include any  
10 reference or plan to address menthol in cigarettes, or else any explanation of  
11 defendants’ decision-making process on this important public health issue. *See*  
12 HHS, Agency Rule List – Fall 2019 (Dec. 26, 2019).<sup>7</sup>

13 12. Defendants’ arbitrary and capricious actions are contrary to what the law  
14 requires, and harm the public health. And, defendants’ years of inaction and unreasonable  
15 refusal to act on this issue have almost certainly contributed to the increasing harms associated  
16 with menthol in cigarettes:

- 17 a. In 2009—at the time the Tobacco Control Act was enacted—menthol  
18 cigarettes represented over 25% of all cigarettes smoked in the United States.  
19 *See* H. Rept., Part 1 at 39. Today, the most recent data shows that figure has  
20 increased to 36%.<sup>8</sup>

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23 <sup>6</sup> Available at <https://www.federalregister.gov/documents/2019/06/24/2019-12004/regulatory-agenda>.

24 <sup>7</sup> Available at  
25 [https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION\\_GET\\_AGENCY\\_RULE\\_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900](https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900).

26 <sup>8</sup> *See* Fed. Trade Commission, Cigarette Rept. for 2017, Table 7B (issued 2019). Available at  
27 [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](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).

1           b. In 2009, more than 12 million individual smokers used menthol cigarettes. *See*  
2           H. Rept., Part 1 at 39. Today, the data shows that over 19 million smokers use  
3           menthol cigarettes—i.e., a majority of the estimated 34 million smokers in the  
4           United States.<sup>9</sup>

5           c. In 2009, nearly 70% of African Americans who smoked, used menthol  
6           cigarettes. *See* H. Rept., Part 1 at 39. Today, that figure has risen to over  
7           85%.<sup>10</sup>

8           13. The COVID-19 pandemic has further showcased the myriad ways in which  
9           menthol cigarettes negatively impact the public health, and the African American community  
10          in particular. A study in the *New England Journal of Medicine* found that coronavirus patients  
11          in China who smoked were more than twice as likely as those who didn't to have severe  
12          infections from COVID-19.<sup>11</sup> An April 8, 2020 advisory from the Massachusetts Attorney  
13          General Maura Healey warned that “it is vital that people are aware of the serious potential  
14          risks associated with smoking or vaping and COVID-19,” noting that “flavored tobacco  
15          products could make lung infections like COVID-19 worse.”<sup>12</sup> And early news reports  
16          concluded that the coronavirus was infecting and killing Black Americans at an alarmingly  
17          high rate, in part because African Americans’ higher rates of diabetes, heart disease and lung  
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20          <sup>9</sup> *See* U.S. Food & Drug Administration, *Menthol and Other Flavors in Tobacco Products*.  
21          Available at [https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-](https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products)  
22          [and-other-flavors-tobacco-products](https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products) (last visited June 13, 2020) (noting that more than 19.5  
23          million people are current smokers of menthol cigarettes); Centers for Disease Control and  
24          Prevention, *Smoking & Tobacco Use, Current Cigarette Smoking Among Adults in the United*  
25          *States* (identifying an estimated 34.3 million adults who smoked cigarettes in 2017). Available at  
26          [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm).

27          <sup>10</sup> *See* FDA, *Menthol and Other Flavors in Tobacco Products*, *id.* (noting that 85.8 percent of  
28          African American smokers use menthol cigarettes).

29          <sup>11</sup> Available at [https://www.nytimes.com/2020/04/09/health/coronavirus-smoking-vaping-](https://www.nytimes.com/2020/04/09/health/coronavirus-smoking-vaping-risks.html)  
30          [risks.html](https://www.nytimes.com/2020/04/09/health/coronavirus-smoking-vaping-risks.html) (citing <https://www.nejm.org/doi/full/10.1056/NEJMoa2002032>).

31          <sup>12</sup> Available at <https://www.mass.gov/doc/covid-vaping-advisory/download>.

1 disease—all conditions that are highly correlated with tobacco use—make people more  
2 vulnerable to the new respiratory disease.<sup>13</sup>

3 14. In sum, FDA’s delay, inaction, and failure “to move quickly” has been  
4 devastating, leading to millions of people initiating smoking cigarettes, and thousands of  
5 premature deaths.

6 15. Plaintiff AATCLC and many others have repeatedly called for FDA to fulfill its  
7 statutory duty to re-evaluate tobacco product standards and take up a rule to ban menthol  
8 cigarettes. But FDA has failed to do so. Until AATCLC filed this lawsuit, FDA refused even  
9 to resolve a Citizen’s Petition that AATCLC filed more than seven years ago, asking FDA to  
10 add menthol to the list of prohibited characterizing flavors in cigarettes and cigarette smoke as  
11 directed by Section 907(a)(1)(A) of the Tobacco Control Act, 21 U.S.C. § 387g.

12 16. On April 29, 2021, FDA finally responded to the 2013 Citizen Petition. *See*  
13 Dkt. 50-1 (“Response”). FDA “grant[ed]” the Petition, *id.* at 2, stating that “based on our  
14 consideration of the existing scientific evidence in the record, FDA believes eliminating  
15 menthol as a characterizing flavor in cigarettes would benefit public health and, therefore, the  
16 Agency intends to issue a proposed rule to prohibit menthol as a characterizing flavor in  
17 cigarettes.” *Id.* at 10.

18 17. The FDA issued a news release the same day, also announcing its intention to  
19 ban menthol cigarettes.<sup>14</sup> As explained by Acting FDA Commissioner Janet Woodcock, M.D.:  
20 “Banning menthol—the last allowable flavor—in cigarettes and banning all flavors in cigars  
21 will help save lives, particularly among those disproportionately affected by these deadly  
22 products. With these actions, the FDA will help significantly reduce youth initiation, increase  
23 the chances of smoking cessation among current smokers, and address health disparities  
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25 <sup>13</sup> Available at [https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-](https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true)  
26 [killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true](https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true).

27 <sup>14</sup> Available at [https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers)  
28 [based-actions-aimed-saving-lives-and-preventing-future-generations-smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers).

1 experienced by communities of color, low-income populations, and LGBTQ+ individuals, all  
2 of whom are far more likely to use these tobacco products.”<sup>15</sup>

3 18. Unfortunately, FDA failed to take any action to begin the rulemaking process.  
4 Nor did it commit to any firm deadline to act on the statements in its press release and Citizen  
5 Petition response, which mirror the (never-implemented) statements made almost three years  
6 ago by then-FDA Commissioner Gottlieb. *See* n.5, *supra* (Statement from FDA Commissioner  
7 Scott Gottlieb, M.D. announcing that FDA “armed with additional years of data” would  
8 advance a “Notice of Proposed Rulemaking that would seek to ban menthol in combustible  
9 tobacco products, including cigarettes and cigars.”) Despite this history, the FDA’s 2021 news  
10 release suggests that the agency would take ***a year, if not more, to even begin the***  
11 ***rulemaking process.***<sup>16</sup> This is the same rule-making process FDA committed to advancing  
12 in 2018, with zero observable progress to date. This proposed timeline is indefensible, and  
13 only serves to confirm that judicial oversight and intervention will be required.

14 19. Under these circumstances, the law requires more than another promise of  
15 future action that may never be fulfilled. By defendants’ own admission, the evidence  
16 conclusively demonstrates that a menthol ban “will help save lives, particularly among those  
17 disproportionately affected by these deadly products.” After years of inaction and the untold  
18 suffering defendants have caused, plaintiffs bring this lawsuit to compel appropriate action by  
19 defendants on this critical and urgent public health issue.

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22 <sup>15</sup> “Available at [https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-  
23 based-actions-aimed-saving-lives-and-preventing-future-generations-smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers).

24 <sup>16</sup> “The FDA is ***working toward issuing proposed product standards within the next***  
25 ***year*** to ban menthol as a characterizing flavor in cigarettes and ban all characterizing flavors  
26 (including menthol) in cigars; the authority to adopt product standards is one of the most  
27 powerful tobacco regulatory tools Congress gave the agency.” FDA Commits to Evidence-Based  
28 Actions Aimed at Saving Lives and Preventing Future Generations of Smokers (Apr. 29, 2021)  
(emphasis added), available at [https://www.fda.gov/news-events/press-announcements/fda-  
commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers).



**JURISDICTION & VENUE**

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2           20.    Jurisdiction: This Court has jurisdiction over this action, pursuant to 28 U.S.C.  
3 §§ 1331 and 1346. Plaintiffs allege violations of the Administrative Procedure Act, Pub. L. No.  
4 404, 60 Stat. 237, ch. 324, §§ 1–12 (1946), and Section 907 of the Tobacco Control Act, 21  
5 U.S.C. § 387g. Their requested relief is authorized by 5 U.S.C. § 706(1) and 28 U.S.C. § 1651.  
6 The United States is also a defendant.

7           21.    Venue: Venue in this judicial district is appropriate, pursuant to 28 U.S.C. §  
8 1391(e)(1). Plaintiff African American Tobacco Control Leadership Council resides in this  
9 judicial district.

10           22.    Intradistrict Assignment: Pursuant to Civil L.R. 3-2(c), intradistrict assignment  
11 is proper in the San Francisco or Oakland Division, as this action arises in the County of San  
12 Francisco, where Plaintiff African American Tobacco Control Leadership Council maintains  
13 its principal place of business.

**PARTIES**

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15           23.    Plaintiff African American Tobacco Control Leadership Council (“AATCLC”)  
16 brings this action on behalf of itself and its members. The AATCLC, which is based in San  
17 Francisco, California, was formed in 2008 to educate the African American community and  
18 public about tobacco use and cessation, and has led the fight to expose the predatory  
19 marketing of menthol cigarettes and flavored little cigars in the Black Community. The  
20 organization’s members include a cadre of dedicated community activists, academics, public  
21 health advocates, and researchers from across the country. FDA’s failure to address the harms  
22 caused by menthol in combustible cigarettes has adversely affected AATCLC, its members,  
23 and its work.

24           24.    The AATCLC’s mission is to save lives by partnering with community  
25 stakeholders and public health agencies to inform and affect the direction of tobacco policy,  
26 practices, and priorities, particularly as it affects the lives of Black Americans and African  
27 Immigrant populations. Its work includes educating the public about the effects of tobacco on  
28

1 these populations, and the need to regulate flavored tobacco products, including menthol  
2 cigarettes.

3 25. One of the AATCLC's key initiatives is the creation of Buffer Zones—local  
4 legislation that prohibits the sale of all flavored tobacco products, including menthol, within a  
5 500 to 1000-foot perimeter around schools. Establishing Buffer Zones to protect inner city  
6 children reduces their access to tobacco products, de-normalizes tobacco consumption, and  
7 pushes back against predatory targeting of these communities. The AATCLC has assisted  
8 Chicago, Minneapolis-St. Paul, Baltimore, and numerous California cities in adopting and  
9 implementing Buffer Zones.

10 26. The AATCLC has expended and continues to expend significant resources to  
11 help create Buffer Zones and to perform other outreach, engagement and education of elected  
12 officials, clergy, community-based organizations, youth groups and the media concerning the  
13 dangers of menthol cigarettes and their harmful effect on the lives of Black American and  
14 African Immigrant populations.

15 27. The defendants' unlawful refusal to ban menthol in tobacco products, and  
16 failure to periodically reevaluate and determine (much less explain) whether the Act's existing  
17 flavor standard should be changed to reflect new data and protect the public health, makes the  
18 AATCLC's work more difficult and impedes its efforts to educate the public about the dangers  
19 of menthol cigarettes. It also requires the AATCLC to divert resources that could otherwise be  
20 used to advance other organizational goals to focus on menthol-related concerns.

21 28. In addition, as detailed below, on or about April 12, 2013, plaintiff AATCLC  
22 (together with others) submitted a Citizen Petition with the FDA. The Petition requested that  
23 the FDA take certain actions to decrease the harms caused by menthol cigarettes and provide  
24 cessation support to smokers of menthol cigarettes who wish to quit. Over seven years have  
25 passed since the AATCLC submitted this Petition, and the defendants did not provide a  
26 substantive response until this lawsuit was filed. On April 29, 2021, almost a year after  
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1 Plaintiffs commenced litigation, FDA finally provided a response, which is deficient for the  
2 reasons discussed in Section V, below.

3 29. Plaintiff Action on Smoking and Health (“ASH”) is a non-profit organization  
4 headquartered in Washington, D.C. ASH was founded in 1967 and has spent the last fifty  
5 years battling against the tobacco industry. Its mission is to advocate for innovative legal and  
6 policy measures to end the global tobacco epidemic. ASH’s past accomplishments include  
7 helping to achieve restrictions on tobacco advertising and smoking bans in workplaces and  
8 various forms of public transit.

9 30. ASH believes that the production, marketing and sale of cigarettes is a human  
10 rights violation. This is in part because the tobacco industry often targets their marketing to  
11 specific populations based on gender, race, sexual identity and age. Some of these groups  
12 smoke at much higher rates than the general population, and they are all protected by various  
13 international and regional human rights treaties and instruments. ASH is currently working to  
14 elevate tobacco as a human rights issue through (a) work with the Human Rights Council, the  
15 Framework Convention on Tobacco Control Conference of the Parties, and other  
16 international bodies; (b) using human rights reporting mechanisms to encourage governments  
17 to advance tobacco control within their own countries; (c) providing legal resources, training,  
18 and support to advocates on how to use human rights norms to advance local tobacco control  
19 measures; and (d) maintaining a repository of human rights resources to assist allies in taking a  
20 human rights approach.

21 31. ASH’s efforts include menthol-related initiatives. For example, on January 2,  
22 2020, ASH staff attended a public hearing of the D.C. City Council Judiciary and Public  
23 Safety Committee, which is considering a ban on the sale of flavored tobacco products. Both  
24 gave formal testimony in favor of the measure, and urged the Council to include menthol in  
25 the final law. ASH also provided information to the Committee concerning the Council’s  
26 authority to phase out the sale of tobacco products in the city. The defendants’ unlawful  
27 refusal to ban menthol in tobacco products, and failure to periodically reevaluate and  
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1 determine whether the Act's existing flavor standard should be changed to reflect new data and  
2 protect the public health, makes ASH's work more difficult and impedes its efforts to educate  
3 the public about the dangers of menthol cigarettes. It also requires ASH to divert resources  
4 that could be used to advance other organizational goals to focus on menthol-related concerns.

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

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

24 34. More recently, AMA has also increased its focus on health equity. The AMA  
25 recognizes that systemwide bias and institutionalized racism contribute to inequities across the  
26 U.S. health care system. The AMA is committed to fighting for greater health equity by  
27 identifying and eliminating inequities through advocacy, community leadership and education.

1 This includes working to eliminate the use of menthol-flavored tobacco products, which  
2 represent a disproportionate and growing share of tobacco use by African Americans, and the  
3 direct cause of thousands of preventable deaths in the African American community. For  
4 example, the AMA has sent numerous letters to and attended meetings with government  
5 officials to encourage the elimination of menthol-flavored cigarettes.

6 35. The defendants' unlawful failure to evaluate and determine whether the Act's  
7 existing flavor standard should be changed to reflect new data and protect the public health,  
8 and to ban menthol flavoring in cigarettes, interferes with the work of the AMA and its  
9 members. Among other things, the defendants' unlawful conduct undermines the efforts of  
10 AMA and its members to educate patients about the dangers of menthol cigarettes and achieve  
11 health equity for all patients. It also forces AMA to divert resources that could be used to  
12 advance other public health initiatives.

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

20 37. The NMA is particularly steadfast in its commitment to the elimination of  
21 health disparities and the promotion of healthy lifestyles among African Americans and other  
22 underserved populations. In furtherance of these goals, the NMA conducts national consumer  
23 education programs on cancer, cardiovascular disease and stroke, HIV/AIDS, women's  
24 health, asthma, smoking cessation, immunization, traffic safety, breastfeeding, clinical trials, as  
25 well as other issues that impact the lives of African Americans. Throughout its history the  
26 National Medical Association has focused primarily on health issues related to African  
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1 Americans and medically underserved populations; however, its principles, goals, initiatives  
2 and philosophy encompass all racial and ethnic groups.

3 38. As the nation's only organization devoted to the needs of African American  
4 physicians, health professionals and their patients, the NMA serves as the conscience of the  
5 medical profession in the ongoing fight to eliminate health disparities in the nation's health  
6 care delivery system. The NMA has been an unwavering advocate for health policies that  
7 improve the quality and availability of health care of African Americans and other underserved  
8 populations. For instance, the National Medical Association was the force behind such  
9 landmark reforms as Medicare and Medicaid. Today, the NMA continues to provide  
10 leadership in shaping the national health policy agenda through continued involvement in a  
11 variety of critical policy matters, including with respect to smoking. For example, the NMA  
12 passed an August 3, 2017 resolution during their Annual Meeting of the House of Delegates,  
13 supporting a prohibition on the sale of flavored tobacco products, including mentholated  
14 cigarettes. As noted on the NMA's website, African Americans have the highest surveyed rate  
15 of desire to quit smoking but are less successful in quit attempts than white and Hispanic  
16 smokers. This is due in part to the anesthetic effects of menthol in mentholated cigarettes and  
17 the high rate of mentholated cigarette use among African Americans. This is precisely the type  
18 of health disparity the NMA seeks to eliminate.

19 39. The defendants' unlawful refusal to comply with their Tobacco Act obligations  
20 and address mentholated cigarettes undermines the NMA's efforts to eliminate health  
21 disparities and promote healthy lifestyles among African Americans and other underserved  
22 populations, and impedes its mission to achieve parity and justice in medicine. Among other  
23 things, the defendants' unlawful conduct hinders the efforts of the NMA and its members to  
24 promote smoking cessation, and forces them to divert resources that could be used for other  
25 health policies.

1           40. Defendant U.S. Department of Health and Human Services (“HHS”) is the  
2 federal agency responsible for administering the Food, Drug and Cosmetic Act, 21 U.S.C. §  
3 301 *et seq.* (1982). HHS is headquartered in Washington, D.C.

4           41. Defendant Xavier Becerra is sued in his official capacity as the Secretary of the  
5 U.S. Department of Health and Human Services. As Secretary, Mr. Becerra is ultimately  
6 responsible for HHS’s activities and policies and for implementing the Tobacco Control Act.  
7 Although the Secretary has delegated many responsibilities under the Act to the Commissioner  
8 of the Food and Drug Administration<sup>17</sup>, the Secretary has nonetheless reserved the authority to  
9 (a) establish procedural rules applicable to tobacco products, such as menthol cigarettes; and  
10 (b) present highly significant public issues involving the availability and marketability of  
11 tobacco products, including menthol cigarettes.

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

20           43. Defendant Janet Woodcock is sued in her official capacity as Acting  
21 Commissioner of the FDA. FDA administers programs at HHS related to tobacco products.  
22 As Acting Commissioner, Ms. Woodcock is responsible for FDA’s activities and policies,  
23 including the agency’s implementation of the Tobacco Control Act.

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27 <sup>17</sup> *See Pub. Citizen Health Research Grp. v. Comm’r, Food & Drug Admin.*, 740 F.2d 21, 23 n.1 (D.C. Cir.  
28 1984).





1           50. This mission includes “regulating the manufacturing, marketing, and  
2 distribution of tobacco products to protect the public health and reduce tobacco use by  
3 minors,” FDA.gov, What We Do,<sup>19</sup> as well as “[p]rotecting consumers and enhancing public  
4 health by maximizing compliance of FDA regulated products and minimizing risk associated  
5 with those products,” FDA Reg. Procedures Manual, Intro., at 3 (Aug. 2018).<sup>20</sup>

6           51. HHS and FDA are also responsible for “identifying and addressing ...  
7 disproportionately high and adverse human health ... effects of its programs, policies, and  
8 activities on minority populations and low-income populations[.]” Executive Order 12898,  
9 § 1-101 (Feb. 11, 1994).<sup>21</sup>

10           **B. Congress directed FDA to move quickly to address menthol.**

11           52. Section 907 of the Tobacco Control Act sets forth FDA’s obligation to address  
12 the public health problems caused by menthol cigarettes. *See* 21 U.S.C. § 387g.

13                           **1. The Act mandates action by the Secretary on menthol.**

14           53. As noted above, when Congress enacted the Tobacco Control Act in 2009,  
15 Congress created a “tobacco product standard” that effectively banned all flavors in cigarettes,  
16 save for tobacco and menthol flavors. *See* 21 U.S.C. § 387g(a)(1)(A).<sup>22</sup>

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18 <sup>19</sup> Available at <https://www.fda.gov/about-fda/what-we-do>.

19 <sup>20</sup> Available at <https://www.fda.gov/media/71923/download>. The Regulatory Procedures  
20 Manual “is a reference manual that provides internal procedures and related information to be  
21 used by FDA employees who process certain regulatory and enforcement matters in support of  
22 the agency’s public health mission.” FDA Reg. Procedures Manual at 1. This Manual further  
23 identifies some of FDA’s values, including the following: “We demonstrate our commitment to  
24 safeguarding the public health in our actions.” *Id.* at 3.

25 <sup>21</sup> Available at <https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf>.

26 <sup>22</sup> Per the Act, “a cigarette or any of its component parts” is prohibited from containing “as a  
27 constituent ... or additive, an artificial or natural flavor (other than tobacco or menthol) or an  
28 herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut,  
licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product  
or tobacco smoke.” 21 U.S.C. § 387g(a)(1)(A). This standard became effective on September 22,  
2009. *See* FDA, Enforcement of General Tobacco Standard Special Rule for Cigarettes, 74 Fed.  
Reg. 48974, Docket No. FDA-2009-N-0449 (Sept. 22, 2009).



1           60.     The Committee’s review was also directed to address the considerations  
2 identified by subsections (a)(3)(B)(i)<sup>23</sup> and (b)<sup>24</sup>—i.e., considerations that FDA would have  
3 otherwise addressed in adopting an additional tobacco product standard or in considering any  
4 proposed standard. *See* 21 U.S.C. § 387g(e)(1).

5           61.     Such considerations would include “scientific evidence” concerning the risks  
6 and benefits of a “proposed standard,” 21 U.S.C. § 387g(a)(3)(B)(i)(I); “the technical  
7 achievability of compliance with such standard,” *id.* § 387g(b)(1); and “other information  
8 submitted in connection with a proposed standard,” *id.* § 387g(b)(2).

9           62.     Congress further mandated that “not later than 1 year after its establishment,”  
10 the Scientific Advisory Committee “shall submit to the Secretary a report and  
11 recommendation,” 21 U.S.C. § 387g(e)(2), and reiterated that nothing in subsection (e) was to  
12 be construed as limiting FDA’s “authority to take action under this section or other sections of  
13 this Act applicable to menthol,” *id.* § 387g(e)(2), (3).

### 14                           **3. Congress intended FDA to address menthol “quickly.”**

15           63.     On March 3, 2009, Rep. Henry A. Waxman along with 124 original  
16 cosponsors introduced H.R. 1256—the “Family Smoking Prevention and Tobacco Control  
17 Act.” The Committee Report and floor statements of the sponsor and committee member in  
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19  
20 <sup>23</sup> “In making a finding described in subparagraph (A), [FDA] shall consider scientific evidence  
21 concerning (I) the risks and benefits the risks and benefits to the population as a whole, including  
22 users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased  
23 likelihood that existing users of tobacco products will stop using such products; and (III) the  
24 increased or decreased likelihood that those who do not use tobacco products will start using such  
25 products.” 21 U.S.C. § 387g(a)(3)(B)(i).

26 <sup>24</sup> “[FDA] shall consider information submitted in connection with a proposed standard  
27 regarding the technical achievability of compliance with such standard.” 21 U.S.C. § 387g(b)(1).  
28 “[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).

1 charge (Rep. Waxman) make clear that Congress considered menthol to be an urgent public  
2 health concern and intended the FDA to move quickly to address it.

3 64. Both the accompanying Committee Report and following floor statements by  
4 Rep. Waxman confirm Congress' intention that FDA act "quickly" to address the special  
5 problem of menthol cigarettes. As explained by the Committee Report:

6 *Section 907. Tobacco product standards* Consistent with the overall  
7 intent of the bill to protect the public health, including by reducing  
8 the number of children and adolescents who smoke cigarettes,  
9 section 907(a)(1) is intended to prohibit the manufacture and sale  
10 of cigarettes with certain "characterizing flavors" that appeal to  
11 youth. ...

12 ***The Committee recognizes the unique issues***  
13 ***surrounding menthol cigarettes and urges the Secretary***  
14 ***to address these issues as quickly as practicable.*** The  
15 Committee is especially concerned about proportionately higher  
16 rates of menthol cigarette use among African American smokers,  
17 as well as the historic targeting of African Americans for menthol  
18 cigarette use by tobacco companies. While it is unclear what  
19 effect the presence of menthol in cigarettes may have on  
20 addictiveness, toxicity, or other qualities of cigarettes, the  
21 Committee recognizes that menthol cigarettes may pose unique  
22 health risks to those who smoke them. Given the high rates of use  
23 among African American smokers, including African American  
24 youth, as well as higher rates of lung cancer documented among  
25 African American smokers as compared to non-African American  
26 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).<sup>25</sup>

65. This emphasis on FDA’s ability to move “quickly” in addressing “the unique public health issues posed by menthol cigarettes” was further emphasized by Rep. Henry A. Waxman, the committee member in charge of H.R. 1256. On two separate occasions, Rep. Waxman noted that menthol cigarettes would be “an early focus” of FDA’s attention.

66. First, on April 1, 2009, Rep. Waxman noted that he and his colleagues had “worked with members of the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus of the agency’s attention.” Cong. Rec.—House, H4318, H4339 (Vol. 155, No. 55).<sup>26</sup>

67. Then, on June 12, 2009, Rep. Waxman reiterated that same understanding, using similarly strong language: “We worked with members of the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus of attention by the agency, and

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<sup>25</sup> The House Committee Report went on to note the following:

Menthol cigarettes currently represent over one quarter of all cigarettes smoked in the United States, representing more than 12 million individual smokers. Additionally, nearly 7 in 10 African Americans who smoke choose to smoke menthol cigarettes. Given the number of open questions related to menthol cigarettes, the legislation authorizes the Secretary to ban or modify the use of menthol in cigarettes based on scientific evidence. Given the large number of Americans who smoke menthol, the disproportionate prevalence of menthol cigarettes among African Americans, the racial and ethnic differences in lung cancer incidence, and the uncertainty about the potentially negative consequences of an immediate menthol ban, the Committee believes that this approach ensures that FDA has the scientific evidence necessary to make the best decisions to protect the public health.

H. Rept., Part 1 at 39.

<sup>26</sup> Available at <https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-2>.

1 that the agency has the authority to deal with these and other products.” Cong. Rec.—House,  
2 H6630, H6652 (Vol. 155, No. 88).<sup>27</sup>

3 **C. FDA confirmed its intention to address menthol in cigarettes.**

4 68. On June 22, 2009, President Barack Obama signed H.R. 1256 into law—the  
5 “Family Smoking Prevention and Tobacco Control Act.” Public Law No. 111-31, 123 Stat.  
6 1776 (codified, in relevant part, at 15 U.S.C. §§ 1333–34 and 21 U.S.C. § 301 *et seq.*) (2009).

7 69. The Act’s flavor ban then became effective on September 22, 2009. *See* FDA,  
8 Enforcement of General Tobacco Standard Special Rule for Cigarettes, 74 Fed. Reg. 48974,  
9 Docket No. FDA-2009-N-0449 (Sept. 22, 2009).

10 70. FDA’s own statements following the Act’s passage reflect that FDA intended to  
11 address menthol in cigarettes, following the issuance of the Tobacco Products Scientific  
12 Advisory Committee’s report and recommendation.

13 71. On September 22, 2009, FDA announced that it would be “examining options”  
14 for regulating menthol cigarettes:

15 The FDA’s ban on candy and fruit-flavored cigarettes, effective  
16 today, highlights the importance of reducing the number of  
17 children who start to smoke, and who become addicted to  
18 dangerous tobacco products. The FDA is also examining options  
19 for regulating both menthol cigarettes and flavored tobacco  
20 products other than cigarettes.<sup>28</sup>

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21  
22 <sup>27</sup> Available at <https://www.congress.gov/congressional-record/2009/06/12/house-section/article/H6630-1>.

23 <sup>28</sup> FDA, News & Events, *Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First*  
24 *Under New Tobacco Law* (Sept. 22, 2009) (noting that “[a]lmost 90 percent of adult smokers start  
25 smoking as teenagers. These flavored cigarettes are a gateway for many children and young  
26 adults to become regular smokers,” said FDA Commissioner Margaret A. Hamburg, M.D. ....  
27 Flavors make cigarettes and other tobacco products more appealing to youth. Studies have  
28 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

1           72. In response to questions from journalists, Dr. Lawrence Deyton—the Center  
2 for Tobacco Products, Director at such time—noted that the Center would be “studying” and  
3 “discussing” the issue of menthol cigarettes with the agency’s Scientific Advisory Committee:

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

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

17 Sept. 22, 2009 Tr. For FDA’s Media Briefing, at 8–9 (emphasis added).<sup>29</sup>

18           73. In similar statements, Dr. Deyton reiterated that the Center would be  
19 addressing the issue of menthol cigarettes “separately”:

20           Miriam Falco: ... I got to say I’m a little confused. Your  
21 answers are all very government-speak, if I  
22 may say so. If you know that young people

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23  
24 young people who start smoking daily.”) (footnote omitted). Available at  
25 [https://web.archive.org/web/20090924140101/http://www.fda.gov/NewsEvents/Newsroom/  
PressAnnouncements/ucm183211.htm](https://web.archive.org/web/20090924140101/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm).

26 <sup>29</sup> Available at  
27 [https://web.archive.org/web/20091104012525/http://www.fda.gov/downloads/NewsEvents/  
Newsroom/MediaTranscripts/UCM183533.pdf](https://web.archive.org/web/20091104012525/http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM183533.pdf).

1 prefer menthol cigarettes, then why aren't  
2 they included in this? ...

3 Lawrence Deyton: ***In terms of the question of menthol,***  
4 ***the law specifically asks us to look at***  
5 ***menthol separately. And we will be***  
6 ***doing that.***

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

8 **II. FDA concludes that banning menthol would improve the public health.**

9 74. Following the Tobacco Control Act's enactment, FDA collected extensive  
10 evidence concerning these critical public health issues.

11 **A. The 2011 Tobacco Products Scientific Advisory Committee Report**

12 75. In 2010, FDA organized a Tobacco Product Scientific Advisory Committee  
13 ("TPSAC") in accordance with the Act's directive. That Committee was comprised of "a  
14 panel of leading public health, scientific experts and representatives of various parts of the  
15 tobacco industry." *See* FDA, Dr. Lawrence R. Deyton, Dir. Center for Tobacco Products,  
16 *FDA Remarks on the Report and Recommendation on the Public Health Impact of Menthol Cigarettes* (Mar.  
17 18, 2011) ("2011 FDA Remarks on Menthol Cigarettes Rept.").<sup>30</sup> This Committee was  
18 charged with "providing advice, information, and recommendations to FDA on health issues  
19 related to tobacco products and other issues relating to the regulation of tobacco products." *Id.*

20 76. As part of the Committee's charter, FDA designated a government  
21 representative to attend each meeting of the full committee and subcommittees; ensure the  
22 Committee's compliance with statutory, regulatory, and administrative directives; and approve  
23

24  
25  
26 <sup>30</sup> Available at [https://wayback.archive-  
it.org/7993/20170112125250/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting  
27 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm](https://wayback.archive-it.org/7993/20170112125250/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247617.htm).



1 and prepare all meeting agendas. *See* FDA, Charter of the Tobacco Products Scientific  
2 Advisory Comm. (Aug. 7, 2009).<sup>31</sup>

3 77. The full Scientific Advisory Committee first met in March 2010, and 11 more  
4 times thereafter. *See* FDA Rept. to Congress, *Progress and Effectiveness of the Implementation of the*  
5 *Family Smoking Prevention and Tobacco Control Act*, at 15 (2013). There were also two meetings of  
6 the Tobacco Products Constituents Subcommittee of the TPSAC and two meetings of the  
7 Menthol Report Subcommittee. *See id.* Each of these Committee and Subcommittee meetings  
8 covered a broad range of materials, presentations, and public submissions. *See* FDA 2010  
9 TPSAC Mtg. Materials and Info.;<sup>32</sup> *see also* FDA 2011 TPSAC Mtg. Materials and Info.<sup>33</sup>

10 78. On March 23, 2011, the TPSAC submitted its report, *Menthol Cigarettes and*  
11 *Public Health: Review of the Scientific Evidence and Recommendations* (2011) (“2011 TPSAC Menthol  
12 Rept.”).<sup>34</sup>

13 79. This Report—also known as the TPSAC Report—contained a number of  
14 findings and conclusions, based on the best available scientific evidence.

### 15 **1. Menthol masks the irritating effects of nicotine.**

16 80. Among other things, the Report found that menthol is a flavor additive that  
17 possesses a minty taste and aroma. *See* 2011 TPSAC Menthol Rept. at 16. In certain  
18 medicinal products such as cough drops, menthol is regulated as a drug. *See id.* The use of  
19

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20 <sup>31</sup> Available at

[https://web.archive.org/web/20090916081752/http://www.fda.gov/AdvisoryCommittees/Co  
21 mmitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180904.htm](https://web.archive.org/web/20090916081752/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180904.htm).

22 <sup>32</sup> Available at [https://wayback.archive-](https://wayback.archive-it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting)

[it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting  
23 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm).

24 <sup>33</sup> Available at [https://wayback.archive-](https://wayback.archive-it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting)

[it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting  
25 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm).

26 <sup>34</sup> Available at [https://wayback.archive-](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/Commit)

[it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/Commit  
27 teesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf).

1 menthol in tobacco products, however, was not. *See id.* Menthol is present in 90% of tobacco  
2 products, including cigarettes that are not marketed as menthol cigarettes. *See id.*

3 81. The Report also found that menthol produces a variety of sensory effects,  
4 including cooling and soothing effects, as well as anesthetic effects. *See id.* at 23. For example,  
5 “[i]n cigarettes with low levels of tar and nicotine, the addition of menthol can enhance the  
6 ‘bite’ or ‘throat grab’ of the smoke, making such cigarettes more acceptable to consumers.  
7 Conversely, the addition of menthol to cigarettes high in tar and nicotine can reduce the  
8 irritating effect of nicotine ... making these cigarettes more palatable.” *Id.* at 24.

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

## 12 **2. The marketing of menthol cigarettes to youth and** 13 **minorities.**

14 83. The Report also found that the tobacco industry spent “as much or more on  
15 magazine advertising for menthol [cigarette brands] as for non-menthol brands, even though  
16 menthol brands represent a much smaller share of the market.” 2011 TPSAC Menthol Rept.  
17 at 61. In particular, the Committee found that—

- 18 a. menthol cigarettes “are marketed disproportionately to younger people,” *id.* at  
19 92;
- 20 b. menthol use is higher among youth and young adult smokers, *see id.*;
- 21 c. women “have been targets of tailored menthol marketing efforts,” *id.*; and
- 22 d. menthol cigarettes are “disproportionately marketed per capita to African  
23 Americans. African Americans have been the subjects of specifically tailored  
24 menthol marketing strategies and messages. ... [And,] [c]onsistent with these  
25 targeted marketing efforts, menthol cigarettes are disproportionately smoked by  
26 African American smokers,” *id.*



1           89. As explained by the Committee, “the availability of menthol cigarettes has led  
2 to an increase in the number of smokers and [] this increase does have adverse public health  
3 impact in the United States.” *Id.* at 220.

4           90. “[O]f particular concern was the high rate of menthol cigarette smoking among  
5 youth and the trend over the last decade of increasing menthol cigarette smoking among 12–  
6 17 year olds, even as smoking of non-menthol cigarettes declines. .... Thus, the availability of  
7 menthol cigarettes increases initiation and reduces cessation, thereby increasing the number of  
8 people who are smoking. This increase in the number of smokers represents an adverse impact  
9 of the availability of menthol cigarettes on public health.” *Id.* at 220–21.

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

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

19                           **4. Recommendation: Remove menthol cigarettes from the**  
20                           **market.**

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

25           94. Per the Committee, the tobacco companies’ marketing of menthol cigarettes  
26 “has been successful”:  
27  
28

1           Menthol cigarettes are now smoked by most African American  
2           smokers and there is a concerning rise of menthol cigarette  
3           smoking among youth. Menthol cannot be considered merely a  
4           flavoring additive to tobacco. Its pharmacological actions reduce  
5           the harshness of smoke and the irritation from nicotine, and may  
6           increase the likelihood of nicotine addiction in adolescents and  
7           young adults who experiment with smoking. Furthermore, the  
8           distinct sensory characteristics of menthol may enhance the  
9           addictiveness of menthol cigarettes, which appears to be the case  
10          among youth. [The Committee] has found that the availability of  
11          menthol cigarettes has an adverse impact on public health by  
12          increasing the numbers of smokers with resulting premature death  
13          and avoidable morbidity.

14       *Id.* at 225.

15           95.     Removing menthol from cigarettes could furthermore result in a substantial  
16          reduction in cigarette smoking by encouraging smokers to quit smoking. *See id.* at 227.

17                   **5. FDA’s re-commitment to addressing menthol in cigarettes.**

18           96.     Following the Committee’s release of this report, FDA announced that it would  
19          conduct a “thorough review” of the report, with its own experts within the FDA Center for  
20          Tobacco Products. 2011 FDA Remarks on Menthol Cigarettes Rept. FDA further  
21          acknowledged “the strong interest in this issue among all stakeholders” and committed itself to  
22          “continu[ing] to communicate the steps FDA is taking as it determines what future regulatory  
23          actions, if any, are warranted.” *Id.*

24           97.     FDA then reiterated that “a top priority for FDA is to protect the public health  
25          from the harmful effects of tobacco use[.]” *Id.*

26           98.     Per FDA’s Center for Tobacco Products Director, “Tobacco is the leading  
27          cause of preventable disease, disability, and death in the United States. Tobacco products are  
28

1 responsible for approximately 443,000 deaths and \$193 billion on medical expenditures and  
2 lost productivity each year in the United States.” *Id.*<sup>35</sup>

3 **B. FDA’s 2013 scientific evaluation of menthol cigarettes.**

4 99. On July 24, 2013, FDA then issued an advance notice of proposed rulemaking  
5 to solicit information and public comment on the “potential regulation of menthol in  
6 cigarettes.” FDA, Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco*  
7 *Products*, Dkt. No. FDA-2013-N-0521, 78 Fed. Reg. 44484, 44484 (July 24, 2013).<sup>36</sup>

8 100. As part of this advance notice, FDA made available its preliminary scientific  
9 evaluation of public health issues relating to the use of menthol in cigarettes. *See* FDA, Prelim.  
10 Scientific Eval. of the Possible Public Health Effects of Menthol Versus Non[-]Menthol  
11 Cigarettes (“2013 FDA Findings”).<sup>37</sup> This undertaking was a “thorough review of the available  
12 science concerning menthol cigarettes.” *Id.* at 3. To accomplish this task, FDA—

- 13 a. “weighed the collective body of evidence for the impact of the use of menthol in  
14 cigarettes on public health”;
- 15 b. “considered the source of information, the type of study, and the quality of  
16 study methods and data”;
- 17 c. “evaluated the peer-reviewed literature, industry submissions and other  
18 materials provided to TPSAC,” and  
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21 <sup>35</sup> At around this same time, the tobacco industry submitted to FDA a competing Industry  
22 Menthol Report. *See* The Industry Menthol Report (Mar. 23, 2011). *Available at*  
23 [https://wayback.archive-  
it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/Commit  
teesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf](https://wayback.archive-it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf).

24 <sup>36</sup> *Available at* [https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-  
in-cigarettes-tobacco-products-request-for-comments](https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-in-cigarettes-tobacco-products-request-for-comments).

25 <sup>37</sup> *See* FDA, Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco Products*, 78  
26 Fed. Reg. 44484, at Reference 1, *Preliminary Scientific Evaluation of the Possible Public Health Effects of*  
27 *Menthol Versus non[-]Menthol Cigarettes*, ID No. FDA-2013-N-0521-0001 (July 24, 2013). *Available at*  
28 <https://www.regulations.gov/document?D=FDA-2013-N-0521-0001>.

- 1 d. “performed or commissioned additional analyses in an attempt to fill in and  
2 inform some of the gaps in the literature.”

3 *Id.* at 3.

4 101. FDA then submitted its findings to a peer review panel, which provided  
5 comments to which FDA then responded to. *See* FDA Rept. to Congress, *Progress and*  
6 *Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act*, at 15  
7 (2013).<sup>38</sup> The agency also posted the peer reviewed comments, and its response to those  
8 comments. *See id.*

9 **1. FDA’s 2013 findings affirm the Committee’s 2011 findings.**

10 102. Based on FDA’s review, FDA found that the weight of the evidence, among  
11 other things, supported the following conclusions:

- 12 a. Menthol in cigarettes is “likely associated with altered physiological responses to  
13 tobacco smoke”;
- 14 b. A majority of African American smokers use menthol cigarettes;
- 15 c. Younger populations have the highest rate of smoking menthol cigarettes;
- 16 d. Female smokers are more likely to smoke menthol cigarettes than male smokers;
- 17 e. The marketing of menthol cigarettes is associated with menthol brand  
18 preference among adolescents and the African American community;<sup>39</sup> and
- 19 f. Menthol in cigarettes is likely associated with—  
20 i. increased initiation and progression to regular cigarette smoking;<sup>40</sup>

21  
22  
23 <sup>38</sup> Available at <https://www.fda.gov/media/86670/download>.

24 <sup>39</sup> “The available data show that advertising is a strong driver of brand preference among  
25 adolescents and that it is likely that the standard marketing mix approach of price, promotion,  
26 product, and place has been used to drive menthol cigarette preference among the urban African  
27 American community.” 2013 FDA Findings, at 5.

28 <sup>40</sup> “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.

- ii. increased dependence;<sup>41</sup> and
- iii. reduced success in smoking cessation, especially among African American menthol smokers.<sup>42</sup>

2013 FDA Findings at 4–6.

103. In summary, FDA concluded that menthol in cigarettes was associated with greater addiction, menthol smokers were less likely to successfully quit smoking, and that 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 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

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<sup>41</sup> “There were consistent findings that menthol smokers more likely to smoke their first cigarette within five minutes of waking.” 2013 FDA Findings, at 6.

<sup>42</sup> “In the reviewed studies, menthol smokers, especially African American menthol smokers, were less likely to successfully stop smoking than their nonmenthol smoking counterparts. This is consistent with the observation that menthol smokers appear to be more nicotine dependent than nonmenthol smokers which can be an important factor in smoking cessation success.” 2013 FDA Findings, at 6.



1 evidence indicating that menthol cigarettes are marketed as a  
2 smoother alternative to nonmenthol cigarettes, make it likely that  
3 menthol cigarettes pose a public health risk above that seen with  
4 nonmenthol cigarettes.

5 *Id.* at 6.

6 **2. FDA commits to addressing menthol in cigarettes.**

7 104. Notably, FDA clarified that this “scientific assessment of public health issues  
8 related to menthol in cigarettes ... [did] not constitute a decision about what regulatory action,  
9 if any, FDA might take with respect to menthol in cigarettes.” FDA 2013 Findings, at 7.

10 105. Rather, FDA would first “review[] all of the available information from this  
11 assessment and the anticipated public comments, from the [2011 Tobacco Product Scientific  
12 Advisory Committee] report and associated public comments, and from the tobacco industry  
13 perspective document[.]” *Id.*

14 106. Upon completing this review, FDA would then “determine[]” whether  
15 “restrictions on the sale and/or distribution of menthol cigarettes or product standards should  
16 be established[.]” *Id.*

17 107. By this time, the Center for Tobacco Products’ Director Mitch Zeller had  
18 acknowledged that “Menthol cigarettes raise critical public health questions.” Michael  
19 Felberbaum, *FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23, 2013).<sup>43</sup> Zeller  
20 further noted that there was “no holdup” on FDA proposing restrictions on menthol, but that  
21 there were still “some important questions” that need to be answered. *See id.*

22 108. To that end, in August 2013, FDA announced that it was funding three  
23 menthol related studies: one to look at whether genetic differences in taste perception explain  
24 why certain racial and ethnic populations are more likely to use menthol cigarettes; the second  
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26  
27 <sup>43</sup> Available at <https://www.usatoday.com/story/news/nation/2013/07/23/fda-menthol-cigarettes-health-risk/2578331/>.

1 to compare exposure to smoke-related toxins and carcinogens from menthol and nonmenthol  
2 cigarettes; and a third to examine the effects of menthol and nonmenthol compounds in  
3 various tobacco products on both tobacco addiction and toxicants of tobacco smoke. *See FDA*  
4 *Invites Public Input on Menthol in Cigarettes*, The ASCO Post, Vol. 4, Issue 13, at 21 (Aug. 13,  
5 2013).<sup>44</sup>

6 109. On information and belief, FDA has already completed and reviewed the  
7 results of these three menthol studies initiated almost seven years ago.

8 **III. AATCLC’s Citizen Petition urges FDA to act on menthol, but to no avail.**

9 110. That same year in 2013, plaintiff AATCLC (together with several other leading  
10 national organizations) submitted a Citizen Petition with FDA. *See Tobacco Control Legal*  
11 *Consortium et al. Citizen Petition*, Dkt. ID FDA-2013-P-0435-0001 (“Citizen Petition”).<sup>45</sup>

12 111. The Petition cited extensive evidence that (a) smoking remains a critical public  
13 health issue; (b) menthol cigarettes hurt kids; (c) menthol cigarettes harm minority smokers; (d)  
14 prohibiting menthol cigarettes would benefit health, and, among other things, asked FDA to  
15 do the following:

- 16 a. Add menthol to the list of additives and constituents in the prohibition on  
17 characterizing flavors in cigarettes and cigarette smoke directed by section 907  
18 (a)(1)(A) of the Federal Food, Drug, and Cosmetic Act, *see id.* at 9–10 (i.e.  
19 prohibit menthol as a characterizing flavoring in cigarettes, *see Citizen Pet.*, at  
20 7); and  
21 b. Work with appropriate entities to provide support to smokers of menthol  
22 cigarettes who will quit as a result of the requested prohibition on menthol in  
23 cigarettes, *see id.* at 10.

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26 <sup>44</sup> Available at [https://issuu.com/ascopost/docs/tap\\_vol\\_4\\_issue\\_13](https://issuu.com/ascopost/docs/tap_vol_4_issue_13).

27 <sup>45</sup> Available at <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

1           112. Roughly six months later on October 7, 2013, defendant Mitchell Zeller  
2 (Director, Center for Tobacco Products), writing on behalf of the defendants, responded as  
3 follows: “FDA has been unable to reach a decision on your petition because it raises significant,  
4 complex issues requiring extensive review and analysis by Agency officials. As you may know,  
5 FDA issued an advance notice of proposed rulemaking on July 24, 2013, seeking comments,  
6 including comments on FDA’s preliminary scientific evaluation of public health issues related  
7 to the use of menthol in cigarettes, and data, research, or other information that may inform  
8 regulatory actions FDA might take with respect to menthol in cigarettes (78 FR 44484). ...  
9 We will respond to your petition as soon as we have reached a decision on your request.”

10           113. To plaintiffs’ knowledge, FDA took no other action in response to the Petition  
11 until plaintiffs filed this lawsuit, despite the passage of nearly seven years since it was presented.

12 **IV. FDA’s continuing delay and unlawful refusal to ban menthol.**

13           114. Meanwhile, despite Director Zeller’s reported assurance in 2013 that “there was  
14 ‘no holdup’” concerning FDA’s determination or regulation of menthol in cigarettes, FDA for  
15 the next four years (i.e., Summer of 2013 – Summer of 2017) remained largely silent about its  
16 potential regulation of menthol cigarettes.

17           115. Around the same time, however, many other countries began moving to ban  
18 menthol in cigarettes.<sup>46</sup>

19           116. Then in 2017, the agency finally seemed poised to take actual steps to regulate  
20 menthol cigarettes, as described below.

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23 <sup>46</sup> For example, in 2012, Brazil approved a ban on all flavors, including menthol, in all tobacco  
24 products. In 2016, the European Union banned all flavored cigarettes including menthol  
25 (effective 2020). And in 2017, Canada banned the sale of menthol cigarettes. *See* Campaign for  
26 Tobacco-Free Kids, Brazil’s Highest Court Upholds Ban on Flavored Tobacco Products (Feb. 1,  
27 2018). Available at [https://www.tobaccofreekids.org/press-releases/2018\\_02\\_01\\_brazil-court-upholds-flavor-ban](https://www.tobaccofreekids.org/press-releases/2018_02_01_brazil-court-upholds-flavor-ban) (last visited June 13, 2020); World Health Organization, Advisory Note:  
28 Banning Menthol in Tobacco Products, 49–50 available at [https://apps.who.int/iris/bitstream/handle/10665/205928/9789241510332\\_eng.pdf;jsessionid=6D55886EDA1A8FDA032CA2B42F4409FC?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/205928/9789241510332_eng.pdf;jsessionid=6D55886EDA1A8FDA032CA2B42F4409FC?sequence=1) s.

1           117. But by 2019, FDA and the other defendants had again backed away, continuing  
2 their ongoing pattern of delay and inaction on this critical public health issue.

3           **A. 2017: FDA continues to delay addressing menthol in cigarettes.**

4           118. In 2017, then-FDA Commissioner Scott Gottlieb announced a “new  
5 comprehensive plan for tobacco and nicotine regulation” that would serve as a multi-year  
6 roadmap to better protect children and significantly reduce tobacco-related disease and death.  
7 *See* FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related  
8 Disease Death (July 27, 2017).<sup>47</sup> Noting that over 480,000 deaths each year were caused by  
9 tobacco use, and that the direct healthcare and lost productivity costs totaled nearly \$300  
10 billion each year, the Commissioner noted that the agency would focus its efforts on starting a  
11 public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels.  
12 *See id.*

13           119. Menthol, however, was relegated to further study and public comment. As part  
14 of that same announcement, FDA noted that it intended to issue yet another advance notice of  
15 proposed rulemaking to “seek public comment on the role that flavors (including menthol) in  
16 tobacco products play in attracting youth[.]” *Id.*

17           **B. 2018: FDA Commissioner Gottlieb commits to banning menthol.**

18           120. Then, on March 14, 2018, FDA Commissioner Gottlieb announced three  
19 advance notices of proposed rulemaking—one each (1) “to explore a product standard to lower  
20 nicotine in cigarettes to minimally or non-addictive levels”; (2) to “solicit additional comments  
21 and data related to the regulation of premium cigars”; and (3) “to seek comment on the role  
22 that flavors—*including menthol*—play in initiation, use and cessation of tobacco products.”  
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27 <sup>47</sup> Available at <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>.  
28

1 FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. (Mar. 14, 2018) (emphasis  
2 added).<sup>48</sup>

3 121. As to menthol in cigarettes, FDA Commissioner Gottlieb noted that “youth  
4 consistently report product flavoring as a leading reason for using tobacco products. Flavors  
5 may disguise the taste of tobacco. But flavored cigarettes ... are every bit as addictive as any  
6 other tobacco products, have the same harmful health effects and may even make it harder to  
7 quit. .... Additionally, youth and young adult smokers are disproportionately more likely to  
8 smoke menthol than nonmenthol cigarettes. And we know that youth who initiate smoking  
9 with menthol cigarettes ... may be at greater risk of progression from experimentation to  
10 established smoking and nicotine dependence.” Statement from FDA Commissioner Scott  
11 Gottlieb, M.D. (Mar. 19, 2018).<sup>49</sup>

12 122. Following the submission of comments to these three advance notices, FDA  
13 Commissioner Gottlieb noted in an interview that “he was revisiting [FDA’s consideration of]

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15 <sup>48</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to  
16 dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or  
17 non-addictive levels (Mar. 14, 2018). Available at [https://www.fda.gov/news-events/press-  
announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-  
dramatically-reduce-smoking](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking).

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

25 <sup>49</sup> Statement from FDA Commission Scott Gottlieb, M.D., on efforts to reduce tobacco use,  
26 especially among youth, by exploring options to address the role of flavors—including menthol—  
27 in tobacco products (Mar. 19, 2018). Available at [https://www.fda.gov/news-events/press-  
announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-  
especially-among-youth](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-especially-among-youth).

1 the use of menthol in certain products, which has been of particular concern in African-  
2 American communities targeted by makers of menthol cigarettes like Newport and Kools in  
3 years past. ***‘It was a mistake for the agency to back away of menthol,’*** he said.”  
4 Sheila Kaplan, *Altria to Stop Selling Some E-Cigarette Brands That Appeal to Youths*, The New York  
5 Times (Oct. 25, 2018) (emphasis added).<sup>50</sup>

6 123. Accordingly, on November 18, 2018, then-FDA Commissioner Gottlieb  
7 announced that FDA would issue a Notice of Proposed Rulemaking “seek[ing] to ban menthol  
8 in combustible tobacco products, including cigarettes and cigars[.]” Statement from FDA  
9 Commissioner Scott Gottlieb, M.D. (Nov. 15, 2018).<sup>51</sup>

10 124. Commissioner Gottlieb described his reasoning as follows:

11 I’m deeply concerned about the availability of menthol-flavored  
12 cigarettes. I believe these menthol-flavored products represent  
13 one of the most common and pernicious routes by which kids  
14 initiate on combustible cigarettes. The menthol serves to mask  
15 some of the unattractive features of smoking that might otherwise  
16 discourage a child from smoking. Moreover, I believe that  
17 menthol products disproportionately and adversely affect  
18 underserved communities. And as a matter of public health, they  
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22 <sup>50</sup> Available at <https://www.nytimes.com/2018/10/25/health/altria-vaping-ecigarettes.html?module=inline>.

23 <sup>51</sup> FDA, Statement from FDA Commission Scott Gottlieb, M.D., on proposed new steps to  
24 protect youth by preventing access to flavored tobacco products and banning menthol in  
25 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=El+oqua](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=El+oqua).



- 1 c. Some studies show that people who smoke menthol cigarettes have a harder  
2 time quitting smoking than those who smoke non-menthol cigarettes.
- 3 d. We can help reduce menthol cigarette smoking and help people who smoke  
4 menthol cigarettes to quit with policies that limit where menthol cigarettes are  
5 sold and marketed, and by reaching out to groups that are more likely to smoke  
6 menthol cigarettes.”<sup>52</sup>

7 **C. 2019: Defendants abandon their plan to address menthol.**

8 127. In March 2019, however, FDA Commissioner Scott Gottlieb resigned.  
9 Norman E. “Ned” Sharpless, M.D. was then appointed Acting FDA Commissioner in April  
10 2019.

11 128. And by June 2019, without any explanation, FDA reversed course and decided  
12 not to initiate its previously announced rulemaking process.

13 **1. FDA’s 2019 vision for the future omits addressing menthol.**

14 129. On June 20, 2019, then-Acting FDA Commissioner Sharpless and defendant  
15 Center for Tobacco Products Director Mitch Zeller announced FDA’s *Achievements in Tobacco*  
16 *Regulation Over the Past Decade and Beyond*. See FDA, *Achievements in Tobacco Regulation Over*  
17 *the Past Decade and Beyond* (June 20, 2019).<sup>53</sup> Among other things, that announcement  
18 noted the passage of the Tobacco Control Act, as well as FDA’s “groundbreaking plan for  
19 tobacco and nicotine regulation,” including FDA’s plan “to take action on flavored cigars and  
20 continue to explore other issues related to flavored tobacco products.” *Id.*

21 130. Absent from defendants’ announcement, however, was any mention of FDA  
22 taking steps to address menthol in cigarettes.

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25 <sup>52</sup> Centers for Disease Control and Prevention, *Menthol and Cigarettes* (last reviewed May 18,  
26 2020). Available at [https://www.cdc.gov/tobacco/basic\\_information/tobacco\\_industry/menthol-cigarettes/index.html](https://www.cdc.gov/tobacco/basic_information/tobacco_industry/menthol-cigarettes/index.html).

27 <sup>53</sup> Available at <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/achievements-tobacco-regulation-over-past-decade-and-beyond>.





1 Info. Services Ctr., *Intro. to the Fall 2019 Regulatory Plan*, Dkt. No. 2019-26533, 84 Fed. Reg.  
2 71085 (Dec. 26, 2019)<sup>57</sup>.

3 135. This Unified Agenda provides data on regulatory and deregulatory activities  
4 under development or review throughout the federal government—e.g., advance notices of  
5 proposed rulemaking, notices of proposed rulemaking, final rules, and long-term plans. *See*  
6 OIRA, *About the Unified Agenda*.<sup>58</sup>

7 136. And it confirms that defendants made no plans to undertake any regulatory  
8 action on menthol in cigarettes. *See id.* (identifying defendants’ regulatory actions at the pre-  
9 rule, proposed rule, and final rule stages of development and review). HHS did not even list  
10 menthol regulation on its list of “Long-Term Actions,” which identifies actions that the agency  
11 intends to pursue but does not anticipate taking action on in the following year. OIRA Long  
12 Term Actions, Agency Rule List – Spring 2019, HHS (identifying defendants’ long-term  
13 actions)<sup>59</sup>, OIRA Long Term Actions, Agency Rule List – Fall 2019, HHS<sup>60</sup>.

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18 <sup>57</sup> Available at <https://www.federalregister.gov/documents/2019/12/26/2019-26533/introduction-to-the-fall-2019-regulatory-plan>.

19 <sup>58</sup> Available at [https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA\\_About.myjsp](https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp).

20 <sup>59</sup> Available at  
21 [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](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* Office of Information and Regulatory Affairs, *About the Unified*  
22 *Agenda*, available at [https://www.reginfo.gov/public/jsp/eAgenda/UA\\_About.myjsp](https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp) (“[A]n  
23 agency may list in the ‘Long-Term Actions’ section of its agenda those rules it expects will have  
24 the next regulatory action more than 12 months after publication of the agenda.”).

25 <sup>60</sup> Available at  
26 [https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION\\_GET\\_AGENCY\\_RULE\\_LIST&currentPubId=201910&showStage=longterm&agencyCd=0900&csrf\\_token=243A419EF187585EFFD83CD9CFA7CB8F1D8F1155635D087656DF62F1D717959D8C6B90FE425F27A717CEC962B0EECE3D5800](https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPubId=201910&showStage=longterm&agencyCd=0900&csrf_token=243A419EF187585EFFD83CD9CFA7CB8F1D8F1155635D087656DF62F1D717959D8C6B90FE425F27A717CEC962B0EECE3D5800).

**V. Plaintiffs initiate this litigation to address defendants' unlawful delay; defendants' response to the Citizen Petition is belated and incomplete.**

137. On June 17, 2020, plaintiffs commenced this action seeking, among other things, to remedy defendants' unlawful delay in proceeding with FDA's own proposed rulemaking to ban menthol in combustible cigarettes (Count I), and to compel a response to AATCLC's 2013 Citizen Petition, which also sought to ban menthol as a characterizing flavor in cigarettes (Count II). In the alternative (Count. III), plaintiffs alleged that defendants had made an arbitrary and capricious decision to keep menthol cigarettes in the market.

138. Defendants conceded they had not provided a substantive response to the Citizen Petition. As a result, they committed to providing a "final response" by a date certain, "at which point," defendants asserted that Count II would "be moot." Dkt. No. 26 (Def. Mot. To Dismiss), n.1. Defendants then moved to dismiss Counts I and III for lack of jurisdiction, arguing that the Complaint "failed to identify a discrete action that the Federal Defendants were legally required to take for Count I or a final agency action for Count III." *Id.* at 2. The Court denied the motion as to Count I, concluding that the Court possessed jurisdiction to hear plaintiffs' undue delay claim, and dismissed Count III without prejudice. *See* Dkt. No. 34.

139. Defendants then asserted that their impending response to the Citizen Petition would also moot Count I of the Complaint, although their motion papers had claimed that it would moot only Count II. Given the change of administrations in early 2021, and to avoid unnecessarily burdening the Court, plaintiffs agreed to a short stay of this action while FDA prepared its response.<sup>61</sup>

140. On April 29, 2021, almost one year after plaintiffs filed this lawsuit, FDA finally provided its response. The response stated: "Your petition requests that the Food and Drug Administration (FDA) prohibit menthol as a characterizing flavor in cigarettes. Specifically, your petition requests that FDA: (1) 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 Tobacco Control Act. Response at 1. FDA "interpret[ed the] petition as a

1 request that the Agency engage in the rulemaking process by proposing a rule to prohibit  
2 menthol as a characterizing flavor in cigarettes,” and stated that “FDA intends to take such  
3 action. .... FDA therefore grants [the] petition in accordance with 21 C.F.R. § 10.30(e)(3). *Id.*  
4 at 2. FDA explained that its decision was based on “the existing scientific evidence in the  
5 record,” which demonstrated that “eliminating menthol as a characterizing flavor in cigarettes  
6 would benefit public health.” *Id.* at 10.

7 141. On the same day, FDA issued a press statement announcing its intention to  
8 issue a rule banning menthol cigarettes.<sup>62</sup> The news release observed that banning menthol  
9 “will help save lives, particularly among those disproportionately affected by these deadly  
10 products, ... significantly reduce youth initiation, increase the chances of smoking cessation  
11 among current smokers, and address health disparities experienced by communities of color,  
12 low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use  
13 these tobacco products.”<sup>63</sup>

14 142. And yet, despite FDA’s clear acknowledgement of the important public health  
15 issues at stake, FDA did not commit to any firm deadline to act on these statements. Worse  
16 still, FDA suggested that it would take a year or more to even begin the rulemaking process.

17 143. Such aspirational goal setting is insufficient. Pursuant to the federal regulation  
18 governing citizen petitions, “[t]he Commissioner shall, in accordance with paragraph (e)(2),  
19 rule upon each petition,” 21 C.F.R. § 10.30(e)(1). If the petition is approved, then “the  
20 Commissioner shall concurrently take appropriate action (e.g., publication of a Federal  
21 Register notice) implementing the approval.” *Id.* § 10.30(e)(2)(i).

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23  
24 <sup>61</sup> Plaintiffs ASH, AMA, and NMA joined AATCLC’s Citizen Petition on January 14, 2021.

25 <sup>62</sup> “Available at [https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers)  
26 [based-actions-aimed-saving-lives-and-preventing-future-generations-smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers).

27 <sup>63</sup> “Available at [https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers)  
28 [based-actions-aimed-saving-lives-and-preventing-future-generations-smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers).



1 would advance a Notice of Proposed Rulemaking seeking to ban menthol in combustible  
 2 tobacco products, including all cigarettes.<sup>65</sup> Three years later, FDA made the same  
 3 announcement, this time in connection with its response to the AATCLC's Citizen Petition.

4 149. And yet, despite FDA's knowledge of these public health harms, FDA and  
 5 defendants have simply failed to do their job—i.e., protecting the public health. Accordingly,  
 6 plaintiffs bring this action, seeking an Order from this Court granting the plaintiffs' requested  
 7 relief on the following claims:

### 8 **CLAIMS FOR RELIEF**

#### 9 **Count I: Violation of the Administrative Procedure Act**

#### 10 **(5 U.S.C. §§ 555(b) & 706(1))**

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

12 151. Section 555(b) of the Administrative Procedure Act requires each agency “to  
 13 conclude a matter presented to it” “within a reasonable time,” 5 U.S.C. § 555(b). Section  
 14 706(1) provides that a reviewing court “shall compel agency action unlawfully withheld or  
 15 unreasonably delayed,” 5 U.S.C. § 706(1).

16 152. Together, Sections 555(b) and 706(1) “indicate a congressional view that  
 17 agencies should act within reasonable time frames and that courts designated by statute to  
 18 review agency actions may play an important role in compelling agency action that has been  
 19 improperly withheld or unreasonably delayed.” *Telecommunications Research & Action Center v.*  
 20 *FCC*, 750 F.2d 70, 76–77 (D.C. Cir. 1984) (“*TRAC*”).

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21  
 22 <sup>65</sup> Additional studies have since further concluded that removing menthol from cigarettes is likely  
 23 to reduce youth smoking initiation, improve smoking cessation outcomes in adult smokers, and in  
 24 turn, benefit public health. *See, e.g.,* Villanti, Andrea C. et al., *Menthol Cigarettes and The Public*  
 25 *Health Standard: A Systematic Review*, BMC Public Health (Dec. 29, 2017). *Available at*  
 26 <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4987-z>. And in a  
 27 follow up study reviewing Canada's menthol ban, at least one study found higher rates of quitting  
 28 among daily and occasional menthol smokers, one year after the implementation of a menthol  
 ban. *See* Chaiton M.O. et al., *Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1*  
*year: a population cohort study*, Tobacco Control (May 30, 2019). *Available at*  
<https://tobaccocontrol.bmj.com/content/early/2019/05/29/tobaccocontrol-2018-054841>.

1           153. Accordingly, “delays that might be altogether reasonable in the sphere of  
2 economic regulation are less tolerable when human lives are at stake.” *Cutler*, 818 F.2d at 898  
3 (footnotes omitted).<sup>66</sup> “This is particularly true when the very purpose of the governing Act is  
4 to protect those lives.” *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157–58  
5 (D.C. Cir. 1983).

6           154. To the extent defendants’ position is that they have not yet made a  
7 determination in accordance with 21 U.S.C. § 387g(a)(5) concerning whether to add menthol  
8 to the flavor ban list, *id.* § 387g(a)(1)(A), defendants’ failure to make such a determination  
9 constitutes agency action “unlawfully withheld or unreasonably delayed,” 5 U.S.C. § 706(1),  
10 and a failure by the agency to “conclude a matter presented” to the agency “within a  
11 reasonable time,” *id.* § 555(b).

12           155. To the extent defendants seek to characterize their recent statements of intent  
13 to ban menthol as a “determination,” for purposes of 21 U.S.C. § 387g(a)(5), statements  
14 unaccompanied by action are inadequate. *See* 21 U.S.C. § 387g(a)(3)(b)(ii) (“In the event that  
15 the Secretary makes a determination, set forth in a proposed tobacco product standard in a  
16 proposed rule ...”); *id.* § 387g(a)(2), (c).

17           156. At the time Congress enacted the Tobacco Control Act, Congress specifically  
18 recognized that menthol cigarettes “may pose unique health risks to those who smoke them.”  
19 H. Rept., Part 1 at 38. And as a result, Congress “urge[d] [FDA] to address these issues as  
20 quickly as practicable.” *Id.* Indeed, Congress believed that it would be “critical for [FDA] to  
21 move quickly to address the unique public health issues posed by menthol cigarettes.” *Id.* at  
22 38–39.

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27           <sup>66</sup> *See also Cutler*, 818 F.2d at 898 n.162 (noting further that “the risk to human life need not be a  
28 certainty to justify expedition”).

1           157. To that end, Congress directed FDA to periodically reevaluate and “determine”  
2 whether the Act’s existing flavor standard “should be changed” to reflect new data and protect  
3 the public health. *See* 21 U.S.C. § 387g(a)(5).

4           158. Since that time, FDA has developed and interested parties have presented to  
5 FDA such new data and public health considerations, including the following:

- 6           a. The Tobacco Product Scientific Advisory Committee Report (2011);
- 7           b. The Industry Menthol Report (2011);
- 8           c. FDA’s own peer-reviewed evaluation of the science concerning menthol in  
9           cigarettes (2013);
- 10           d. FDA’s Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco*  
11           *Products*, 78 Fed. Reg. 44484, and the comments received by FDA (2013); and
- 12           e. FDA’s Advance Notice of Proposed Rulemaking, *Regulation of Flavors in Tobacco*  
13           *Products*, 83 Fed. Reg. 12294, and the comments received by FDA (2018).

14           159. From these submissions, former FDA Commissioner Scott Gottlieb announced  
15 that FDA would begin the rulemaking process for banning menthol in combustible cigarettes.

16           160. On April 29, 2021, FDA again announced that it would implement a menthol  
17 ban—this time claiming that it would take a year or more to even begin the rulemaking  
18 process.

19           161. Without explanation, FDA and the defendants have repeatedly declined to  
20 begin the rulemaking process, including by failing to publish a notice of proposed rulemaking.

21           162. Accordingly, FDA’s failure to make and/or act on such a determination  
22 constitutes agency action “unlawfully withheld or unreasonably delayed,” 5 U.S.C. § 706(1),  
23 and a failure by the agency to “conclude a matter presented to it” “within a reasonable time,”  
24 *id.* § 555(b). *See Sierra Club v. Gorsuch*, 715 F.2d 653, 659 (D.C. Cir. 1983) (“judicial review of  
25 decisions not to regulate must not be frustrated by *blind* acceptance of an agency’s claim that a  
26 decision is still under study”) (emphasis in original); *Cutler v. Hayes*, 818 F.2d 879, 897 n.156  
27 (D.C. Cir. 1987) (“[t]here comes a point when relegating issues to proceedings that go on  
28



1 without conclusion in any kind of reasonable time frame is tantamount to refusing to address  
2 the issues at all—and the result is a denial of justice”).

3 163. FDA’s unreasonable delay and inaction constitutes a violation of the  
4 Administrative Procedure Act.

5 **Count II: Violation of the Administrative Procedure Act**  
6 **(5 U.S.C. §§ 555(b) & 706(1)—Citizen Petition)**

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

8 165. On or about April 12, 2013, plaintiff African American Tobacco Control  
9 Leadership Council (together with several other leading national organizations) submitted a  
10 Citizen Petition with FDA. *See Tobacco Control Legal Consortium et al. Citizen Petition*, Dkt. ID  
11 FDA-2013-P-0435-0001 (“Citizen Petition”).<sup>67</sup> This Petition, among other things, asked FDA  
12 to do the following:

- 13 a. Add menthol to the list of additives and constituents in the prohibition on  
14 characterizing flavors in cigarettes and cigarette smoke directed by section 907  
15 (a)(1)(A) of the Federal Food, Drug, and Cosmetic Act, *see id.* at 9–10 (i.e.  
16 prohibit menthol as a characterizing flavoring in cigarettes, *see Citizen Pet.*, at  
17 7); and  
18 b. Work with appropriate entities to provide support to smokers of menthol  
19 cigarettes who will quit as a result of the requested prohibition on menthol in  
20 cigarettes, *see id.* at 10.

21 166. Roughly six months later on October 7, 2013, defendant Mitchell Zeller  
22 (Director, Center for Tobacco Products), writing on behalf of the defendants, responded as  
23 follows: “FDA has been unable to reach a decision on your petition because it raises significant,  
24 complex issues requiring extensive review and analysis by Agency officials. As you may know,  
25 FDA issued an advance notice of proposed rulemaking on July 24, 2013, seeking comments,  
26

27 <sup>67</sup> Available at <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

1 including comments on FDA’s preliminary scientific evaluation of public health issues related  
2 to the use of menthol in cigarettes, and data, research, or other information that may inform  
3 regulatory actions FDA might take with respect to menthol in cigarettes (78 FR 44484). ...  
4 We will respond to your petition as soon as we have reached a decision on your request.”

5 167. FDA has a mandatory duty to respond to the citizen petition under the  
6 Administrative Procedure Act and FDA’s own regulations adopted thereunder. *See* 5 U.S.C. §  
7 553(e) (“Each agency shall give an interested person the right to petition for the issuance,  
8 amendment, or repeal of a rule.”); 21 C.F.R. § 10.30 (e) (providing a 180-day timeframe within  
9 which the agency must provide a response to the petitioner). *See also Henley v. Food & Drug*  
10 *Admin. (Dep’t of Health & Human Servs.)*, 873 F. Supp. 776, 780 (E.D.N.Y. 1995), *aff’d sub nom.*  
11 *Henley v. Food & Drug Admin.*, 77 F.3d 616 (2d Cir. 1996) (*citing National Organization for Reform of*  
12 *Marijuana Laws v. Ingersoll*, 497 F.2d 654, 657–58 (D.C. Cir. 1974)) (“the [FDA] Commissioner  
13 must consider the petition and must give written notice of the decision accompanied by an  
14 explanatory statement.”).

15 168. On April 29, 2021, FDA responded to the Citizen Petition stating that it was  
16 granting the petition and intended to ban menthol-flavored cigarettes and cigars. However,  
17 defendants did not “concurrently take appropriate action ... implementing the approval,” as  
18 21 C.F.R. § 10.30(e)(2)(i) requires.

19 169. FDA’s unreasonable delay and inaction on addressing plaintiff’s Citizen Petition  
20 violates the Administrative Procedure Act. *See Pub. Citizen*, 740 F.2d at 34–35 (remanding  
21 citizen petition to district court for a determination whether agency had unduly delayed  
22 responding to such petition).

### 23 **REQUESTED RELIEF**

24 WHEREFORE, Plaintiffs request that this Court enter the following:

- 25 1. An Order declaring defendants to be in violation of the Administrative  
26 Procedure Act;
- 27 2. An Order declaring defendants to be in violation of the Tobacco Control Act;

