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9 *Control Leadership Council and Action on Smoking*
10 *and Health*

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA
13 SAN FRANCISCO DIVISION

14 AFRICAN AMERICAN TOBACCO)
15 CONTROL LEADERSHIP COUNCIL and)
16 ACTION ON SMOKING AND HEALTH,)

17 Plaintiffs,)
18)
19)
20)

21 vs.)
22)
23)
24)

25 U.S. DEPARTMENT OF HEALTH AND)
26 HUMAN SERVICES; ALEX M. AZAR II, in)
27 his official capacity as Secretary of the U.S.)
28 Department of Health and Human Services;)
U.S. FOOD AND DRUG)
ADMINISTRATION; STEPHEN HAHN, in)
his official capacity as 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,)

29 Defendants.)
30)
31)
32)

Case No.:

COMPLAINT
(Administrative Procedure Act Case)

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

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

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

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

22 8. For the African American community, this would have meant that (a) by 2020,
23 roughly 4,700 premature deaths would have been avoided, and about 461,000 African
24 Americans would not have started smoking; and (b) by 2050, over 66,000 premature deaths
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27 ⁴ *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).⁵ “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 decided to allow 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 ⁵ 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=Elouqua](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=Elouqua).

1 HHS, 84 Fed. Reg. 29623 (June 24, 2019).⁶ 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).⁷

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%.⁸

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

24 ⁷ Available at
25 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=0900.

26 ⁸ *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.

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.⁹

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%.¹⁰

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-19.¹¹ 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.”¹² 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 ⁹ *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
States* (identifying an estimated 34.3 million adults who smoked cigarettes in 2017). Available at
https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

25 ¹⁰ *See* FDA, *Menthol and Other Flavors in Tobacco Products*, *id.* (noting that 85.8 percent of
African American smokers use menthol cigarettes).

26 ¹¹ 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)
27 [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>).

28 ¹² 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.¹³

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 other many others have repeatedly called for FDA to
7 fulfill its statutory duty to re-evaluate tobacco product standards and take up a rule to ban
8 menthol cigarettes. FDA has failed to do so, refusing even to resolve a Citizen’s Petition that
9 AATCLC filed more than seven years ago. After these years of inaction and the untold
10 suffering defendants have caused, plaintiffs bring this lawsuit to compel appropriate action by
11 defendants on this critical and urgent public health issue.

12 **JURISDICTION & VENUE**

13 16. Jurisdiction: This Court has jurisdiction over this action, pursuant to 28 U.S.C.
14 §§ 1331 and 1346. Plaintiffs allege violations of the Administrative Procedure Act, Pub. L. No.
15 404, 60 Stat. 237, ch. 324, §§ 1–12 (1946), and Section 907 of the Tobacco Control Act, 21
16 U.S.C. § 387g. Their requested relief is authorized by 5 U.S.C. § 706(1) and 28 U.S.C. § 1651.
17 The United States is also a defendant.

18 17. Venue: Venue in this judicial district is appropriate, pursuant to 28 U.S.C. §
19 1391(e)(1). Plaintiff African American Tobacco Control Leadership Council resides in this
20 judicial district.

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

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27 ¹³ Available at <https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true>.

PARTIES

1
2 19. Plaintiff African American Tobacco Control Leadership Council (“AATCLC”)
3 brings this action on behalf of itself and its members. The AATCLC, which is based in San
4 Francisco, California, was formed in 2008 to educate the African American community and
5 public about tobacco use and cessation, and has led the fight to expose the predatory
6 marketing of menthol cigarettes and flavored little cigars in the Black Community. The
7 organization’s members include a cadre of dedicated community activists, academics, public
8 health advocates, and researchers from across the country. FDA’s failure to address the harms
9 caused by menthol in combustible cigarettes has adversely affected AATCLC, its members,
10 and its work.

11 20. The AATCLC’s mission is to save lives by partnering with community
12 stakeholders and public health agencies to inform and affect the direction of tobacco policy,
13 practices, and priorities, particularly as it affects the lives of Black Americans and African
14 Immigrant populations. Its work includes educating the public about the effects of tobacco on
15 these populations, and the need to regulate flavored tobacco products, including menthol
16 cigarettes.

17 21. One of the AATCLC’s key initiatives is the creation of Buffer Zones—local
18 legislation that prohibits the sale of all flavored tobacco products, including menthol, within a
19 500 to 1000-foot perimeter around schools. Establishing Buffer Zones to protect inner city
20 children reduces their access to tobacco products, de-normalizes tobacco consumption, and
21 pushes back against predatory targeting of these communities. The AATCLC has assisted
22 Chicago, Minneapolis-St. Paul, Baltimore, and numerous California cities in adopting and
23 implementing Buffer Zones.

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

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

9 24. In addition, as detailed below, on or about April 12, 2013, plaintiff AATCLC
10 (together with others) submitted a Citizen Petition with the FDA. The Petition requested that
11 the FDA take certain actions to decrease the harms caused by menthol cigarettes and provide
12 cessation support to smokers of menthol cigarettes who wish to quit. Over seven years have
13 passed since the AATCLC submitted this Petition, and the defendants still have not provided
14 any substantive response.

15 25. Plaintiff Action on Smoking and Health ("ASH") is a non-profit organization
16 headquartered in Washington, D.C. ASH was founded in 1967 and has spent the last fifty
17 years battling against the tobacco industry. Its mission is to advocate for innovative legal and
18 policy measures to end the global tobacco epidemic. ASH's past accomplishments include
19 helping to achieve restrictions on tobacco advertising and smoking bans in workplaces and
20 various forms of public transit.

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

6 27. ASH's efforts include menthol-related initiatives. For example, on January 2,
7 2020, ASH staff attended a public hearing of the D.C. City Council Judiciary and Public
8 Safety Committee, which is considering a ban on the sale of flavored tobacco products. Both
9 gave formal testimony in favor of the measure, and urged the Council to include menthol in
10 the final law. ASH also provided information to the Committee concerning the Council's
11 authority to phase out the sale of tobacco products in the city. The defendants' unlawful
12 refusal to ban menthol in tobacco products, and failure to periodically reevaluate and
13 determine whether the Act's existing flavor standard should be changed to reflect new data and
14 protect the public health, makes ASH's work more difficult and impede its efforts to educate
15 the public about the dangers of menthol cigarettes. It also requires ASH to divert resources
16 that could be used to advance other organizational goals to focus on menthol-related concerns.

17 28. Defendant U.S. Department of Health and Human Services ("HHS") is the
18 federal agency responsible for administering the Food, Drug and Cosmetic Act, 21 U.S.C. §
19 301 *et seq.* (1982). HHS is headquartered in Washington, D.C.

20 29. Defendant Alex M. Azar II is sued in his official capacity as the Secretary of the
21 U.S. Department of Health and Human Services. As Secretary, Mr. Azar is ultimately
22 responsible for HHS's activities and policies and for implementing the Tobacco Control Act.
23 Although the Secretary has delegated many responsibilities under the Act to the Commissioner
24 of the Food and Drug Administration¹⁴, the Secretary has nonetheless reserved the authority to
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27 ¹⁴ 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 (a) establish procedural rules applicable to tobacco products, such as menthol cigarettes; and
2 (b) present highly significant public issues involving the availability and marketability of
3 tobacco products, including menthol cigarettes.

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

12 31. Defendant Stephen Hahn is sued in his official capacity as Commissioner of the
13 FDA. FDA administers programs at HHS related to tobacco products. As Commissioner, Mr.
14 Hahn is responsible for FDA’s activities and policies, including the agency’s implementation of
15 the Tobacco Control Act.

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

20 33. Defendant Mitch Zeller is sued in his official capacity as the Center for Tobacco
21 Products, Director. The Center implements the Secretary and FDA’s responsibilities under
22 the Tobacco Control Act.

23 **FACTUAL & LEGAL BACKGROUND**

24 34. This section sets forth defendants’ obligations¹⁵ and their failure to “quickly”
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27 ¹⁵ This complaint accordingly refers defendants’ obligations globally where applicable, and
28 specifies the relevant defendant when a particular defendant has a unique role.

1 address the public health issue of menthol in cigarettes, to undertake a “periodic evaluation of
2 tobacco product standards,” and to make a determination based on “new medical, scientific, or
3 other technological data.”

4 **I. FDA and The Tobacco Control Act**

5 35. As shown below, FDA is well-aware of the critical public health issues and
6 harms surrounding menthol in cigarettes. Nonetheless, FDA has unreasonably delayed and
7 unlawfully withheld its duty to evaluate and determine whether to issue a tobacco product
8 standard aimed at removing menthol from cigarettes for the protection of public health.

9 36. The FDA’s knowing inaction on this issue is contrary to FDA’s mission
10 statement and statutory obligations, as well as Congress’s expressed intent and direction to
11 defendants when enacting the Tobacco Control Act.

12 **A. FDA’s mission is to protect the public health.**

13 37. By statute, FDA’s mission is to “promote the public health *by promptly and*
14 *efficiently reviewing clinical research and taking appropriate action* on the marketing of regulated
15 products *in a timely manner*,” 21 U.S.C. § 393(b)(1) (emphasis added).

16 38. This mission includes “regulating the manufacturing, marketing, and
17 distribution of tobacco products to protect the public health and reduce tobacco use by
18 minors,” FDA.gov, What We Do,¹⁶ as well as “[p]rotecting consumers and enhancing public
19 health by maximizing compliance of FDA regulated products and minimizing risk associated
20 with those products,” FDA Reg. Procedures Manual, Intro., at 3 (Aug. 2018).¹⁷

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23 ¹⁶ Available at <https://www.fda.gov/about-fda/what-we-do>.

24 ¹⁷ Available at <https://www.fda.gov/media/71923/download>. The Regulatory Procedures
25 Manual “is a reference manual that provides internal procedures and related information to be
26 used by FDA employees who process certain regulatory and enforcement matters in support of
27 the agency’s public health mission.” FDA Reg. Procedures Manual at 1. This Manual further
28 identifies some of FDA’s values, including the following: “We demonstrate our commitment to
safeguarding the public health in our actions.” *Id.* at 3.

1 39. HHS and FDA are also responsible for “identifying and addressing ...
2 disproportionately high and adverse human health ... effects of its programs, policies, and
3 activities on minority populations and low-income populations[.]” Executive Order 12898,
4 § 1-101 (Feb. 11, 1994).¹⁸

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

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

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

9 41. As noted above, when Congress enacted the Tobacco Control Act in 2009,
10 Congress created a “tobacco product standard” that effectively banned all flavors in cigarettes,
11 save for tobacco and menthol flavors. *See* 21 U.S.C. § 387g(a)(1)(A).¹⁹

12 42. Significantly, however, this standard did not “limit the Secretary’s [i.e., FDA’s]
13 authority to take action under this section or other sections of this Act applicable to menthol,”
14 21 U.S.C. § 387g(a)(1)(A); *see also* H. Rept., Part 1 at 4 (granting FDA “the authority to require
15 product changes in current and future tobacco products, such as the reduction or elimination
16 of ingredients, additives, and constituents”).

17 43. On the contrary, Congress expressly directed defendants to move quickly to
18 gather evidence concerning “the impact of the use of menthol in cigarettes on the public
19 health, including such use among children, African-Americans, Hispanics, and other racial and
20 ethnic minorities,” 21 U.S.C. § 387g(e)(1), and then determine whether the tobacco product
21 standard should be changed to ban it. 21 U.S.C. § 387g(a)(5).

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23 ¹⁸ Available at <https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf>.

24 ¹⁹ Per the Act, “a cigarette or any of its component parts” is prohibited from containing “as a
25 constituent ... or additive, an artificial or natural flavor (other than tobacco or menthol) or an
26 herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut,
27 licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product
28 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 44. In particular, the Act mandates further investigation concerning the use of
2 menthol in cigarettes and requires that FDA “shall periodic[ally] evaluat[e]” the “tobacco
3 product standards established under this section[, including the previously identified flavor
4 ban, 21 U.S.C. § 387g(a)(1)(A),] to determine whether such standards should be changed to
5 reflect new medical, scientific, or other technological data.” 21 U.S.C. § 387g(a)(5) (“Periodic
6 Reevaluation of Tobacco Product Standards”).

7 45. Taken together then, these above-identified subsections require FDA to (a)
8 periodically re-evaluate the existing tobacco product standard, which does not currently ban
9 menthol in cigarettes; and (b) “determine” whether such standard “should be changed” to (i)
10 reflect new data, and (ii) to protect the public health.

11 **2. The Act creates an advisory committee to assist FDA.**

12 46. To assist FDA in making that determination, Congress directed FDA to create a
13 Tobacco Products Scientific Advisory Committee. *See* 21 U.S.C. § 387g(e)(1).

14 47. Per the Act, FDA “shall refer to the Committee for report and recommendation
15 ... the issue of the impact of the use of menthol in cigarettes on the public health, including
16 such use among children, African-Americans, Hispanics, and other racial and ethnic
17 minorities.” 21 U.S.C. § 387g(e)(1).

18 48. The Committee’s review was also directed to address the considerations
19 identified by subsections (a)(3)(B)(i)²⁰ and (b)²¹—i.e., considerations that FDA would have
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21 ²⁰ “In making a finding described in subparagraph (A), [FDA] shall consider scientific evidence
22 concerning (I) the risks and benefits the risks and benefits to the population as a whole, including
23 users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased
24 likelihood that existing users of tobacco products will stop using such products; and (III) the
25 increased or decreased likelihood that those who do not use tobacco products will start using such
26 products.” 21 U.S.C. § 387g(a)(3)(B)(i).

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

1 otherwise addressed in adopting an additional tobacco product standard or in considering any
2 proposed standard. *See* 21 U.S.C. § 387g(e)(1).

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

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

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

13 51. On March 3, 2009, Rep. Henry A. Waxman along with 124 original
14 cosponsors introduced H.R. 1256—the “Family Smoking Prevention and Tobacco Control
15 Act.” The Committee Report and floor statements of the sponsor and committee member in
16 charge (Rep. Waxman) make clear that Congress considered menthol to be an urgent public
17 health concern and intended the FDA to move quickly to address it.

18 52. Both the accompanying Committee Report and following floor statements by
19 Rep. Waxman confirm Congress’ intention that FDA act “quickly” to address the special
20 problem of menthol cigarettes. As explained by the Committee Report:

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

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27 creation of a significant demand for contraband or other tobacco products that do not meet the
28 requirements of this chapter and the significance of such demand.” *Id.* § 387g(b)(2).

1 of cigarettes with certain “characterizing flavors” that appeal to
2 youth. ...

3 ***The Committee recognizes the unique issues***
4 ***surrounding menthol cigarettes and urges the Secretary***
5 ***to address these issues as quickly as practicable.*** The
6 Committee is especially concerned about proportionately higher
7 rates of menthol cigarette use among African American smokers,
8 as well as the historic targeting of African Americans for menthol
9 cigarette use by tobacco companies. While it is unclear what
10 effect the presence of menthol in cigarettes may have on
11 addictiveness, toxicity, or other qualities of cigarettes, the
12 Committee recognizes that menthol cigarettes may pose unique
13 health risks to those who smoke them. Given the high rates of use
14 among African American smokers, including African American
15 youth, as well as higher rates of lung cancer documented among
16 African American smokers as compared to non-African American
17 smokers, the Committee believes that ***it is critical for the***
18 ***Secretary to move quickly to address the unique public***
19 ***health issues posed by menthol cigarettes.***

20 H. Rept., Part 1 at 37–39 (emphasis added).²²

21
22 ²² The House Committee Report went on to note the following:

23 Menthol cigarettes currently represent over one quarter of all
24 cigarettes smoked in the United States, representing more than 12
25 million individual smokers. Additionally, nearly 7 in 10 African
26 Americans who smoke choose to smoke menthol cigarettes. Given
27 the number of open questions related to menthol cigarettes, the
28 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

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

5 54. First, on April 1, 2009, Rep. Waxman noted that he and his colleagues had
6 “worked with members of the Congressional Black Caucus to ensure that menthol cigarettes
7 will be an early focus of the agency’s attention.” Cong. Rec.—House, H4318, H4339 (Vol.
8 155, No. 55).²³

9 55. Then, on June 12, 2009, Rep. Waxman reiterated that same understanding,
10 using similarly strong language: “We worked with members of the Congressional Black
11 Caucus to ensure that menthol cigarettes will be an early focus of attention by the agency, and
12 that the agency has the authority to deal with these and other products.” Cong. Rec.—House,
13 H6630, H6652 (Vol. 155, No. 88).²⁴

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

15 56. On June 22, 2009, President Barack Obama signed H.R. 1256 into law—the
16 “Family Smoking Prevention and Tobacco Control Act.” Public Law No. 111-31, 123 Stat.
17 1776 (codified, in relevant part, at 15 U.S.C. §§ 1333–34 and 21 U.S.C. § 301 *et seq.*) (2009).

21 racial and ethnic differences in lung cancer incidence, and the
22 uncertainty about the potentially negative consequences of an
23 immediate menthol ban, the Committee believes that this approach
24 ensures that FDA has the scientific evidence necessary to make the
25 best decisions to protect the public health.

H. Rept., Part 1 at 39.

26 ²³ Available at <https://www.congress.gov/congressional-record/2009/04/01/house-section/article/H4318-2>.

27 ²⁴ Available at <https://www.congress.gov/congressional-record/2009/06/12/house-section/article/H6630-1>.

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

4 58. FDA’s own statements following the Act’s passage reflect that FDA intended to
5 address menthol in cigarettes, following the issuance of the Tobacco Products Scientific
6 Advisory Committee’s report and recommendation.

7 59. On September 22, 2009, FDA announced that it would be “examining options”
8 for regulating menthol cigarettes:

9 The FDA’s ban on candy and fruit-flavored cigarettes, effective
10 today, highlights the importance of reducing the number of
11 children who start to smoke, and who become addicted to
12 dangerous tobacco products. The FDA is also examining options
13 for regulating both menthol cigarettes and flavored tobacco
14 products other than cigarettes.²⁵

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

18 Jennifer Corbett: The question I have is—and you
19 mentioned in your press release—that
20 you’re looking at menthol cigarettes,

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

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because my understanding (about) is the—
that’s the biggest flavor out there that ...

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

Sept. 22, 2009 Tr. For FDA’s Media Briefing, at 8–9 (emphasis added).²⁶

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

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

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

Id. at 15 (emphasis added).

²⁶ Available at
<https://web.archive.org/web/20091104012525/http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM183533.pdf>.

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

2 62. Following the Tobacco Control Act's enactment, FDA collected extensive
3 evidence concerning these critical public health issues.

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

5 63. In 2010, FDA organized a Tobacco Product Scientific Advisory Committee
6 ("TPSAC") in accordance with the Act's directive. That Committee was comprised of "a
7 panel of leading public health, scientific experts and representatives of various parts of the
8 tobacco industry." *See* FDA, Dr. Lawrence R. Deyton, Dir. Center for Tobacco Products,
9 *FDA Remarks on the Report and Recommendation on the Public Health Impact of Menthol Cigarettes* (Mar.
10 18, 2011) ("2011 FDA Remarks on Menthol Cigarettes Rept.").²⁷ This Committee was
11 charged with "providing advice, information, and recommendations to FDA on health issues
12 related to tobacco products and other issues relating to the regulation of tobacco products." *Id.*

13 64. As part of the Committee's charter, FDA designated a government
14 representative to attend each meeting of the full committee and subcommittees; ensure the
15 Committee's compliance with statutory, regulatory, and administrative directives; and approve
16 and prepare all meeting agendas. *See* FDA, Charter of the Tobacco Products Scientific
17 Advisory Comm. (Aug. 7, 2009).²⁸

18 65. The full Scientific Advisory Committee first met in March 2010, and 11 more
19 times thereafter. *See* FDA Rept. to Congress, *Progress and Effectiveness of the Implementation of the*
20 *Family Smoking Prevention and Tobacco Control Act*, at 15 (2013). There were also two meetings of
21 the Tobacco Products Constituents Subcommittee of the TPSAC and two meetings of the
22 Menthol Report Subcommittee. *See id.* Each of these Committee and Subcommittee meetings
23 covered a broad range of materials, presentations, and public submissions. *See* FDA 2010
24 TPSAC Mtg. Materials and Info.;²⁹ *see also* FDA 2011 TPSAC Mtg. Materials and Info.³⁰

25 66. On March 23, 2011, the TPSAC submitted its report, *Menthol Cigarettes and*
26 *Public Health: Review of the Scientific Evidence and Recommendations* (2011) ("2011 TPSAC Menthol
27 Rept.").³¹

1 67. This Report—also known as the TPSAC Report—contained a number of
2 findings and conclusions, based on the best available scientific evidence.

3 **1. Menthol masks the irritating effects of nicotine.**

4 68. Among other things, the Report found that menthol is a flavor additive that
5 possesses a minty taste and aroma. *See* 2011 TPSAC Menthol Rept. at 16. In certain
6 medicinal products such as cough drops, menthol is regulated as a drug. *See id.* The use of
7 menthol in tobacco products, however, was not. *See id.* Menthol is present in 90% of tobacco
8 products, including cigarettes that are not marketed as menthol cigarettes. *See id.*

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

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

20 ²⁸ 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 ²⁹ Available at [https://wayback.archive-
it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting
23 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm](https://wayback.archive-it.org/7993/20170111122711/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm).

24 ³⁰ Available at [https://wayback.archive-
it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeeting
25 Materials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm](https://wayback.archive-it.org/7993/20170111122706/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm).

26 ³¹ Available at [https://wayback.archive-
it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/Commit
27 teesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf).

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

4 **2. The marketing of menthol cigarettes to youth and minorities.**

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

- 9 a. menthol cigarettes “are marketed disproportionately to younger people,” *id.* at
10 92;
- 11 b. menthol use is higher among youth and young adult smokers, *see id.*;
- 12 c. women “have been targets of tailored menthol marketing efforts,” *id.*; and
- 13 d. menthol cigarettes are “disproportionately marketed per capita to African
14 Americans. African Americans have been the subjects of specifically tailored
15 menthol marketing strategies and messages. ... [And,] [c]onsistent with these
16 targeted marketing efforts, menthol cigarettes are disproportionately smoked by
17 African American smokers,” *id.*

18 72. The Report further found that “although cigarette smoking is becoming less
19 prevalent, menthol cigarette smoking is declining at [a] slower rate than is non-menthol
20 cigarette smoking.” *Id.* at 148.

21 73. In addition, menthol cigarettes were associated with “increased transition to
22 greater or established smoking and dependence.” *Id.* at 149.

23 74. In sum, the Report noted that sufficient evidence existed to conclude that the
24 availability of menthol cigarettes—

- 25 a. increases experimentation and regular smoking, *id.* at 216;
- 26 b. increases the likelihood of addiction and the degree of addiction in youth
27 smokers, *id.* at 216; and
- 28

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

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

11 **3. Conclusion: Menthol cigarettes harm the public health.**

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

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

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

25 79. Notably, the Committee found that if menthol cigarettes had been removed
26 from the market in 2010, then by 2020, roughly 17,000 premature deaths would have been
27 avoided, and about 2.3 million people would not have started smoking. By 2050, the
28

1 cumulative gains would have resulted in over 327,000 premature deaths avoided, and over 9.1
2 million people that would not have started smoking. *See id.* at 221.

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

7 **4. Recommendation: Remove menthol cigarettes from the market.**

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

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

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

27 *Id.* at 225.

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

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

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

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

12 86. Per FDA’s Center for Tobacco Products Director, “Tobacco is the leading
13 cause of preventable disease, disability, and death in the United States. Tobacco products are
14 responsible for approximately 443,000 deaths and \$193 billion on medical expenditures and
15 lost productivity each year in the United States.” *Id.*³²

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

17 87. On July 24, 2013, FDA then issued an advance notice of proposed rulemaking
18 to solicit information and public comment on the “potential regulation of menthol in
19 cigarettes.” FDA, Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco*
20 *Products*, Dkt. No. FDA-2013-N-0521, 78 Fed. Reg. 44484, 44484 (July 24, 2013).³³

23 ³² At around this same time, the tobacco industry submitted to FDA a competing Industry
24 Menthol Report. *See* The Industry Menthol Report (Mar. 23, 2011). *Available at*
25 [https://wayback.archive-](https://wayback.archive-it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf)
26 [it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/Commit-](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf)

27 ³³ *Available at* [https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-](https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-in-cigarettes-tobacco-products-request-for-comments)
28 [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).

1 88. As part of this advance notice, FDA made available its preliminary scientific
2 evaluation of public health issues relating to the use of menthol in cigarettes. *See* FDA, Prelim.
3 Scientific Eval. of the Possible Public Health Effects of Menthol Versus Non[-]Menthol
4 Cigarettes (“2013 FDA Findings”).³⁴ This undertaking was a “thorough review of the available
5 science concerning menthol cigarettes.” *Id.* at 3. To accomplish this task, FDA—

- 6 a. “weighed the collective body of evidence for the impact of the use of menthol in
7 cigarettes on public health”;
- 8 b. “considered the source of information, the type of study, and the quality of
9 study methods and data”;
- 10 c. “evaluated the peer-reviewed literature, industry submissions and other
11 materials provided to TPSAC,” and
- 12 d. “performed or commissioned additional analyses in an attempt to fill in and
13 inform some of the gaps in the literature.”

14 *Id.* at 3.

15 89. FDA then submitted its findings to a peer review panel, which provided
16 comments to which FDA then responded to. *See* FDA Rept. to Congress, *Progress and*
17 *Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act*, at 15
18 (2013).³⁵ The agency also posted the peer reviewed comments, and its response to those
19 comments. *See id.*

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

21 90. Based on FDA’s review, FDA found that the weight of the evidence, among
22 other things, supported the following conclusions:

23
24
25 ³⁴ *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>.

³⁵ Available at <https://www.fda.gov/media/86670/download>.

- a. Menthol in cigarettes is “likely associated with altered physiological responses to tobacco smoke”;
- b. A majority of African American smokers use menthol cigarettes;
- c. Younger populations have the highest rate of smoking menthol cigarettes;
- d. Female smokers are more likely to smoke menthol cigarettes than male smokers;
- e. The marketing of menthol cigarettes is associated with menthol brand preference among adolescents and the African American community;³⁶ and
- f. Menthol in cigarettes is likely associated with—
 - i. increased initiation and progression to regular cigarette smoking;³⁷
 - ii. increased dependence;³⁸ and
 - iii. reduced success in smoking cessation, especially among African American menthol smokers.³⁹

2013 FDA Findings at 4–6.

91. 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”:

³⁶ “The available data show that advertising is a strong driver of brand preference among adolescents and that it is likely that the standard marketing mix approach of price, promotion, product, and place has been used to drive menthol cigarette preference among the urban African American community.” 2013 FDA Findings, at 5.

³⁷ “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.

³⁸ “There were consistent findings that menthol smokers more likely to smoke their first cigarette within five minutes of waking.” 2013 FDA Findings, at 6.

³⁹ “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 The impact of cigarette smoking upon public health is
2 indisputable. More than 400,000 deaths per year in the United
3 States are caused by tobacco use. Consistent patterns have
4 emerged as a result of FDA's evaluation of the scientific evidence
5 relevant to the impact of menthol tobacco products on public
6 health. ... [A]dequate data suggest that menthol use is likely
7 associated with increased smoking initiation by youth and young
8 adults. Further, the data indicate that menthol in cigarettes is
9 likely associated with greater addiction. Menthol smokers show
10 greater signs of nicotine dependence and are less likely to
11 successfully quit smoking. These findings, combined with the
12 evidence indicating that menthol's cooling and anesthetic
13 properties can reduce the harshness of cigarette smoke and the
14 evidence indicating that menthol cigarettes are marketed as a
15 smoother alternative to nonmenthol cigarettes, make it likely that
16 menthol cigarettes pose a public health risk above that seen with
17 nonmenthol cigarettes.

18 *Id.* at 6.

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

20 92. Notably, FDA clarified that this "scientific assessment of public health issues
21 related to menthol in cigarettes ... [did] not constitute a decision about what regulatory action,
22 if any, FDA might take with respect to menthol in cigarettes." FDA 2013 Findings, at 7.

23 93. Rather, FDA would first "review[] all of the available information from this
24 assessment and the anticipated public comments, from the [2011 Tobacco Product Scientific
25 Advisory Committee] report and associated public comments, and from the tobacco industry
26 perspective document[.]" *Id.*

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

4 95. By this time, the Center for Tobacco Products’ Director Mitch Zeller had
5 acknowledged that “Menthol cigarettes raise critical public health questions.” Michael
6 Felberbaum, *FDA: Menthol cigarettes likely pose health risk*, USA Today (July 23, 2013).⁴⁰ Zeller
7 further noted that there was “no holdup” on FDA proposing restrictions on menthol, but that
8 there were still “some important questions” that need to be answered. *See id.*

9 96. To that end, in August 2013, FDA announced that it was funding three
10 menthol related studies: one to look at whether genetic differences in taste perception explain
11 why certain racial and ethnic populations are more likely to use menthol cigarettes; the second
12 to compare exposure to smoke-related toxins and carcinogens from menthol and nonmenthol
13 cigarettes; and a third to examine the effects of menthol and nonmenthol compounds in
14 various tobacco products on both tobacco addiction and toxicants of tobacco smoke. *See FDA*
15 *Invites Public Input on Menthol in Cigarettes*, The ASCO Post, Vol. 4, Issue 13, at 21 (Aug. 13,
16 2013).⁴¹

17 97. On information and belief, FDA has already completed and reviewed the
18 results of these three menthol studies initiated almost seven years ago.

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

20 98. That same year in 2013, plaintiff AATCLC (together with several other leading
21 national organizations) submitted a Citizen Petition with FDA. *See Tobacco Control Legal*
22 *Consortium et al. Citizen Petition*, Dkt. ID FDA-2013-P-0435-0001 (“Citizen Petition”).⁴²

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25 ⁴⁰ Available at <https://www.usatoday.com/story/news/nation/2013/07/23/fda-menthol-cigarettes-health-risk/2578331/>.

26 ⁴¹ Available at https://issuu.com/ascopost/docs/tap_vol_4_issue_13.

27 ⁴² Available at <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

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

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

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

22 101. To plaintiffs’ knowledge, FDA has taken no other action in response to the
23 Petition, despite the passage of nearly seven years since it was presented.

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

25 102. Meanwhile, despite Director Zeller’s reported assurance in 2013 that “there was
26 ‘no holdup’” concerning FDA’s determination or regulation of menthol in cigarettes, FDA for
27
28

1 the next four years (i.e., Summer of 2013 – Summer of 2017) remained largely silent about its
2 potential regulation of menthol cigarettes.

3 103. Around the same time, however, many other countries began moving to ban
4 menthol in cigarettes.⁴³

5 104. Then in 2017, the agency finally seemed poised to take actual steps to regulate
6 menthol cigarettes, as described below.

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

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

10 106. In 2017, then-FDA Commissioner Scott Gottlieb announced a “new
11 comprehensive plan for tobacco and nicotine regulation” that would serve as a multi-year
12 roadmap to better protect children and significantly reduce tobacco-related disease and death.
13 *See* FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related
14 Disease Death (July 27, 2017).⁴⁴ Noting that over 480,000 deaths each year were caused by
15 tobacco use, and that the direct healthcare and lost productivity costs totaled nearly \$300
16 billion each year, the Commissioner noted that the agency would focus its efforts on starting a
17 public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels.
18 *See id.*

21 ⁴³ For example, in 2012, Brazil approved a ban on all flavors, including menthol, in all tobacco
22 products. In 2016, the European Union banned all flavored cigarettes including menthol
23 (effective 2020). And in 2017, Canada banned the sale of menthol cigarettes. *See* Campaign for
24 Tobacco-Free Kids, Brazil’s Highest Court Upholds Ban on Flavored Tobacco Products (Feb. 1,
25 2018). Available at [https://www.tobaccofreekids.org/press-releases/2018_02_01_brazil-court-
26 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:
27 Banning Menthol in Tobacco Products, 49–50 available at
28 [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.

⁴⁴ Available at [https://www.fda.gov/news-events/press-announcements/fda-announces-
comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death](https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death).

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

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

6 108. Then, on March 14, 2018, FDA Commissioner Gottlieb announced three
7 advance notices of proposed rulemaking—one each (1) “to explore a product standard to lower
8 nicotine in cigarettes to minimally or non-addictive levels”; (2) to “solicit additional comments
9 and data related to the regulation of premium cigars”; and (3) “to seek comment on the role
10 that flavors—*including menthol*—play in initiation, use and cessation of tobacco products.”
11 FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. (Mar. 14, 2018) (emphasis
12 added).⁴⁵

13 109. As to menthol in cigarettes, FDA Commissioner Gottlieb noted that “youth
14 consistently report product flavoring as a leading reason for using tobacco products. Flavors
15 may disguise the taste of tobacco. But flavored cigarettes ... are every bit as addictive as any
16 other tobacco products, have the same harmful health effects and may even make it harder to
17

18 ⁴⁵ Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to
19 dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or
20 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>.

21 The three advance notices of proposed rulemaking were later published that same month: See
22 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
23 <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*,
24 Dkt. No. FDA-2017-N-6565, 83 Fed. Reg. 12294 (Mar. 21, 2018). Available at
25 <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.
26 12901 (Mar. 26, 2018). Available at
27 <https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes>.

1 quit. Additionally, youth and young adult smokers are disproportionately more likely to
 2 smoke menthol than nonmenthol cigarettes. And we know that youth who initiate smoking
 3 with menthol cigarettes ... may be at greater risk of progression from experimentation to
 4 established smoking and nicotine dependence.” Statement from FDA Commissioner Scott
 5 Gottlieb, M.D. (Mar. 19, 2018).⁴⁶

6 110. Following the submission of comments to these three advance notices, FDA
 7 Commissioner Gottlieb noted in an interview that “he was revisiting [FDA’s consideration of]
 8 the use of menthol in certain products, which has been of particular concern in African-
 9 American communities targeted by makers of menthol cigarettes like Newport and Kools in
 10 years past. ***‘It was a mistake for the agency to back away of menthol,’*** he said.”
 11 Sheila Kaplan, *Altria to Stop Selling Some E-Cigarette Brands That Appeal to Youths*, The New York
 12 Times (Oct. 25, 2018) (emphasis added).⁴⁷

13 111. Accordingly, on November 18, 2018, then-FDA Commissioner Gottlieb
 14 announced that FDA would issue a Notice of Proposed Rulemaking “seek[ing] to ban menthol
 15 in combustible tobacco products, including cigarettes and cigars[.]” Statement from FDA
 16 Commissioner Scott Gottlieb, M.D. (Nov. 15, 2018).⁴⁸

18 ⁴⁶ Statement from FDA Commission Scott Gottlieb, M.D., on efforts to reduce tobacco use,
 19 especially among youth, by exploring options to address the role of flavors—including menthol—
 20 in tobacco products (Mar. 19, 2018). Available at [https://www.fda.gov/news-events/press-
 21 announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-
 22 especially-among-youth](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-especially-among-youth).

23 ⁴⁷ Available at [https://www.nytimes.com/2018/10/25/health/altria-vaping-
 24 cigarettes.html?module=inline](https://www.nytimes.com/2018/10/25/health/altria-vaping-cigarettes.html?module=inline).

25 ⁴⁸ FDA, Statement from FDA Commission Scott Gottlieb, M.D., on proposed new steps to
 26 protect youth by preventing access to flavored tobacco products and banning menthol in
 27 cigarettes (Nov. 15, 2018). Available at [https://www.fda.gov/news-events/press-
 28 announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-
 youth-preventing-
 access?utm_campaign=111518+Statement+FDA%20Commissioner%20statement%20on%20pr
 oposals%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).

1 112. Commissioner Gottlieb described his reasoning as follows:

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

12 ...

13 I noted that the popularity of menthol cigarettes with youth is
14 especially troubling. In fact, youth smokers are more likely to
15 use menthol cigarettes than any other age group. More than
16 half (54 percent) of youth smokers ages 12–17 use menthol
17 cigarettes, compared to less than one-third of smokers ages 35
18 and older. Prevalence of menthol use is even higher among
19 African-American youth, with data showing that seven out of 10
20 African-American youth smokers select menthol cigarettes.
21 And, ... there's no evidence to suggest that menthol-flavored
22 cigarettes may play a role in harm reduction for adult smokers.

23 *Id.*

24 113. Accordingly, FDA would “advance a Notice of Proposed Rulemaking that
25 would seek to ban menthol in combustible tobacco products, including cigarettes and cigars.”

26 *Id.* And significantly, FDA would “accelerate the proposed rulemaking process to ensure that
27 [its] policies on flavored tobacco products protect public health[.]” *Id.*

1 114. Such actions would be consistent with guidance from the National Centers for
2 Disease Control and Prevention (“CDC”), which noted the following “bottom line”:

- 3 a. “Tobacco companies add menthol to make cigarettes seem less harsh and more
4 appealing to new smokers and young people. ...
5 b. Different groups of people—like some racial/ethnic minorities, LGBT people,
6 people with mental health conditions, etc.—are more likely to smoke menthol
7 cigarettes than the rest of the population. This is particularly true for African
8 Americans.
9 c. Some studies show that people who smoke menthol cigarettes have a harder
10 time quitting smoking than those who smoke non-menthol cigarettes.
11 d. We can help reduce menthol cigarette smoking and help people who smoke
12 menthol cigarettes to quit with policies that limit where menthol cigarettes are
13 sold and marketed, and by reaching out to groups that are more likely to smoke
14 menthol cigarettes.”⁴⁹

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

16 115. In March 2019, however, FDA Commissioner Scott Gottlieb resigned.
17 Norman E. “Ned” Sharpless, M.D. was then appointed Acting FDA Commissioner in April
18 2019.

19 116. And by June 2019, without any explanation, FDA reversed course and decided
20 not to initiate its previously announced rulemaking process.

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

22 117. On June 20, 2019, then-Acting FDA Commissioner Sharpless and defendant
23 Center for Tobacco Products Director Mitch Zeller announced FDA’s *Achievements in Tobacco*
24 *Regulation Over the Past Decade and Beyond*. See FDA, *Achievements in Tobacco Regulation Over*
25

26 ⁴⁹ Centers for Disease Control and Prevention, *Menthol and Cigarettes* (last reviewed May 18,
27 2020). Available at [https://www.cdc.gov/tobacco/basic_information/tobacco_industry/menthol-](https://www.cdc.gov/tobacco/basic_information/tobacco_industry/menthol-cigarettes/index.html)
28 [cigarettes/index.html](https://www.cdc.gov/tobacco/basic_information/tobacco_industry/menthol-cigarettes/index.html).

1 the Past Decade and Beyond (June 20, 2019).⁵⁰ Among other things, that announcement
 2 noted the passage of the Tobacco Control Act, as well as FDA’s “groundbreaking plan for
 3 tobacco and nicotine regulation,” including FDA’s plan “to take action on flavored cigars and
 4 continue to explore other issues related to flavored tobacco products.” *Id.*

5 118. Absent from defendants’ announcement, however, was any mention of FDA
 6 taking steps to address menthol in cigarettes.

7 119. Similarly, on June 24, 2019, HHS published its inventory of rulemaking actions
 8 under development (“Spring 2019 Agenda”). *See* Regulatory Agenda, Ofc. of the Secretary,
 9 HHS, 84 Fed. Reg. 29623 (June 24, 2019).⁵¹ This Spring 2019 Agenda presented “the
 10 regulatory activities that the Department [i.e., HHS, FDA, and the defendant Center for
 11 Tobacco Products] expects to undertake in the foreseeable future,” *id.* at 29624 (citing various
 12 proposed rules, final rules, and long-term actions).

13 120. No plans to address menthol were included in this Regulatory Agenda by
 14 defendants. *See* HHS Regulatory Agenda, *generally*; HHS, Agency Rule List – Spring 2019.

15 121. Likewise, no plans to address menthol were included with HHS’s most recent
 16 Regulatory Agenda, published on December 26, 2019. *See* Regulatory Agenda, Ofc. of the
 17 Secretary, HHS, 84 Fed. Reg. 71129 (Dec. 26, 2019) (“Fall 2019 Agenda”).⁵²

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 19 ⁵⁰ Available at <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/achievements-tobacco-regulation-over-past-decade-and-beyond>.

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 21 ⁵¹ Available at <https://www.federalregister.gov/documents/2019/06/24/2019-12004/regulatory-agenda>. *See also* HHS, Agency Rule List – Spring 2019. Available at
 22 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201904&showStage=active&agencyCd=0900&csrf_token=AC9CA9308A92E9EACBFB612B667086E9017C80260FDDB0D9364F9F5F2137B6554EA1929687D28B0AFFBE211B4AB531B5D1F4.

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 24 ⁵² Available at <https://www.federalregister.gov/documents/2019/12/26/2019-26539/regulatory-agenda>. *See also* HHS, Agency Rule List – Fall 2019. Available at
 25 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=0900&csrf_token=AC9CA9308A92E9EACBFB612B667086E9017C80260FDDB0D9364F9F5F2137B6554EA1929687D28B0AFFBE211B4AB531B5D1F4,

1 Term Actions, Agency Rule List – Spring 2019, HHS (identifying defendants’ long-term
2 actions)⁵⁶, OIRA Long Term Actions, Agency Rule List – Fall 2019, HHS⁵⁷.

3 125. On this record, defendants’ unexplained and unjustifiable determination not to
4 proceed with its own proposed rulemaking to ban menthol in combustible tobacco products
5 violates the Tobacco Control Act and is unlawful.

6 * * *

7 126. Over ten years ago, Congress directed defendants to address the public health
8 harms caused by menthol in cigarettes. Since that time, however, defendants have simply
9 pushed aside the mounting body of medical and scientific evidence that menthol in cigarettes
10 harms the public health.

11 127. In 2011, FDA knew about these harms, as set forth by its own Scientific
12 Advisory Committee. In 2013, FDA’s own findings and conclusions confirmed those harms to
13 the public health. And in 2018, then-FDA Commissioner Gottlieb announced that FDA
14 would advance a Notice of Proposed Rulemaking seeking to ban menthol in combustible
15 tobacco products, including all cigarettes.⁵⁸

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17 ⁵⁶ Available at
18 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201904&showStage=longterm&agencyCd=0900&Image58.x=66&Image58.y=13; see generally Office of Information and Regulatory Affairs, About the Unified
19 Agenda, available at https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp (“[A]n
20 agency may list in the ‘Long-Term Actions’ section of its agenda those rules it expects will have
21 the next regulatory action more than 12 months after publication of the agenda.”).

22 ⁵⁷ Available at
23 https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPubId=201910&showStage=longterm&agencyCd=0900&csrf_token=243A419EF187585EFFD83CD9CFA7CB8F1D8F1155635D087656DF62F1D717959D8C6B90FE425F27A717CEC962B0EECE3D5800.

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25 ⁵⁸ Additional studies have since further concluded that removing menthol from cigarettes is likely
26 to reduce youth smoking initiation, improve smoking cessation outcomes in adult smokers, and in
27 turn, benefit public health. See, e.g., Villanti, Andrea C. et al., *Menthol Cigarettes and The Public
28 Health Standard: A Systematic Review*, BMC Public Health (Dec. 29, 2017). Available at
<https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4987-z>. And in a
follow up study reviewing Canada’s menthol ban, at least one study found higher rates of quitting

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

7 134. At the time Congress enacted the Tobacco Control Act, Congress specifically
8 recognized that menthol cigarettes "may pose unique health risks to those who smoke them."
9 H. Rept., Part 1 at 38. And as a result, Congress "urge[d] [FDA] to address these issues as
10 quickly as practicable." *Id.* Indeed, Congress believed that it would be "critical for [FDA] to
11 move quickly to address the unique public health issues posed by menthol cigarettes." *Id.* at
12 38–39.

13 135. To that end, Congress directed FDA to periodically reevaluate and "determine"
14 whether the Act's existing flavor standard "should be changed" to reflect new data and protect
15 the public health. *See* 21 U.S.C. § 387g(a)(5).

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

- 18 a. The Tobacco Product Scientific Advisory Committee Report (2011);
- 19 b. The Industry Menthol Report (2011);
- 20 c. FDA's own peer-reviewed evaluation of the science concerning menthol in
21 cigarettes (2013);
- 22 d. FDA's Advance Notice of Proposed Rulemaking, *Menthol in Cigarettes, Tobacco*
23 *Products*, 78 Fed. Reg. 44484, and the comments received by FDA (2013); and
- 24 e. FDA's Advance Notice of Proposed Rulemaking, *Regulation of Flavors in Tobacco*
25 *Products*, 83 Fed. Reg. 12294, and the comments received by FDA (2018).

26 137. From these submissions, former FDA Commissioner Scott Gottlieb announced
27 that FDA would begin the rulemaking process for banning menthol in combustible cigarettes.
28

1 138. And yet, without explanation, FDA and the defendants have declined to begin
2 the rulemaking process.

3 139. Accordingly, FDA’s failure to make such a determination constitutes agency
4 action “unlawfully withheld or unreasonably delayed,” 5 U.S.C. § 706(1), and a failure by the
5 agency to “conclude a matter presented to it” “within a reasonable time,” *id.* § 555(b). *See Sierra*
6 *Club v. Gorsuch*, 715 F.2d 653, 659 (D.C. Cir. 1983) (“judicial review of decisions not to regulate
7 must not be frustrated by *blind* acceptance of an agency’s claim that a decision is still under
8 study”) (emphasis in original); *Cutler v. Hayes*, 818 F.2d 879, 897 n.156 (D.C. Cir. 1987)
9 (“[t]here comes a point when relegating issues to proceedings that go on without conclusion in
10 any kind of reasonable time frame is tantamount to refusing to address the issues at all—and
11 the result is a denial of justice”).

12 140. FDA’s unreasonable delay and inaction constitutes a violation of the
13 Administrative Procedure Act.

14 **Count II: Violation of the Administrative Procedure Act**
15 **(5 U.S.C. §§ 555(b) & 706(1)—Citizen Petition)**

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

17 142. On or about April 12, 2013, plaintiff African American Tobacco Control
18 Leadership Council (together with several other leading national organizations) submitted a
19 Citizen Petition with FDA. *See Tobacco Control Legal Consortium et al. Citizen Petition*, Dkt. ID
20 FDA-2013-P-0435-0001 (“Citizen Petition”).⁶⁰ This Petition, among other things, asked FDA
21 to do the following:

- 22 a. Add menthol to the list of additives and constituents in the prohibition on
23 characterizing flavors in cigarettes and cigarette smoke directed by section 907
24 (a)(1)(A) of the Federal Food, Drug, and Cosmetic Act, *see id.* at 9–10 (i.e.

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27 ⁶⁰ Available at <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

1 prohibit menthol as a characterizing flavoring in cigarettes, *see* Citizen Pet., at
2 7); and

- 3 b. Work with appropriate entities to provide support to smokers of menthol
4 cigarettes who will quit as a result of the requested prohibition on menthol in
5 cigarettes, *see id.* at 10.

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

15 144. FDA has a mandatory duty to respond to the citizen petition under the
16 Administrative Procedure Act and FDA’s own regulations adopted thereunder. *See* 5 U.S.C. §
17 553(e) (“Each agency shall give an interested person the right to petition for the issuance,
18 amendment, or repeal of a rule.”); 21 C.F.R. § 10.30 (e) (providing a 180-day timeframe within
19 which the agency must provide a response to the petitioner). *See also Henley v. Food & Drug*
20 *Admin. (Dep’t of Health & Human Servs.)*, 873 F. Supp. 776, 780 (E.D.N.Y. 1995), *aff’d sub nom.*
21 *Henley v. Food & Drug Admin.*, 77 F.3d 616 (2d Cir. 1996) (*citing National Organization for Reform of*
22 *Marijuana Laws v. Ingersoll*, 497 F.2d 654, 657–58 (D.C. Cir. 1974)) (“the [FDA] Commissioner
23 must consider the petition and must give written notice of the decision accompanied by an
24 explanatory statement.”).

25 145. To date, however, defendants have not yet substantively responded to plaintiff’s
26 Citizen Petition.

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

5 **Count III: Violation of the Administrative Procedure Act**
6 **(5 U.S.C. § 706(2)—Arbitrary and Capricious)**

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

8 148. Plaintiffs allege this claim in the alternative to Counts I and II, *see* Fed. R. Civ.
9 P. 8(d), and in response to any argument by defendants that they have made a permissible
10 decision not to ban menthol.

11 149. Despite the overwhelming evidence that removing menthol cigarettes from the
12 marketplace would benefit public health and defendant FDA’s own stated intention to ban
13 menthol in combustible cigarettes for these reasons, defendants have declined to add menthol
14 to the flavor ban list, *id.* § 387g(a)(1)(A).

15 150. Defendants’ calculated decision to allow menthol cigarettes to remain in the
16 marketplace despite the overwhelming evidence that the Tobacco Act’s existing flavor
17 standard “should be changed” to reflect new data and protect the public health, *see* 21 U.S.C. §
18 387g(a)(5), constitutes “agency action” subject to judicial review, a denial of plaintiff
19 AATCLC’s Citizen Petition, and is arbitrary, capricious, an abuse of discretion, or otherwise
20 not in accordance with law, *see* 5 U.S.C. § 706(2).

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

24 152. Defendants’ unreasonable process and decision constitute violations of the
25 Administrative Procedure Act.

REQUESTED RELIEF

WHEREFORE, Plaintiffs request that this Court enter the following:

1. An Order declaring defendants to be in violation of the Administrative Procedure Act;
2. An Order declaring defendants to be in violation of the Tobacco Control Act;
3. An Order directing defendants to begin the rulemaking process for adding menthol to the list of characterizing flavors banned by the Tobacco Control Act within 60 days of the date of any such Order;
4. An Order directing defendants to respond to the Citizen Petition submitted by plaintiff African American Tobacco Control Leadership Council et al.;
5. An Order directing defendants to provide for publication in the Federal Register, the basis for defendants' decision to either (a) add menthol to the list of banned characterizing flavors for combustible cigarettes, or else (b) not add menthol to such list, within 60 days of the date of such Order;
6. An Order directing defendants to undertake and complete an evaluation of tobacco product standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data;
7. An Order awarding plaintiffs their reasonable costs and attorneys' fees, under 28 U.S.C. § 2412; and
8. An Order granting all other appropriate relief, pursuant to 28 U.S.C. § 2202.

Respectfully submitted,

Date: June 17, 2020
New York, NY

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Action on Smoking and Health*

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