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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 vs.)

19 U.S. DEPARTMENT OF HEALTH AND)
20 HUMAN SERVICES; ALEX M. AZAR II, in)
21 his official capacity as Secretary of the U.S.)
22 Department of Health and Human Services;)
23 U.S. FOOD AND DRUG)
24 ADMINISTRATION; STEPHEN HAHN, in)
25 his official capacity as Commissioner of the)
26 U.S. Food and Drug Administration;)
27 CENTER FOR TOBACCO PRODUCTS;)
28 MITCH ZELLER in his official capacity as)
the Center for Tobacco Products, Director,)

Defendants.)

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
25

26
27 ⁴ *See* 21 U.S.C. § 387q(a); *id.* § 387g(e)(1).
28

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,
21

22
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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 22
 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.

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