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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, ACTION ON SMOKING AND HEALTH, AMERICAN MEDICAL ASSOCIATION, and NATIONAL MEDICAL ASSOCIATION,

Plaintiffs,

vs.

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

Defendants.

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

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

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

INTRODUCTION

2. In 2009, Congress passed—and President Obama signed into law—the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified, in relevant part, at 15 U.S.C. §§ 1333–34 and 21 U.S.C. § 301 *et seq.*) (2009) ("Tobacco Control Act"). This Act authorized the U.S. Food & Drug Administration ("FDA") to regulate tobacco products, 21 U.S.C. § 387a, and prohibited all flavors in cigarettes, save for tobacco and menthol (i.e., the "flavor ban"), *id.* § 387g(a)(1).

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

4. Congress therefore took steps to ensure that the issue of menthol in cigarettes would be "an early focus" for FDA and that FDA would have "the authority to deal with these and other products."[3] It specifically directed FDA to (1) create a Tobacco Products Scientific

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[1] H. Rept. 111-58, Part 1, Tobacco Control Act, 111th Congress (2009–10), 38 (Energy and Commerce Comm.) ("H. Rept., Part 1"). *Available at* https://www.congress.gov/111/crpt/hrpt58/CRPT-111hrpt58-pt1.pdf.

[2] *Id.*

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

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

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

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

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

8. For the African American community, this would have meant that (a) by 2020, roughly 4,700 premature deaths would have been avoided, and about 461,000 African Americans would not have started smoking; and (b) by 2050, over 66,000 premature deaths

[4] *See* 21 U.S.C. § 387q(a); *id.* § 387g(e)(1).

would have been avoided, and over 1.6 million African Americans would not have started smoking.

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

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

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

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

[5] FDA, Statement from FDA Commission Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes (Nov. 15, 2018). *Available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access?utm_campaign=111518_Statement_FDA%20Commissioner%20statement%20on%20proposals%20to%20address%20youth%20tobacco%20use&utm_medium=email&utm_source=Eloqua.

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

b. HHS's Fall 2019 inventory of rulemaking actions also failed to include any reference or plan to address menthol in cigarettes, or else any explanation of defendants' decision-making process on this important public health issue. *See* HHS, Agency Rule List – Fall 2019 (Dec. 26, 2019).[7]

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

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

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[6] *Available at* https://www.federalregister.gov/documents/2019/06/24/2019-12004/regulatory-agenda.

[7] *Available at* https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900.

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

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