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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

PLAINTIFFS' SUPPLEMENTAL BRIEF IN OPPOSITION TO DEFENDANTS' SECOND MOTION TO DISMISS

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INTRODUCTION

Pursuant to the Court's September 7, 2021 Order (ECF No. 63), plaintiffs African American Tobacco Control Leadership Council, Action on Smoking and Health, the American Medical Association, and the National Medical Association submit this supplemental brief in opposition to defendants' second motion to dismiss.

For years, defendants have known that banning menthol in cigarettes would protect the public health. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified in part at 15 U.S.C. §§ 1334–34 and 21 U.S.C. § 301 *et seq.*) (2009) ("Tobacco Control Act" or "Act") and the Administrative Procedure Act, Pub. L. No. 404, 60 Stat. 237, ch. 324 §§ 1–12 (1946) ("APA"), required defendants to act on that information. Instead, defendants made multiple statements of intent to impose a menthol ban, and never issued a notice of proposed rulemaking—a necessary first step in the rulemaking process.

Most recently, defendants have claimed that at least another year is needed before issuing such a notice. But that timeline is unreasonable. Each day, defendants' delay results in additional lives lost to a smoking-related illness. Thus, whether this Court considers defendants' obligation to act as beginning in 2013, 2018, or even 2020, there is no question that this Court can and should order defendants to finally comply with their obligations to address menthol in cigarettes.

I. Defendants have unduly delayed issuing a rule banning menthol.

Plaintiffs' complaint alleges multiple instances of undue delay by defendants.

First, plaintiffs allege that the Tobacco Control Act required defendants to take certain actions concerning menthol, and to take such action on an expedited basis. Essentially, once defendants had completed their research and amassed the data showing that a menthol ban was appropriate under the Act, they were required to make a determination about whether to ban menthol as a characterizing flavor in combustible cigarettes.

One of plaintiffs' primary complaints in this lawsuit has always been that defendants have unduly delayed and/or unlawfully withheld action on removing menthol from cigarettes, despite a growing body of evidence demonstrating the harms caused by menthol, and FDA's own

conclusions that a ban would benefit public health. *See, e.g.*, 2d Am. Compl. (1st Suppl.) ¶¶ 18–19. Although the Act itself did not mandate a menthol ban, the application of the Act's standards to the evidence collected by defendants did. In other words, once defendants had collected evidence showing a menthol ban was appropriate, they were obligated to act on that evidence by imposing a menthol ban within a reasonable amount of time.

By 2013, defendants had more than enough evidence to conclude that a menthol ban was necessary. Defendants unduly delayed acting on that evidence, however, despite repeated statements that a menthol ban was coming. These included then-FDA Commissioner Scott Gottlieb announcing in 2018 that FDA would advance a "Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars." 2d Am. Compl. (1st Suppl.) ¶¶ 10, 18, 123–25, 145 (citations omitted).

The Court did not hold otherwise in denying defendants' first motion to dismiss. Defendants wrongly suggest that the Court made a blanket holding that defendants are not required to ban menthol. *See* Defs.' Reply at 2 (ECF No. 59). In fact, the Court simply ruled that the Act required FDA (which claimed that it had not yet made any determination concerning a menthol ban, despite its Commissioner's public statements to the contrary) to analyze whether a menthol ban was appropriate. Because that question is for the FDA in the first instance, the Court did not pre-judge the issue by "suggest[ing] that the FDA must ban menthol cigarettes." Order at 8 (ECF No. 34). Rather, the Court held that FDA was required to "make a decision on modifying the flavor ban, particularly in light of the advisory committee's findings and the FDA's own investigations." *Id.*

Notably, those findings and investigations lead to the inescapable conclusion that a menthol ban is appropriate under the standards set forth in the Tobacco Control Act. Indeed, FDA did, in fact, reach this same conclusion no later than 2013. And, the fact that defendants instead reached this conclusion only after plaintiffs filed this lawsuit in 2020 does not reset the clock on defendants' longstanding delay.

Second, as noted above, in response to Plaintiff's original complaint, filed on June 13, 2020, defendants argued that they had not yet made any determination concerning menthol—even though defendant FDA had, in 2013, issued an Advance Notice of Proposed Rulemaking seeking to ban menthol in cigarettes, and then-FDA Commissioner Gottlieb's 2018 announcement 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) (cited in 2d Am. Compl. (1st Suppl.) ¶¶ 10, 18, 123–25, 145. Now, however, defendants argue that a statement of intent to issue a NPRM is a "determination." If the Court accepts defendants' view, then plaintiffs would also argue that there has been undue delay in implementing the 2013 ANPRM and the 2018 determination to issue a NPRM (i.e., in addition to defendants' undue delay in acting on the clear evidence concerning menthol, defendants have also unduly delayed acting on these prior determinations).

Finally, given this history, plaintiffs also allege that defendants have unreasonably delayed implementing their April 21, 2021 response "approving" the citizen petition and deciding (yet again) to ban menthol at some indefinite future date. For the reasons discussed below, each *TRAC* factor weighs in favor of the plaintiffs and a finding by this Court of defendants' undue delay.

II. Each *TRAC* factor confirms that Defendants' delay is unreasonable.

Under the Administrative Procedure Act ("APA"), a court may compel "agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). This "analysis is fact-intensive: 'Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances before the court.'" *Addala v. Renaud*, 2021 WL 244951, *2 (D.D.C. Jan. 25, 2021) (quoting *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1100 (D.C. Cir. 2003)). That said, courts look to the following *TRAC* factors in assessing whether relief is appropriate:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"[;] (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason[;] (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake[;] (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority[;] (5) the court should also take into account the nature and extent of the interests prejudiced by the delay[;] and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Indep. Min. Co. v. Babbitt, 105 F.3d 502, 507 n. 7 (9th Cir. 1997).[1] Here, each factor supports a finding of undue delay.

A. Defendants' delay is ongoing and unreasonable.

"The most important *TRAC* factor is the first factor, the 'rule of reason,' under which [courts] consider whether the time for agency action has been reasonable." *In re Nat. Res. Def. Council, Inc.*, 956 F.3d 1134, 1139 (9th Cir. 2020) (cleaned up). "Repeatedly, courts in this and other circuits have concluded that a reasonable time for agency action is typically counted in weeks or months, not years." *Id.* at 1139 (citation and internal quotations omitted).

In analyzing this factor, Courts consider an agency's actions prior to the grant of a citizen petition in determining whether there was unreasonable delay in issuing a notice of rulemaking. For example, in *Public Citizen Health Research Group v. Commissioner, Food & Drug Admin.*, 724 F. Supp. 1013, 1020 (D.D.C. 1989), the plaintiffs had filed suit against FDA alleging the agency's

[1] Such matters are not well-suited to resolution on a 12(b)(6) motion. Additionally, "grounds for agency delay will often be unknown to plaintiffs at the pleading stage." *Raju v. Cuccinelli* No. 20-cv-01386-AGT, 2020 WL 4915773, *1 (N.D. Cal. Aug. 14, 2020). For these reasons, "unreasonable-delay claims are ordinarily best resolved on or after summary judgment, not on motions to dismiss for failure to state a claim." *Id.*; *see also Moghaddam v. Pompeo*, 424 F. Supp. 3d 104, 117 n.4 (D.D.C. 2020) ("Defendants separately argue that Plaintiffs' claims must be dismissed because the delay alleged is not unreasonable. As the Court finds that analyzing whether the delay was unreasonable would be premature at the motion to dismiss stage and before discovery has been completed, it does not reach this argument.").

unreasonably delay in failing to promulgate long-needed regulations relating to tampon absorbency information. As here, the plaintiff in that case had filed a citizen petition prior to filing suit against the agency. The FDA "respond[ed] [to the plaintiff's citizen petition] in a positive manner and issue[d] a notice of proposed rulemaking" in 1988. *Id.* at 1018. Significantly, however, the court there did not limit its analysis of the plaintiff's undue delay claim to the agency's post-1988 conduct. Instead, the court also considered the defendants' pre-1988 actions:

> As late as 1984, defendants decided that a regulation standardizing tampon absorbency information was necessary. Since then, on several occasions the FDA planned to require consistent tampon absorbency labeling. Yet it was not until September 23, 1988, that it finally issued a proposed regulation …. In deciding that a regulation was necessary, the FDA took on the duty to promulgate one in a reasonable time. It cannot hide behind the argument that no duty to do so existed.

Id. at 1020. Based on this history, the Court concluded that: "defendants ha[d] unduly delayed in issuing a regulation requiring standardized tampon absorbency labeling. The Food and Drug Administration first learned of the association between tampon absorbency and Toxic Shock Syndrome ("TSS") more than seven years ago." *Id.* at 1020 (emphasis added).

The same holds true here. At the earliest, defendants first learned of the harms caused by menthol cigarettes over ten years ago when the Committee rendered its initial 2011 report concluding that banning menthol in cigarettes would benefit public health—a finding FDA then confirmed through its own peer-reviewed studies in 2013. *See* 2d Am. Compl. (1st Suppl.) ¶ 9. Since then, on several occasions the FDA announced plans to ban menthol. *Id.* ¶¶ 10, 17–18, 123–25, 145, 148. Yet defendants still have not even issued a notice of proposed rulemaking. Unless this Court intervenes, it will be years before any rule is implemented. This timeline is inconsistent with any "rule of reason." And the large gaps of time during which defendants took no action on menthol, *id.* ¶ 113, provide further evidence that the delay is unreasonable. *Am. Acad. of Pediatrics v. United States FDA*, 330 F. Supp. 3d 657, 666 (D. Mass. 2018) ("even more

troubling is the gaps of time where little to no work was completed …. The FDA fails the first and second [*TRAC*] factors.")

Courts have also observed that the *TRAC* factors "are not "ironclad," but rather are intended to provide "useful guidance in assessing claims of agency delay." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008). Defendants' long history of delay and inaction on menthol is plainly a relevant factor that should be considered. *See id.*; *see also In re Nat. Res. Def. Council, Inc.*, 956 F.3d 1134, 1140 (9th Cir. 2020) ("Whether we measure from April 2009—the time of NRDC's initial Administrative Petition—or from March 2017—the date that a final response should have been made according to the EPA's own representations to this court—the EPA has stretched the 'rule of reason' beyond its limits. … EPA's ambiguous plan to possibly issue a proposed rule [more than twelve years] after the administrative petition is too little, too late. The rule of reason tips sharply in favor of mandamus relief."); *Env't Def. Fund v. E.P.A.*, 852 F.2d 1316, 1331 (D.C. Cir. 1988) ("EPA argues that the relief requested by petitioners is unnecessary because the Agency is now conducting the required § 8002 studies on various processing wastes and 'may well conclude that Subtitle C regulation is appropriate for these wastes.' EPA's history of delay and missed deadlines with respect to its statutory obligations to complete the § 8002 mining waste studies, however, indicates that a court-imposed schedule is necessary here.")

Finally, defendants' argument that they can reset the clock and erase a decade of delay by re-stating their intent to issue a menthol ban is inconsistent with the logic of numerous cases where courts seek to avoid creating perverse incentives for agencies. *See, e.g., Am. Acad. of Pediatrics*, 330 F. Supp. 3d at 664 ("In the wake of the D.C. Circuit's vacatur and remand back to the agency, it cannot be the case that the FDA has freed itself from Congressional mandates and may now take the opportunity to promulgate this rule at whatever pace it chooses."); *In re A Cmty. Voice*, 878 F.3d 779, 785 (9th Cir. 2017) ("We also note that failing to find a duty would create a perverse incentive for the EPA …. Under the EPA's view, were it not to respond to the petition

at all, this court could grant mandamus and compel a time table for rulemaking, yet if EPA 'grants' the petition it can then delay indefinitely, without any recourse to the Petitioners.").

B. Congress intended defendants to move quickly on menthol.

The timetables provided in the Tobacco Control Act further confirm that Congress expected FDA to move quickly on menthol, supplying additional content for the rule of reason discussed above. Although the Act lacks a specific deadline for FDA's final determination on menthol, Congress clearly directed FDA to focus "immediately" on menthol and take concrete steps by dates certain to address it. *See* 21 U.S.C. § 387g(e) (directing FDA to consider menthol cigarettes specifically); *id.* § 387g(a)(5)). For example, the Act created a Scientific Advisory Committee, *see id.* § 387g(e)(1), and required that "[i]mmediately upon the establishment of" the Committee, the FDA "shall refer to the Committee for report and recommendation … the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." *Id.* § 387g(e)(1); *see also* 2d Am. Compl. (1st Suppl.) ¶ 55. The Act also directed that "not later than 1 year after its establishment," the Committee "shall submit to the Secretary a report and recommendation," on these topics. *Id.* ¶ 62.

The bill's sponsor and committee member in charge, Rep. Henry A. Waxman, further noted that menthol cigarettes would be "an early focus" of FDA's attention. *See id.* ¶¶ 63, 65–67; 2A Sutherland § 48.14 (noting that statements made by the committeeman's remarks have the same interpretative weight as formal committee reports). The Act's accompanying Committee Report further expressed Congress' view "that it [wa]s critical for the Secretary to move quickly to address the unique public health issues posed by menthol cigarettes." *See id.* ¶ 64 (emphasis added). *See* 2A Sutherland § 48.6 (noting that courts generally view committee reports as the most persuasive indicia of legislative intent); *Miller v. Fed. Mine Safety and Health Review Comm'n*, 687 F.2d 194, 195 (7th Cir. 1982) ("In the absence of any contrary legislative history, so clear a statement in the principal committee report is powerful evidence of legislative purpose, which we are obliged to give effect to even if it is imperfectly expressed in the statutory language."); *Train v.*

Colorado Public Interest Research Group, 426 U.S. 1, 10 (1976) (noting that to ignore an Act's legislative history would be "in error"); *SEC v. Joiner*, 320 U.S. 344, 350–51 (1943) ("courts will construe the details of an act in conformity with its dominating general purpose, will read text in the light of context and will interpret the text so far as the meaning of the words fairly permits so as to carry out in particular cases the generally expressed legislative policy").

Indeed, Congress's concern about the use of menthol in cigarettes "among children, African-Americans, Hispanics, and other racial and ethnic minorities," 21 U.S.C. § 387g(e)(1), has proved all too on point. While defendants delayed taking any action on menthol, the disproportionate harms suffered by these groups have only grown more pronounced. *See, e.g.*, *Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014* ("Although overall smoking prevalence has decreased, the proportion of past 30-day cigarette smokers using menthol cigarettes was higher (39%) in 2012–2014 compared to 2008–2010 (35%). Youth smokers remain the most likely group to use menthol cigarettes compared to all other age groups.");[2] *Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980–2018* ("Our results show that menthol cigarettes were responsible for 1.5 million new smokers, 157 000 smoking-related premature deaths and 1.5 million life-years lost among African Americans over 1980–2018. While African Americans constitute 12% of the total US population, these figures represent, respectively, a staggering 15%, 41% and 50% of the total menthol-related harm.").[3]

Plaintiffs will present additional evidence on this point at the summary judgment stage. Needless to say, but for defendants' inaction on menthol (i.e., defendants' disregard of the speed with which Congress expected the agency to proceed), these tragic developments could have been avoided. In short, the first two *TRAC* factors favor plaintiffs.

[2] Available at https://tobaccocontrol.bmj.com/content/25/Suppl_2/ii14.

[3] Summary available at https://tobaccocontrol.bmj.com/content/early/2021/09/16/tobaccocontrol-2021-056748.full.

C. Health and human welfare are at stake.

Courts often consider the third and fifth *TRAC* factors together, as plaintiffs do here. "Delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake. This is particularly true when the very purpose of the governing Act is to protect those lives." *Pub. Citizen Health Rsch. Grp. v. Auchter*, 702 F.2d 1150, 1157–58 (D.C. Cir. 1983).

Here, the Tobacco Control Act was designed to save lives by addressing smoking-related harms, including the harms caused by menthol cigarettes. *See* Point B, *supra*.[4] Defendants' inaction, however, has likely led to roughly 17,000 premature deaths. *See* 2d Am. Compl. (1st Suppl.) ¶¶ 7, 91. In 2011, FDA's Scientific Advisory Committee report noted 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. *Id.* ¶¶ 7, 91.

In addition, the public health harms already observed by Congress in 2009 have only gotten worse over time. As alleged in plaintiffs' complaint, *id.* ¶ 12, "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. The most recent data shows that figure has increased to 36%.[5]

[4] *See also Am. Acad. of Pediatrics*, 330 F. Supp. 3d at 666 ("In enacting the Tobacco Control Act, Congress found that "[t]obacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illness related to smoking.' … The interests prejudiced by delay are substantial.").

[5] New data from earlier this year shows that menthol cigarettes in 2019 comprised 37% of the market—"an all-time high[.]" Fed. Trade Comm'n Cigarette Report for 2019, at 10 (issued Mar. 30, 2021), available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2019-smokeless-tobacco-report-2019/cigarette_report_for_2019.pdf.

b. In 2009, more than 12 million individual smokers used menthol cigarettes. Today, the data shows that over 19 million smokers use menthol cigarettes—i.e., a majority of the estimated 34 million smokers in the United States.
c. In 2009, nearly 70% of African Americans who smoked, used menthol cigarettes. Today, that figure has risen to over 85%.

Id. (citations omitted).

There are few matters that involve a more serious impact on health and human welfare. As recently explained by Acting FDA Commissioner Janet Woodcock, M.D.: "Banning menthol—the last allowable flavor—in cigarettes and banning all flavors in cigars will help save lives, particularly among those disproportionately affected by these deadly products. With these actions, the FDA will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products." 2d Am. Compl. (1st Suppl.) ¶ 17. These factors weigh strongly in favor of finding undue delay.

D. Even FDA agrees that the menthol ban should be an urgent priority.

An Order directing expedited action from FDA would have little, if any, effect on FDA's "higher or competing" priorities. Defendants concede that a final rule banning menthol is "'one of the Agency's highest priorities.'" Defs.' 2d MTD at 6 (citing Defs.' Citizen Pet. Response at 14). The FDA's 2022 budget describes only two other matters in a similar way—FDA's efforts to (1) "ameliorate the opioid crisis," and (2) to "ensur[e] the development of safe and effective COVID-19 therapeutics, vaccines, and other medical products[.]" FDA Fiscal Year 2022 Justification of Estimates for Appropriations Committees, 90 (opioids; *see id.* at 92, 111, 389, 394), 131 (COVID) (2021), available at https://www.fda.gov/media/149616/download. *See id.* at 12 (describing need for menthol rule), 260 (same).

FDA furthermore appears to have more than enough resources available to achieve each of these priorities. *See* U.S. Dep't of Health and Human Services, Fiscal Year 2022, Budget in

Brief, 23 (noting that of FDA's requested budget of $6.5 billion, over $781 million is earmarked for work relating to "Tobacco Products"), available at https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf; *see also* FDA Fiscal Year 2022 Justification of Estimates, at 14 (describing FDA's enterprise risk management methodology to align the agency's public health mission, priorities, and budgetary requests).

Notably, "in cases concerning the issue of competing priorities, the culprit is often limited resources or budget. … However, [unlike other agencies] the FDA does not suffer from limited resources …." *Am. Acad. of Pediatrics*, 330 F. Supp. 3d at 667; *see also In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004) ("While FERC vacillates between claiming that it is not obligated to respond to the 1997 petition and asserting it can do no more, it has in no way indicated that any practical impediments have prevented a response or that any 'agency activities of a higher or competing priority' have required its attention."). As then-FDA Commissioner Scott Gottlieb observed in 2018: "[W]e need to address the impact that menthol in cigarettes has on the public health. … I can think of no more impactful action the FDA could possibly take on my watch to help American families."[6] This factor also weighs in favor of plaintiffs.

E. Impropriety is not required to find undue delay.

Finally, although plaintiffs are not required to show that defendants' delay is in bad faith, little else explains why an agency would take so long to implement an action that it has known for years will save thousands of lives. To the extent this factor has any relevance, it favors plaintiffs.

Courts have found defendants to have unreasonably delayed fulfilling their obligations under the Tobacco Control Act in at least two cases. In *Am. Acad. Of Pediatrics v. U.S. Food & Drug Admin.*, No. 1:16-cv-11985 (D. Mass. Oct. 4, 2016), the American Academy of Pediatrics, together with other public health groups sought to address FDA's delay in issuing a rule requiring

[6] Statement from FDA Commissioner 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://wayback.archive-it.org/7993/20191212190712/https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access (last visited Sept. 21, 2021).

graphic warning labels on cigarette packages and advertisements. Recognizing the important public health interests involved, the court there found that the agency had unreasonably delayed issuing the graphic warning label rule at issue and imposed a remedy that set a deadline by which the agency was required to issue a final rule. *See Am. Acad. of Pediatrics*, 330 F. Supp. 3d at 667. Likewise in *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md.) *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020), the same plaintiff challenged FDA's unreasonable delay in implementing and enforcing the premarket review process applicable to certain tobacco products. Again, the court in that case concluded that the agency had unreasonably delayed acting and imposed deadlines on the agency's review of new products in light of the important public health interests at stake. 399 F. Supp. 3d at 487.

The same is true here. For reasons that are unclear, defendants appear to be engaged in an ongoing campaign to avoid fulfilling their legal obligations concerning menthol, at the cost of thousands of lives. The Court can and should put a stop to defendants' endless delay.

CONCLUSION

For all of the above reasons, the Court should deny defendants' second motion to dismiss, order defendants to immediately produce the declaration they were to have produced following the Court's order denying their first motion to dismiss (*see* Civ. Minutes; ECF No. 25), and set a briefing schedule for plaintiffs' anticipated motion for summary judgment.

Respectfully submitted,

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