UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 20-cv-04012-KAW

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: Dkt. No. 26

On June 17, 2020, Plaintiffs African American Tobacco Control Leadership Council, Action on Smoking and Health, and American Medical Association filed the instant case asserting violations of the Administrative Procedure Act ("APA"). (Compl., Dkt. No. 1.) Plaintiffs allege that, contrary to the duties imposed by the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Defendants have failed to act on menthol cigarettes. (*See* First Amended Compl. ("FAC") ¶¶ 12, 15.)

Pending before the Court is Defendants' motion to dismiss. (Defs.' Mot. to Dismiss, Dkt. No. 26.) Having considered the parties' filings, the legal authority, and the arguments made at the November 5, 2020 hearing, the Court GRANTS IN PART and DENIES IN PART Defendants' motion to dismiss.

I. BACKGROUND

In 2009, the Tobacco Control Act became law, banning all flavors in cigarettes except for tobacco and menthol. (FAC ¶ 2; 21 U.S.C. § 387g(a)(1).) The Tobacco Control Act also authorized the Food and Drug Administration ("FDA") to regulate tobacco products. (FAC ¶ 2;

21 U.S.C. § 387a.)

Although the Tobacco Control Act did not ban menthol flavoring, Congress observed that menthol cigarettes "may pose unique health risks to those who smoke them," and that it was "especially concerned about proportionately higher rates of menthol cigarette use among African American smokers." (FAC ¶ 3; *see* H.R. REP. NO. 111-58, pt. 1, at 38 (2009).) The Tobacco Control Act specifically directed the FDA to create a Tobacco Products Scientific Advisory Committee ("Committee"), and to immediately refer to the Committee for a report and recommendation on "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." (FAC ¶ 4; 21 U.S.C. § 387g(3)(1).) The Tobacco Control Act also requires the FDA to "provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." (FAC ¶ 4; 21 U.S.C. § 387g(a)(5).)

In 2011, the Committee released its report, concluding: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." (FAC ¶ 6.) In 2013, the FDA conducted a peer-reviewed investigation, which concluded that menthol cigarettes was associated with increased smoking initiation, and that it likely posed "a public health risk above that seen with nonmenthol cigarettes." (FAC ¶ 9.) In 2018, then-FDA Commissioner Scott Gottlieb announced that the FDA would advance a Notice of Proposed Rulemaking to ban menthol in cigarettes. (FAC ¶ 10.) In June 2019, however, the Health and Human Services ("HHS") published its Spring 2019 inventory of rulemaking actions under development, but it did not include any reference or plan to address menthol in cigarettes. (FAC ¶¶ 11(a), (b).)

Plaintiffs then filed the instant lawsuit, asserting: (1) violation of APA § 706(1) based on an "agency action unlawfully withheld or unreasonably delayed," (2) violation of APA § 706(1) based on a failure to respond to Plaintiffs' citizen petition,[1] and (3) violation of APA § 706(2)

[1] On April 12, 2013, Plaintiff African American Tobacco Control Leadership Council filed a Citizen Petition with the FDA, requesting that the FDA add menthol to the flavor ban. (FAC ¶ 146.) Defendants do not move to dismiss this claim, as Defendants assert that the FDA has committed to providing a final response to the Citizen Petition by January 29, 2021 and that this

based on an agency action that is arbitrary and capricious. On September 18, 2020, Defendants moved to dismiss the first and third claims for lack of subject matter jurisdiction. (Defs.' Mot. to Dismiss at 1.) On October 2, 2020, Plaintiffs filed their opposition. (Pls.' Opp'n, Dkt. No. 28.) On October 14, 2020, Defendants filed their reply.[2] (Defs.' Reply, Dkt. No. 30.)

II. LEGAL STANDARD

A defendant may move to dismiss an action for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). A motion to dismiss for lack of subject matter jurisdiction will be granted if the complaint on its face fails to allege facts sufficient to establish subject matter jurisdiction. *See Savage v. Glendale Union High Sch.*, 343 F.3d 1036, 1039 n.2 (9th Cir. 2003). In considering a Rule 12(b)(1) motion, the Court "is not restricted to the face of the pleadings, but may review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the existence of jurisdiction." *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988). Once a party has moved to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the opposing party bears the burden of establishing the court's jurisdiction. *See Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010). "[I]f the existence of jurisdiction turns on disputed factual issues, the district court may resolve those factual disputes itself." *Leite v. Crane Co.*, 749 F.3d 1117, 1121-22 (9th Cir. 2014). An exception exists, however, where "a court must leave the resolution of material factual disputes to the trier of fact when the issue of subject-matter jurisdiction is intertwined with an element of the merits of the plaintiff's claim." *Id.* at 1122 n.3.

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response will moot the claim. (Defs.' Mot. to Dismiss at 10.)

[2] The Court observes that the parties appear to circumvent page limits through the liberal use of footnotes. Plaintiffs' opposition includes nineteen footnotes, one of which is over half a page long. (*See* Pls.' Opp'n at 13-14 n.9.) Defendants' reply includes seven footnotes, several of which are quite lengthy. Both sides are reminded that it is inappropriate to put substantive arguments in footnotes. *See Estate v. Saunders v. Comm'r of Internal Revenue*, 745 F.3d 953, 962 n.8 (9th Cir. 2014) ("Arguments raised only in footnotes . . . are generally deemed waived."). If the parties require additional pages, they should so request.

III. DISCUSSION

A. Section 706(1) Claim

"The APA provides relief for a failure to act in § 706(1): 'The reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed.'" *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) (quoting 5 U.S.C. § 706(1)). The court's "ability to 'compel agency action' is carefully circumscribed to situations where an agency has ignored a specific legislative command." *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010). Specifically, the agency action at issue must be a "'discrete action[], such as rules, orders, licenses, sanctions, and relief." *Id.*; *see also Norton*, 542 U.S. at 63. Further, the agency action must be one that the agency is legally required to take. *Norton*, 542 U.S. at 64; *Hells Canyon Pres. Council*, 593 F.3d at 932.

Here, the parties dispute whether § 387g(a)(5) is a discrete agency action that the FDA is required to take. (*See* Pls.' Opp'n at 12; Defs.' Reply at 2.) Again, § 387g(a)(5) requires the "periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." Plaintiffs contend that this section requires the FDA to make a specific determination concerning whether menthol should be added to the flavor ban, which was established by § 387g(a)(1). (Pls.' Opp'n at 12.) Defendants, in turn, argue that this section imposes no duty to revise existing tobacco product standards or adopt new ones, but only requires "periodic evaluations," a requirement that the FDA has satisfied by undertaking evaluations of menthol cigarettes. (Defs.' Reply at 15.)

The Court finds that the Tobacco Control Act requires that the FDA not only make periodic evaluations, but to make a determination of whether to *modify* the standard, which may include adding menthol cigarettes to the flavor ban. If "tasked with interpreting this section without context," the Court "would agree that this language suggests discretionary, not mandatory authority." *Earth Island Inst. v. Wheeler*, Case No. 20-cv-670-WHO, 2020 WL 2850285, at *4 (N.D. Cal. June 2, 2020). The Ninth Circuit's decision in *In re A Community Voice*, however, compels a different conclusion.

In *In re A Community Voice*, the Ninth Circuit considered the Residential Lead-Based Paint Hazard Reduction Act of 1992 ("Paint Hazard Act"), whose goal was to regulate the risk of childhood lead poisoning. 878 F.3d 779, 782 (9th Cir. 2017). The Environmental Protection Agency ("EPA") was given sole authority to establish national dust-lead hazard standards, and was required to issue initial rules identifying dust-lead hazards. *Id.* Additionally, the Paint Hazard Act established an initial standard for lead-based paint, and then divided authority between the EPA and the Department of Housing and Urban Development to adjust the standard as needed. *Id.* In the years following the establishment of the initial standards, scientific research established that both the lead-based paint standard and the dust-lead hazard standard were insufficient to protect children. *Id.* In 2009, a petition was filed asking the EPA to use its rulemaking authority to lower the dust-lead hazard standard; the EPA granted the petition, but did not commit to a specific outcome or deadline. *Id.* at 783. By 2016, the EPA had done further research, but had not established any rules. *Id.* Thus, a lawsuit was filed, requesting that the court find that the EPA had unreasonably delayed promulgation of the proposed rule and asking that the court compel the EPA to issue a final rule in the near future. *Id.*

The Ninth Circuit concluded that the EPA was legally required to act. *In re A Community Voice*, 878 F.3d at 784. Specifically, the Ninth Circuit found that by "enacting the Paint Hazard Act, Congress was clear about what it wanted: to prevent childhood lead poisoning and eliminate lead-based paint hazards in all housing as expeditiously as possible." *Id.* (internal quotation omitted). To that end, the EPA was required to identify lead-based paint hazards that would result in adverse human health effects. *Id.* Moreover, the Ninth Circuit found that the statute made clear that "this is an ongoing duty," relying on 15 U.S.C. § 2687, which stated: "The regulations may be amended from time to time as necessary." Finally, the Ninth Circuit pointed to the fact that "Congress specifically demanded the creation of task force that would be instructed to advise EPA and HUD as to revising regulations . . . relating to lead-based paint poisoning prevention." *Id.* (internal quotation omitted).

Based on this, the Ninth Circuit concluded:

> This statutory framework clearly indicates that Congress did not

> want EPA to set initial standards and then walk away, but to engage in an ongoing process, accounting for new information, and to modify initial standards when necessary to further Congress's intent: to prevent childhood lead poisoning and eliminate lead-based paint hazards. . . . Congress did not simply state a goal when enacting the . . . Paint Hazard Act; Congress established statutory standards that the EPA must enforce[, including] § 2687 ("The regulations may be amended from time to time as necessary.").

Id. at 784.

Applying *In re A Community Voice*, the district court in *Earth Island Institute v. Wheeler* likewise found that facially permissive language was mandatory. 2020 WL 2850285, at *4. There, the statute at issue stated: "The [EPA] may, from time to time, as the [EPA] deems advisable, revise or otherwise amend the National Contingency Plan [("NCP")]." 33 U.S.C. § 1321(d)(3). While the district court agreed that this language suggested discretionary authority, it acknowledged that per *In re A Community Voice*, "the word 'may' does not always indicate discretionary or permissive action." *Id.* Rather, in the context of the statute, "the terms indicate the same thing: the regulations should be amended as appropriate, but without a specified deadline." *Id.* Looking to the statute, the district court explained that § 1321(d)(1) required the NCP to provide efficient, coordinated, and effective action, as well as requiring specific activities to ensure the efficacy of the NCP. *Id.* at *5. Further, § 132(d)(2) provided for continuing operations and mandated an effective and efficient response to pollution. Thus, the district court concluded that "Section 1321(d) contemplates an ongoing duty that in turn strongly suggests that the duty to update and revise the NCP 'as advisable' is not discretionary, but required." *Id.* Otherwise, the EPA could "fail to review, update, or amend the NCP for decades, despite scientific advances, the occurrence of incidences involving discharge of oil and hazardous substances, and an internal report concluding that the NCP was outdated and inadequate." *Id.*

Like *In re a Community Voice* and *Earth Island Institute*, the language relied upon by Plaintiffs in this case appears, without context, to be discretionary. As required by *In re a Community Voice*, however, the Court must consider the statute as a whole. Here, in enacting the Tobacco Control Act, Congress made clear its public health goals, including the need "to address the public health crisis created by actions of the tobacco industry" and "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." (Tobacco

Control Act § 2(29), 123 Stat. at 1778; § 3(9), 123 Stat. at 1782.) To this end, the FDA has been instructed to provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." 21 U.S.C. § 387g(5). Further, the Tobacco Control Act makes clear that this is an ongoing duty, stating that the FDA "may revise the tobacco product standards in paragraph (1)," *i.e.*, the flavor ban. 21 U.S.C. §387g(a)(2). Additionally, the FDA "may adopt tobacco product standards . . . if the [FDA] finds that a tobacco product standard is appropriate for the protection of the public health." 21 U.S.C. § 387g(a)(3)(A). Finally, like the statute in *In re a Community Voice*, the Tobacco Control Act specifically requires the creation of an advisory committee to issue a report and recommendation on "the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." 21 U.S.C. § 387g(e). Taken together, the Tobacco Control Act intends for the FDA to engage in an ongoing process, accounting for new information and periodically evaluating the tobacco product standards – including the flavor ban – to determine if the standard should be changed to reflect new data and protect the public health. *Compare with In re A Community Voice*, 878 F.3d at 784.

Defendants argue that *In re A Community Voice* is distinguishable. (Defs.' Reply at 5.) First, Defendants argue that there was an "ongoing duty" to modify standards in the Paint Hazard Act, while no such ongoing duty exists here. (*Id.*) The Court disagrees that there is no ongoing duty; the Ninth Circuit found an ongoing duty from the provision that "[t]he regulations may be amended from time to time as necessary." *In re A Community Voice*, 878 F.3d at 784. Here, the Tobacco Control Act likewise states that the FDA "may revise" the flavor ban and "may adopt tobacco product standards" if that "standard is appropriate for the protection of the public health." 21 U.S.C. §§ 387(g)(a)(2), (3)(A). While the Tobacco Control Act uses permissive language, such language was interpreted as being mandatory in *In re A Community Voice. See also Earth Island Inst.*, 2020 WL 2850285, at *4-5.

Second, Defendants argue that in *In re A Community Voice*, the EPA had granted a petition to issue the sought-after rule. (Defs.' Reply at 5.) While true, the Ninth Circuit found that the

petition was a *separate* basis for finding a clear duty to act. *See In re A Community Voice*, 878 F.3d at 784-85 (finding that "even if we could conclude the EPA had no duty to act under the . . . Paint Hazard Act," the EPA still had a duty to act by granting the 2009 petition).

Finally, Defendants contend that the Paint Hazard Act made clear that the EPA must eliminate lead-based paint hazards, whereas the Tobacco Control Act does not require the banning of menthol cigarettes. (Defs.' Reply at 5-6.) Again, while this is true, the Tobacco Control Act does require the FDA to consider whether to consider whether standards should be changed. Such standards specifically include the flavor ban, and would encompass whether menthol should be added to that ban. In so finding, the Court does not suggest that the FDA must ban menthol cigarettes. Rather, at issue is whether the FDA must make a decision on modifying the flavor ban, particularly in light of the advisory committee's findings and the FDA's own investigations.

Defendants also argue that the Tobacco Control Act imposes no statutory deadline, and therefore the FDA "cannot be compelled to take such action now." (Defs.' Mot. to Dismiss at 14.) As Plaintiffs point out, however, the Ninth Circuit has found that "even though agency action may be subject to no explicit time limit, a court may compel an agency to act within a reasonable time" under the APA. *Houseton v. Nimmo*, 670 F.2d 1375, 1377 (9th Cir. 1982). Additionally, to the extent Defendants suggest that the FDA has satisfied § 387g(a)(5) by undertaking evaluations of menthol cigarettes, this is insufficient as the statute also states that the FDA must determine whether the standards should be changed. (*See* Defs.' Mot. at 15; Defs.' Reply at 3.) Defendants do not suggest that such a determination has been made, only that the evaluation has occurred. Again, this does not necessarily require that the FDA modify the flavor ban, but a determination of whether the flavor ban should be modified is required by the statute.

At the hearing, Defendants argued that they are entitled to make "tentative decisions" indefinitely, none of which would be reviewable. This argument appears to go to the merits, not subject matter jurisdiction. Moreover, to the extent Defendants are essentially suggesting that they are permitted to not make a final decision indefinitely, this could constitute a failure to act in a reasonable amount of time.

Accordingly, the Court DENIES Defendants' motion to dismiss this claim.

B. Section 706(2) Claim

Defendants also argue that Plaintiffs' third claim based on an arbitrary and capricious agency action must be dismissed because the "FDA has not decided not to ban menthol." (Defs.' Mot. to Dismiss at 18.) Thus, "[b]ecause there is no final agency action for this Court to review, Count III must be dismissed." (*Id.*)

The Court agrees. Plaintiffs argue that the Court should not accept Defendants' statement that the FDA has not made a final decision to regulate menthol cigarettes, but instead "allow [P]laintiffs to test those assertions through discovery." (Pls.' Opp'n at 24.) Plaintiffs, however, have the burden of demonstrating that subject matter jurisdiction exists, which includes demonstrating that the FDA has, in fact, made a decision not to add menthol to the flavor ban list. *See Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d at 1122. Furthermore, this claim was pled "*in the alternative* to Counts I and II, . . . and in response to any argument by defendants that they have made a permissible decision not to ban menthol." (FAC ¶ 152.) As Count I is proceeding and dependent on Defendants *not* having made a decision regarding menthol cigarettes, and Defendants have disclaimed any decision not to ban menthol, there is no agency action for the Court to find is arbitrary and capricious. (*See* Defs.' Mot. at 19; Defs.' Reply at 14.)

Plaintiffs also argue that the Court should find a final agency decision because "tobacco companies have argued that local jurisdictions are pre-empted from regulating in this space because the FDA's lack of action on menthol reflects a federal decision." (Pls.' Opp'n at 23.) As Defendants correctly observe, "the self-serving statements of tobacco companies in unrelated litigation" have no bearing on whether the FDA has, in fact, decided not to regulate menthol cigarettes. (Defs.' Reply at 15.)

Accordingly, the Court GRANTS Defendants' motion to dismiss this claim. In the event the FDA does make a final decision not to regulate menthol cigarettes, Plaintiffs can bring their claim then.

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IV. CONCLUSION

For the reasons stated above, the Court DENIES Defendants' motion to dismiss as to the first claim, and GRANTS Defendants' motion to dismiss as to the third claim.

IT IS SO ORDERED.

Dated: November 12, 2020

KANDIS A. WESTMORE
United States Magistrate Judge