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 HOLDING DEFENDANTS' SECOND MOTION TO DISMISS IN ABEYANCE

Re: Dkt. No. 53

On June 9, 2021, Defendants filed the instant motion to dismiss the case as moot. (Defs.' Mot. to Dismiss, Dkt. No. 53.) Specifically, on April 12, 2013, Plaintiffs submitted a citizen petition to the Food and Drug Administration ("FDA"), requesting that the FDA add menthol to the Tobacco Control Act's flavor ban. (*See* Second Amended Compl. ("SAC") ¶¶ 28, 111.) On April 29, 2021 -- after the filing of this litigation -- the FDA granted the citizen petition. (SAC ¶ 28.) That same day, the FDA stated its intent to publish a notice of proposed rulemaking within a year. Press Release, FDA, FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers (Apr. 29, 2021) (available at https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers); *see also* Defs.' Mot. to Dismiss at 6. Thus, Defendants contend that the grant of Plaintiffs' citizen petition moots the case. (Defs.' Mot. to Dismiss at 2.)

Plaintiffs, in turn, assert that the FDA's response was insufficient because it was not accompanied by formal rulemaking action to implement a menthol ban, *i.e.*, a notice of

rulemaking. (SAC ¶¶ 143-44.) Plaintiffs have essentially alleged that: (1) the FDA has not actually made a determination on the citizen petition due to its failure to "concurrently take appropriate action implementing the approval," specifically a notice of rulemaking, and (2) to the extent the FDA's response is deemed adequate by the Court, there has been undue delay because the notice of rulemaking has not been issued. (SAC ¶¶ 161, 168-69; *see also* Pls.' Opp'n at 9-10, Dkt. No. 58.) Thus, Plaintiffs assert that the case is not moot because they seek a judicial order requiring Defendants to, for example, issue a Notice of Rulemaking within 60 days. (Pls.' Opp'n at 10; *see also* SAC at 46.)

The Court has reviewed the parties' briefing extensively, as well as the relevant legal authority. Having done so, the Court believes the most efficient use of judicial resources will be to hold Defendants' motion to dismiss in abeyance until May 2022, after the FDA expects to issue the Notice of Rulemaking.

To Plaintiffs' first argument that the FDA has not made a determination, the Court does not agree that there is a statutory requirement that the FDA issue a notice of rulemaking in order to make a determination on Plaintiffs' citizen petition. Plaintiffs rely on 21 U.S.C. § 387g(a)(3)(b)(ii), which states: "In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate" to reduce or eliminate a tobacco product component, any party objecting to the proposed standard may provide scientific evidence for the Secretary's consideration. (Pls.' Opp'n at 22.) Plaintiffs suggest that this is a definition for "determination," and that this definition requires that the proposed standard be in a proposed rule. (*Id.*) This, however, is not a logical reading of the statute. Rather, this statute is talking about a specific circumstance, *i.e.*, when a determination is set forth in a proposed rule. It does not itself require that the determination always be in a proposed rule. The Secretary could make a determination that is not in a proposed rule, such as a determination not to regulate a tobacco product component.

In the alternative, Plaintiff points to 21 C.F.R. § 10.30(e)(2)(i), which states that when the Commission approves a petition, "the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval." The plain

language does not require a Notice of Rulemaking; a Notice of Rulemaking is simply an example of an appropriate action. *See Dibble v. Fenimore*, 545 F.3d 208, 219 (2d Cir. 2008) (explaining that "e.g." denotes an example, in contrast to "i.e." which "when used properly, would indicate an exhaustive list"); *Sealant Sys. Int'l, Inc. v. Tek Global S.R.L.*, Case No. 11-cv-774-PSG, Case No. 11-cv-1649-PSG, 2012 U.S. Dist. LEXIS 123313, at *30-31 (N.D. Cal. Aug. 29, 2012) ("The plain language of the specification demonstrates this by referring to the 'lever-operated,' fast-fit coupling as an example only (using 'e.g.' and not 'i.e.')").

Thus, the primary issue is whether Defendants have engaged in undue delay in promulgating the Notice of Rulemaking. (*See* Pls.' Opp'n at 24-25.) The FDA has stated that it intends to issue a notice of rulemaking by April 2022, or in approximately five months. If the FDA does not issue the Notice of Rulemaking, the Court may find that the delay is unreasonable under the factors set forth in *Telecommunications Research and Action Center v. FCC* ("TRAC") for determining unreasonable delay.

The Court finds *In re a Community Voice* most instructive. There, the Environmental Protection Agency ("EPA") was tasked by statute to identify lead-based paint hazards that would result in adverse human health effects. 878 F.3d 779, 784 (9th Cir. 2017). As early as 2007, the EPA was aware of the health risks of lead-based paint, but did not act. Thus, in 2009, the plaintiffs filed a petition for a rulemaking, which the EPA granted that same year. *Id.* at 783. After the EPA did not issue a rule, the plaintiffs filed suit in 2016. *Id.* The Ninth Circuit determined that, under the TRAC factors, there was unreasonable delay based on the eight years that had passed since the petition was granted. In so finding, the Ninth Circuit observed: "This is not a case like *Independence Mining* or *California Power Exchange* where the delay has been only months or a few years. Further, . . . unlike *Independence Mining* or *California Power Exchange*, there is a clear threat to human welfare . . . ." 878 F.3d at 787; *see also id.* ("a 14-month time period without more is not unreasonable").

Thus, *In re a Community Voice* recognizes that delays of months or a few years is generally not an unreasonable delay unless there is something more, *e.g.*, a threat to human welfare. Such a threat could be found here, based on the significant threat to human health posed

by menthol cigarettes. Should the FDA not issue a notice of rulemaking in the year since granting Plaintiff's citizen petition, a delay of more than one year could very well be unreasonable (particularly as that delay continues). Further, as Plaintiffs observe, other TRAC factors could support a finding of undue delay, as the FDA has described a final rule banning menthol as "'one of the Agency's highest priorities.'" (Pls.' Supp. Br. at 10 (quoting Defs.' Mot. to Dismiss at 6).)

In short, whether the FDA issues the Notice of Rulemaking as currently planned is potentially determinative to the Court's disposition of the pending motion to dismiss. The Court therefore finds it prudent to hold the motion in abeyance in order to give the FDA an opportunity to issue the Notice of Rulemaking on its stated schedule. Accordingly, the Court CONTINUES the hearing on Defendants' motion to dismiss to **June 2, 2022**. The parties shall file a joint status report by **May 2, 2022**, explaining whether the Notice of Rulemaking has been issued and, if so, how the Notice of Rulemaking affects the parties' positions on the pending motion to dismiss. The joint status report shall be no more than **four pages**. If the parties believe supplemental briefing is required, the parties shall propose a schedule that permits the Court at least two weeks between the end of briefing and the hearing date.

IT IS SO ORDERED.

Dated: November 17, 2021

KANDIS A. WESTMORE
United States Magistrate Judge

United States District Court
Northern District of California