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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

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

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

13 To Plaintiffs’ first argument that the FDA has not made a determination, the Court does
14 not agree that there is a statutory requirement that the FDA issue a notice of rulemaking in order to
15 make a determination on Plaintiffs’ citizen petition. Plaintiffs rely on 21 U.S.C. §
16 387g(a)(3)(b)(ii), which states: “In the event that the Secretary makes a determination, set forth in
17 a proposed tobacco product standard in a proposed rule, that it is appropriate” to reduce or
18 eliminate a tobacco product component, any party objecting to the proposed standard may provide
19 scientific evidence for the Secretary’s consideration. (Pls.’ Opp’n at 22.) Plaintiffs suggest that
20 this is a definition for “determination,” and that this definition requires that the proposed standard
21 be in a proposed rule. (*Id.*) This, however, is not a logical reading of the statute. Rather, this
22 statute is talking about a specific circumstance, *i.e.*, when a determination is set forth in a proposed
23 rule. It does not itself require that the determination always be in a proposed rule. The Secretary
24 could make a determination that is not in a proposed rule, such as a determination not to regulate a
25 tobacco product component.

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

1 language does not require a Notice of Rulemaking; a Notice of Rulemaking is simply an example
2 of an appropriate action. *See Dibble v. Fenimore*, 545 F.3d 208, 219 (2d Cir. 2008) (explaining
3 that “e.g.” denotes an example, in contrast to “i.e.” which “when used properly, would indicate an
4 exhaustive list”); *Sealant Sys. Int’l, Inc. v. Tek Global S.R.L.*, Case No. 11-cv-774-PSG, Case No.
5 11-cv-1649-PSG, 2012 U.S. Dist. LEXIS 123313, at *30-31 (N.D. Cal. Aug. 29, 2012) (“The
6 plain language of the specification demonstrates this by referring to the ‘lever-operated,’ fast-fit
7 coupling as an example only (using ‘e.g.’ and not ‘i.e.’”).

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

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

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

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

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

16 IT IS SO ORDERED.

17 Dated: November 17, 2021

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19 KANDIS A. WESTMORE
20 United States Magistrate Judge
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