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UNITED STATES DISTRICT COURT FOR THE

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, v. 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 Food and Drugs; CENTER FOR TOBACCO PRODUCTS; MITCH ZELLER in his official capacity as the Director, Center for Tobacco Products. Defendants.	Case No. 4:20-cv-4012-KAW **DEFENDANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF THEIR SECOND MOTION TO DISMISS (Dkt. 53)**

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INTRODUCTION

On September 7, 2021, the Court ordered supplemental briefing on "whether there has been undue delay in issuing a notice of rulemaking." Order, Dkt. 63 at 2. There has been no such delay. On April 29, 2021, the United States Food and Drug Administration (FDA) made a determination under 21 U.S.C. § 387g(a)(5) that the cigarette flavor ban, 21 U.S.C. § 387g(a)(1)(A), should be changed to include menthol, and provided a final response to Plaintiffs' citizen petition stating that the agency would issue a proposed rule. Prior to those actions, nothing required FDA to issue a notice of proposed rulemaking (NPRM). Accordingly, no delay could accrue before those actions occurred.

Since the determination and citizen petition approval, FDA has not delayed, much less *unreasonably* delayed, the issuance of an NPRM. The agency continues to adhere to its original twelve-month timetable for the NPRM, and any claims of future delay are not ripe. Defendants also easily prevail in an analysis under *Telecommunications Research and Action Center v. FCC* (*TRAC*), 750 F.2d 70, 80 (D.C. Cir. 1984). Judicial intervention in agency rulemaking is an extraordinary remedy, reserved only for the rare circumstance when an agency's delay is egregious and the agency is not making meaningful progress on its own. In undertaking a *TRAC* analysis, courts do not consider agency action prior to the agency's duty to act. Instead, courts focus on the time that has elapsed since the agency came under a duty to act and whether that amount of time is reasonable. Here, less than six months have passed since FDA approved the citizen petition and announced its plan to engage in rulemaking; and FDA plans to issue the NPRM six months from now. Plaintiffs have thus failed to state a claim for such extraordinary relief and the motion to dismiss should be granted.

ARGUMENT

I. FDA Was Not Required to Prepare an NPRM Before April 29, 2021.

Plaintiffs are nowhere close to stating an unreasonable delay claim with respect to the NPRM. Before April 29, 2021, FDA could not unreasonably delay the NPRM because the agency had no duty to prepare an NPRM prior to that date, and "an agency cannot unreasonably delay that which it is not required to do." *In re A Community Voice*, 878 F.3d 779, 784 (9th Cir. 2017) (*Community Voice*). Indeed, "the first step before applying the TRAC factors is necessarily to determine when the agency is

under a duty to act." *Id.* (following *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 n.1 (2004)). So "[i]t is to the question of duty we turn first." *Community Voice,* 878 F.3d at 784.

Congress left the regulation of menthol as a characterizing flavor in cigarettes to FDA's discretion, and therefore did not impose a duty to ban menthol, let alone to prepare or issue an NPRM. *See* Order, Dkt. 34 at 4, 8 (interpreting 21 U.S.C. § 301 *et seq.*). Accordingly, any duty could arise only after FDA determined that it should initiate rulemaking. *See* C.P. Resp., Dkt. 50-1 at 14. FDA's determination is a key initiating step in federal rulemaking: all subsequent rulemaking tasks depend on a determination by the agency that it should issue a proposed rule. *See* 2d MTD, Dkt. 53 at 6-7 (explaining the rulemaking process). Although Plaintiffs now strain to argue that a determination may be found in a 2013 advanced notice of proposed rulemaking or a 2018 press announcement, *see* Pls. Supp. Br., Dkt. 65 at 3, they previously asserted the exact opposite, telling the Court that "[w]e have not seen any sort of determination…." 11/5/20 Hearing Tr., Dkt. 36, at 9:9-10. And, in fact, the Court denied, in part, Defendants' first motion to dismiss, specifically because FDA had not made a determination. *See* Order, Dkt. 34 at 9 (allowing Count I to proceed because it was "dependent on Defendants *not* having made a decision regarding menthol cigarettes." (emphasis original)).

Plaintiffs also attempt to find a pre-determination requirement by arguing that FDA was "obligated to act on [] evidence" and "should have been working on a notice of proposed rulemaking long before now." Pls. Supp. Br., Dkt. 65 at 2; Pls. Opp., Dkt. 58 at 10. But before FDA's determination, there was no legal obligation to begin the resource-intensive process of rulemaking. *See* Order, Dkt. 34 at 4, 8. Indeed, Plaintiffs' attempts to "cobble together a legal requirement from various interim proposals, information-gathering steps, and FDA press statements" already failed on the first motion to dismiss, because they could not identify "a specific, unequivocal command" that arose from such actions. *See* 1st MTD, Dkt. 26 at 12, 16-18, (explaining why prior actions created no duty); Order, Dkt. 34 at 4-8 (discussing FDA's specific duties under § 387g). Before April 29, 2021, FDA's only outstanding duty with respect to menthol was to make a determination whether the flavor ban should be changed. *See* Order, Dkt. 34 at 4, 8. In fact, on April 29, 2021, FDA had the discretion to determine that the flavor ban should *not* be changed to include menthol and to *deny* Plaintiffs' citizen petition. *See* 21

U.S.C. § 387g(a)(5) (requiring periodic evaluation to determine "whether" a standard should be changed); 21 C.F.R. § 10.30(e)(2)(ii) (denial of citizen petitions). Thus, FDA was under no duty to engage in rulemaking before it decided to do so on April 29, 2021.

II. The NPRM Is Not Delayed.

Since April 29, 2021, FDA has not delayed the NPRM. The Tobacco Control Act does not set a timetable for modifying tobacco product standards. *See* 21 U.S.C. § 387g(c) ("Proposed Standards"). Based on the agency's assessment of the efforts and coordination required, FDA determined that twelve months were adequate to prepare the rule on a prioritized basis. *See* 2d MTD, Dkt. 53 at 6. On that timetable, the NPRM is not due for publication in the Federal Register until April 2022. There is still every indication that the NPRM will be published consistent with the agency's plan. Plaintiffs deny that FDA should have "a schedule of its own choosing," *see* Pls. Opp., Dkt. 58 at 2-3, but the Tobacco Control Act left the timetable for preparing an NRPM to FDA's discretion, *see* 21 U.S.C. § 387g(c).

Without any current delay on the NPRM, Plaintiffs suggest that FDA will engage in future delay if the Court does not intervene, *see e.g.*, Pls. Supp. Br., Dkt. 65 at 5, 12 (predicting "endless delay"), but any claim based on alleged future delay is speculative and not ripe. *Action on Smoking & Health v. Dept. of Labor*, 28 F.3d 162, 165 (D.C. Cir. 1994). And, in any event, it would still be *years* before courts would typically consider granting the "extraordinary" relief of intervening in a complex, public-health rulemaking that Congress entrusted to FDA. *See In re Cal Power Exchange Corp.*, 245 F.3d 1110, 1125 (9th Cir. 2001) ("The cases in which courts have afforded relief involved delays of years, not months."). Intervention in agency rulemaking is granted only after "egregious" delays. *Id*. And, even after years-long delays, the Ninth Circuit hesitates to intervene as long as the agency is still making progress. *See Cent. Sierra Env't Res. Ctr. v. Stanislaus Nat'l Forest*, 304 F. Supp. 3d 916, 951 (E.D. Cal. 2018) (discussing the Ninth Circuit's reluctance to impose deadlines in agency rulemaking while the agency is making progress on its own).

Indeed, courts generally are "loath" to intervene in agency rulemaking, and "should avoid if possible any direct judicial meddling with the details of [an agency's] rulemaking schedule." *See Public Citizen Health Research Group v Brock*, 823 F.2d 626, 629 (D.C. Cir. 1987) (per curiam) (holding that

even if a court is "disappointed with [the agency's] target date," that does not make the action "impermissibly slow."). This reluctance to intervene is because "the agency is in a unique—and authoritative—position to view its projects as a whole, evaluate the prospects for each, and allocate its resources in the optimal way." *In re Barr Labs. Inc*., 930 F.2d 72, 76 (D.C. Cir. 1991); *accord Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985) (finding FDA "far better equipped than the court to deal with the many variables involved in the proper ordering of its' priorities."). Courts also are reluctant because the public interest is best served by allowing agencies the time they need to carefully and thoroughly construct regulations. *See United Steelworkers of Am. AFL-CIO-CLC v. Rubber Mfrs. Ass'n,* 783 F.2d 1117, 1120 (D.C. Cir. 1986) (per curiam). After all, it is the agency's responsibility to ensure any final rule will pass judicial scrutiny. *Id.*

Here, the Tobacco Control Act's stated purpose is to give FDA authority to regulate tobacco products based on the agency's unique expertise. Pub. L. 111-31, 2(44)-2(45), *codified at* 21 U.S.C. § 387. Allowing FDA to use that expertise on its own timetable satisfies Congress's intent and best serves the public's interest in carefully and thoroughly constructed regulations.

III. Defendants Easily Prevail on a *TRAC* Analysis Regarding the Issuance of an NPRM.

Defendants easily prevail on the six *TRAC* factors because the agency is progressing on its original timetable for the rulemaking and any duty to issue an NPRM arose less than six months ago. *See TRAC*, 750 F.2d at 80 (providing six factors to identify "delays so egregious as to warrant mandamus"). Plaintiffs argue that the court should defer this decision because "grounds for agency delay will often be unknown to plaintiffs at the pleading stage," Pls. Supp. Br., Dkt. 65 at 4, n.1 (citation omitted), but that argument assumes that Plaintiffs sufficiently pleaded a delay in the first place, which they have not. The parties should not incur the time and expense of summary judgment briefing when Plaintiffs cannot identify any delay that would be sufficient to state a claim. *See* 2d MTD, Dkt. 53 at 19, *citing In re Cal Power Exchange*, 245 F.3d at 1125 (actionable delays are measured in years).

A. A *TRAC* Analysis Does Not Consider Agency Action Prior to a Duty to Act.

The Court instructed the parties to identify cases "in which a court considered or declined to 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." Order, Dkt. 63 at 2. As the case law shows, courts generally do not consider an agency's actions prior to the time that a duty arose because the APA focuses on the performance of the agency's *present* duty. *See United Steelworkers*, 783 F.2d at 1120 (holding that the court did "not… have occasion to decide" whether past delay was unreasonable); *Community Voice,* 878 F.3d at 784 (addressing duty as the first question in "unreasonable delay"). Instead, courts calculate delay by examining "the length of time that has elapsed *since the agency came under a duty to act*." *In re Intn'l Chem. Workers Union,* 958 F.2d 1144, 1150 (D.C. Cir. 1992) (emphasis added, citations omitted). Thus, under *TRAC*, an agency is not penalized for its actions (or inaction) prior to the time that a duty arose, and the agency is not suddenly liable for unreasonable delay—and potentially subject to a judicially-imposed schedule—the moment it decides to grant a petition for discretionary rulemaking. *See Community Voice*, 878 F.3d at 784.

The Ninth Circuit's holding in *Community Voice* is instructive. The Ninth Circuit held that the Environmental Protection Agency (EPA) had a statutory duty to modify lead-based paint hazard standards and noted that the agency did not dispute that, as early as 2001, evidence showed that the EPA's standard was insufficient. 878 F.3d at 782-84. Yet, the Ninth Circuit did not calculate delay on lead hazard standards from 2001, but instead calculated delay from 2009—the year that the EPA granted a rulemaking petition to set new standards and came "under a clear duty to act." *Id.* at 785, 787 (deciding that, in 2017, "EPA's delay… [was] into its eighth year," *i.e.* measuring from 2009 to 2017). Thus, contrary to the amici's argument, the Ninth Circuit did not count delay from the "many years after recognizing and documenting a serious health hazard," but instead counted delay from the date the agency came under a clear duty to act. *Compare id. with* Amici Br., Dkt. 66-2 at 15.[1] Here, by contrast, FDA granted the petition *less than six months ago*, and has provided a concrete twelve-month timetable to issue the NPRM. *See* C.P. Resp., Dkt. 50-1. For a period of time as long as that in *Community Voice*,

[1] On October 4, 2021, the Court granted, in part, the "Medical and Public Health Groups'" motion for leave to file an amici curiae brief. *See* Order, Dkt. 69.. The Court ruled that the proposed amici curiae brief would be considered for the TRAC analysis only. *See* Order, Dkt. 69. The TRAC argument appears in the amici curiae brief from page 15, line 25 to page 17, line 25, *see* Dkt. 66-2.

Plaintiffs would need to bring their lawsuit in 2029. *See Community Voice*, 878 F.3d at 787 (distinguishing its holding from cases in which only a few months had passed).

Two additional cases are helpful in explaining why courts do not consider periods of alleged delay that predate an agency's duty to act. In *United Steelworkers*, the plaintiffs argued that the court should impose an accelerated rulemaking schedule after the Occupational Health and Safety Administration (OSHA) allegedly delayed an earlier part of the rulemaking. 783 F.2d at 1118-19. A unanimous D.C. Circuit panel rejected that argument, holding that any claim based on prior agency delay was mooted when the agency acted, and the court "did not… have occasion to decide whether the period of [prior] delay… was unreasonable." *Id*. at 1120. Moreover, even if there had been delay in the past, the court "decline[d] the invitation to 'punish'" the agency by imposing a mandatory, accelerated timetable for the rest of the rulemaking because "judicial imposition of an overly hasty timetable… would ill serve the public interest." *Id.* The court instead recognized that the agency needed adequate time to carefully construct the rule and explain its rationale. *Id.* The same is true here. Any unreasonable delay claims based on FDA responding to the citizen petition or making a determination are moot now that the agency has acted: the court has no jurisdiction to consider them. *See* 2d MTD, Dkt. 53 at 9-11. And any delay on those completed actions would not be a reason to impose an expedited schedule now in connection with future agency action. *See* 783 F.2d at 1120. The public interest is best served by giving FDA time to carefully construct the NPRM and explain the agency's rationale.

In *Natural Resources Defense Council v. Fox,* the plaintiffs argued that two decades of slow action by EPA justified judicial intervention and weighed against the EPA in the *TRAC* analysis. *See* 93 F. Supp. 2d 531, 548 (S.D.N.Y. 2000). The court disagreed, explaining that the EPA was presently providing "acceptable oversight" for the regulatory program at issue and that the "APA does not provide plaintiffs with any substantive rights vis-à-vis past agency action (or inaction); it merely gives them a cause of action to seek judicial enforcement of the agency's present duties." *Id*. at 548-49. Similarly, Plaintiffs here do not have a right to seek relief with respect to prior agency action, even if they are frustrated by the amount of time their citizen petition was pending. The APA only allows them to seek enforcement of FDA's present duty with respect to the NPRM if it was delayed, which it is not.

Plaintiffs and amici do not refute or even address these principles. Instead, they identify half a dozen cases, but none provides guidance on whether to consider prior agency action in the *TRAC* analysis. *See* Pls. Supp. Br., Dkt. 65 at 4-6; Amici Br., Dkt. 66-2 at 16-17. Plaintiffs rely heavily on *Public Citizen Health Research Group v. FDA*, 724 F. Supp. 1013, 1020 (D.D.C. 1989), attaching significance to the fact that the Court considered agency action before 1988 when it imposed a rulemaking schedule for tampon warnings. *See* Pls. Supp. Br., Dkt. 65 at 4-5. But Plaintiffs' argument ignores the record in that case and specifically overlooks the citizen petition that FDA granted in 1984. *See id*. (finding it significant that the Court considered "pre-1988 actions"). Indeed, a review of the record shows that the plaintiff filed a rulemaking petition in 1982, and FDA granted it upon reconsideration two years later, agreeing to undertake rulemaking. *See Medical Devices; Labeling; User Labeling for Menstrual Tampons*, 53 Fed. Reg. 37,250, 37,253 (Sept. 23, 1988) (describing the citizen petition history). In examining the length of delay, the court noted that FDA had "first learned" of the health risk earlier, but it focused on the length of time that had elapsed since 1984 because that was when "FDA took on the duty to promulgate [a regulation] in a reasonable [period of] time." 724 F. Supp. at 1019-20. Thus, *Public Citizen* actually supports Defendants' position that any alleged delay on the NPRM should be measured from the date of FDA's citizen petition response and determination. *See also Community Voice*, 878 F.3d at 787 (doing the same).

Plaintiffs and amici also rely on two Ninth Circuit decisions that are inapposite because they involve circumstances where the agency had not yet provided a final response to a rulemaking petition. *See* Pls. Supp. Br., Dkt 65 at 6*, citing In re Natural Resources Defense Council*, 956 F.3d 1134 (9th Cir. 2020); Amici Br., Dkt. 66-2, at 16-17, *citing In re Pesticide Action Network v. EPA,* 798 F.3d 809 (9th Cir. 2015). In *In re Natural Resources Defense Council*, the EPA failed to provide a final response to a rulemaking petition for more than ten years. 956 F.3d at 1136. At one point, the EPA denied the petition, but when the same plaintiffs challenged the denial, the agency received a voluntary remand. *Id.* at 1137. As a result of the remand, there was no longer a final response to the petition, and the EPA repeatedly missed its own deadlines to provide one. *Id*. Similarly, in *In re Pesticide Action Network*, petitioners had been waiting eight years for a response to their petition, and still did not have one. *See* 798 F.3d at 811-

13. The EPA had repeatedly missed its own deadlines for a promised response and did not have a concrete timetable. *Id.* Rather, the EPA stated that it might issue a proposed rule in a year, or "might not" depending on ongoing settlement discussions with industry. *Id.* at 814. Here, by contrast, FDA has provided a *final,* judicially-reviewable response to Plaintiffs' citizen petition, agreeing that it will publish an NPRM. *See* C.P. Resp, Dkt. 50-1. Thus, FDA has fully satisfied its duty to respond to the citizen petition, and unlike these two cases, there is no failure to respond that could serve as a source of ongoing delay.

Plaintiffs' and amici's reliance on three other cases is equally misplaced. *In re Core Communications Inc*., 531 F.3d 849 (D.C. Cir. 2008), is inapplicable because it involved an agency's persistent failure to respond to a judicial order and did not consider any prior agency action. *See* Pls. Supp. Br., Dkt. 65 at 6. Similarly, *Environmental Defense Fund v. EPA,* 852 F.2d 1316 (D.C. Cir. 1988), is inapplicable because that case did not involve unreasonable delay under 5 U.S.C. § 706(1). *See* Pls. Supp. Br., Dkt. 65 at 6. Rather, the Court remanded certain hazardous waste regulations as arbitrary and capricious and imposed a schedule for EPA to promulgate new regulations. 852 F.2d at 1331. Finally, amici cite a D.C. Circuit case that pre-dates *TRAC*. *See* Amici Br., Dkt. 66-2 at 17, *citing Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983). But that case also did not involve prior agency action, and it considered a specific OSHA statutory provision for emergency action that is not at issue here. 702 F.2d at 1153-4 (disagreeing with OSHA's decision to deny "emergency rulemaking" under 29 U.S.C. § 655(g)). Accordingly, none of these cases provides guidance on considering prior agency action in determining unreasonable delay.

B. The "Rule of Reason" and Lack of a Statutory Timetable Strongly Favor Defendants.

The first two *TRAC* factors strongly favor Defendants. *See* 750 F.2d at 80 (describing the "rule of reason" and the statutory scheme). The first and most important factor is the "rule of reason," which assesses the timeframe that the agency takes to act. *Community Voice*, 878 F.3d at 786. This factor is closely related to the second, which considers any statutory timeline. *Id.* As discussed *supra* in Part II, the Act provides no timetable for preparing an NPRM for a tobacco product standard. *See* 21 U.S.C.

§ 387g(c). Absent a statutory timetable, the agency's control over the pace of rulemaking proceedings is entitled to "considerable deference." *Mexichem Specialty Resins Inc v. EPA,* 787 F.3d 544, 555 (D.C. Cir. 2004), *quoting Sierra Club v. Gorsuch*, 715 F.2d 653, 658 (D.C. Cir. 1983). "Such deference derives from an agency's discretion to set its own priorities, which may reflect a variety of factors outside the focus of a rulemaking." *Gorsuch*, 715 F.2d at 658. Courts are also especially deferential to rulemaking schedules that involve complex scientific questions, because the agency is in the best position to determine the time needed to analyze such questions and reach a considered result. *See Sierra Club v. Thomas,* 828 F.2d 783, 798 (D.C. Cir. 1987) *superseded in part by* Pub. L. 101-549. And, "it is to be expected that consideration of [complex] matters will take longer than might [agency] rulings on more routine items." *In re Monroe Commc'ns Corp*., 840 F.2d 942, 946 (D.C. Cir. 1988).

Twelve months is a reasonable amount of time for an agency to develop an NPRM for a complex public health matter, particularly one where care and consideration is needed given the likelihood of an industry challenge to the rule. *See* C.P. Resp., Dkt. 50-1 at 14 (anticipating "substantial interest" in the NPRM). NPRMs are often lengthy documents that incorporate extensive technical and scientific analysis into the agency's supporting rationale for the proposed rule. *See, e.g., Tobacco Products' Required Warning for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754-42,798 (proposed August 16, 2019) (34 single-spaced pages, explaining the basis for the proposed rule, which relied on 220 references); *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23,142-23,207 (proposed Apr. 25, 2014) (50 single-spaced pages, explaining the basis for the proposed rule, which relied on 194 references). And the process for preparing these documents is time consuming and resource intensive. *See* 2d MTD, Dkt. 53 at 6-8 (describing the formal rulemaking steps before publishing an NPRM and providing a diagram that shows "approve rulemaking" as step two of ten).

Of course, Plaintiffs and amici would prefer to jump ahead from the decision to undertake rulemaking directly to the issuance of an NPRM (step six of ten, *id*.), or even a final rule (step ten of ten, *id.*). *See e.g.,* Pls. Supp. Br., Dkt 65 at 1 (arguing for a menthol ban). But notice-and-comment

rulemaking is an incremental process in which agencies progress in defined steps. 2d MTD, Dkt. 53 at 6-7; *see also FCC v. Fox Television Station,* 556 U.S. 502, 522 (2009) ("Nothing prohibits federal agencies from moving in an incremental manner."). Indeed, "the [Administrative Procedure Act (APA)] is patient" and "[a]gencies need not address all regulatory obligations in one fell swoop." *Environmental Defense Fund v. EPA*, 922 F.3d 446, 457 (D.C. Cir. 2019) (quotation omitted).

Plaintiffs and amici have cited no authority for the proposition that twelve months for NPRM preparation is unreasonable. The case law generally does not support that conclusion. *See Community Voice*, 878 F.3d at 787 (agreeing that "a '14-month time period' without more is not unreasonable," and citing *Steelworkers*, 783 F.2d at 1120). Moreover, their desire to rush the NPRM is short-sighted. "[A]dditional time spent reviewing a rulemaking proposal before it is adopted may well ensure earlier, not later, implementation of any eventual regulatory scheme." *Thomas*, 828 F.2d at 798-99 (noting that time spent on the rulemaking proposal "decrease[s] the risk of later invalidation and remand to the agency"). By taking sufficient time to carefully draft and review the NRPM, FDA may shorten the overall time needed for the rulemaking on menthol flavoring because the agency can resolve now any issues that could potentially result in litigation. *See In re United Mine Workers of Am. Intn'l Union*, 190 F.3d 545, 555 (D.C. Cir. 1999) (holding that time spent modifying an NPRM to include more supporting data "may well shorten the overall period of delay by resolving issues that would otherwise be subject to litigation").

C. The Remaining Four *TRAC* Factors Also Favor Defendants.

The remaining four *TRAC* factors also favor Defendants. *See* 750 F.2d at 80 (listing the remaining factors). The third factor, public health and welfare, does not determine the outcome, because the vast majority of the agency's workload involves the public health, and the agency regularly balances competing public health crises. *See In re Pesticide Action Network N. Am.,* 532 Fed. App'x 649, 651 (9th Cir. 2013) (unpublished) (finding this factor not determinative because the EPA "by its nature, regulates almost entirely in the realm of human health and welfare"); *accord Thomas*, 828 F.2d at 798 (holding that this *TRAC* factor "can hardly be considered dispositive" when "accelerating [a] particular [public health] rulemaking… may come at the expense of delay of [another public health] action

elsewhere"). Likewise, the fourth *TRAC* factor, competing agency priorities, has no weight at this time because the NPRM is currently "one of the Agency's highest priorities," and there is no evidence that a competing priority is drawing resources away from this rulemaking. *See* C.P. Resp., Dkt. 50-1 at 14. On the fifth *TRAC* factor, other interests prejudiced by the delay, Plaintiffs and amici have identified smoking-related public health harms. *See* Pls. Supp. Br., Dkt. 65 at 9-10; Amici Br., Dkt. 62-2 at 3-14. But their haste to publish an NPRM is at odds with the public's interest in carefully and thoroughly-constructed regulations that effectively protect the public health. Indeed, Plaintiffs' and amici's efforts would be self-defeating if they rushed FDA to issue a rule that could not withstand judicial scrutiny. *See United Steelworkers*, 783 F.2d at 1120 (noting that the public interest is not well served by "an overly hasty timetable," even for serious public health issues); *United Mine Workers*, 190 F.3d at 555 (noting that time spent on an NPRM can shorten the overall rulemaking). Sixth, and finally, there is no evidence of "impropriety" to refute the "well-established presumption that public officials… act in good faith and are conscientiously proper in the discharge of their duties." *Beyond Pesticides/Nat'l Coalition against the Misuse of Pesticides v. Johnson*, 407 F. Supp. 2d 38, 41 (D.D.C. 2005) (internal citations omitted); *accord Am. Cargo Transport Inc. v. United States,* 625 F.3d 1176, 1180 (9th Cir. 2010) ("[W]e presume the government is acting in good faith.").

D. Plaintiffs' Final Cases Have No Place in a *TRAC* Analysis.

At the conclusion of their brief, Plaintiffs include two cases regarding other tobacco product initiatives. But a *TRAC* analysis is focused on the particular facts and circumstances of the agency action at issue, and allegations of delay in connection with different initiatives stemming from other provisions of the Tobacco Control Act are not useful here. *See Mashpee Wampanoag Tribal Council Inc. v. Norton,* 336 F.3d 1094, 1100 (D.C. Cir. 2003) ("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."). Moreover, although Plaintiffs discuss these cases under a heading about "impropriety," Pls. Supp. Br., Dkt. 65 at 11-12, neither case found impropriety by FDA. In one case, "[p]laintiffs concede[d] that there was no impropriety on the part of the agency." *Am. Acad. of Pediatrics v. FDA*, 330 F.Supp. 3d 657, 667 (D. Mass. 2018). And the other case did not even consider unreasonable delay,

much less impropriety. Despite Plaintiffs' assertion that the court concluded that FDA had "unreasonably delayed acting and imposed deadlines on FDA's review… ", *see* Pls. Supp. Br., Dkt. 65 at 12 (characterizing *Am. Acad. of Pediatrics v. FDA*. 399 F. Supp. 3d 479, 487 (D. Md. 2019)), the plaintiffs in that case did not allege unreasonable delay claims. *See Compl. for Decl. & Injunc. Relief*, 2018 WL 1516735, No. 8:18-cv-883 (*filed in* D. Md., March 27, 2018). Rather, the plaintiffs alleged that FDA abused its discretion when it deferred deadlines for e-cigarette companies to submit premarket review applications. *Id.* The court considered "both the FDA's laudable efforts to guide the premarket approval process and the Industry's lack of effort to obtain approval without an imminent deadline" before imposing FDA's suggested schedule for the industry. 399 F. Supp. 3d at 481.

CONCLUSION

The NRPM on menthol as a characterizing-flavor in cigarettes is not delayed. FDA determined that it would engage in discretionary rulemaking, and announced its intent to issue the NPRM only six months ago. Since then, the agency has continued to progress on its established timetable. Defendants easily prevail on a *TRAC* analysis regarding the issuance of the NPRM—an analysis that does not consider allegations of past delay arising before a duty to act, and instead focuses on providing enough time for the agency to carefully and thoroughly consider the proposed rule. The Court should grant Defendants' second motion to dismiss.

Dated: October 5, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on October 5, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Christopher K. Leung: chris@pollockcohen.com

Timothy David Byron: tbyron@byronrapheal.com

There are no manual recipients. I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: October 5, 2021

/s/ Sarah Williams
SARAH WILLIAMS