UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, MASSACHUSETTS CHAPTER OF AMERICAN ACADEMY OF PEDIATRICS, INC., AMERICAN CANCER SOCIETY, INC., AMERICAN CANCER SOCIETY ACTION NETWORK, INC., AMERICAN HEART ASSOCIATION, INC., AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, TRUTH INITIATIVE FOUNDATION, D/B/A TRUTH INITIATIVE, DR. TED KREMER, DR. JONATHAN WINICKOFF, and DR. LYNDA YOUNG, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 1:16-cv-11985-IT

MEMORANDUM AND
ORDER GRANTING INJUNCTIVE RELIEF
March 5, 2019

TALWANI, D.J.

Plaintiffs brought this action seeking a declaration that Defendant United States Food and Drug Administration ("FDA") "unlawfully withheld" or "unreasonably delayed" promulgating a final rule mandating color graphic warnings on cigarette packs and in cigarette advertisements as required by the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"), Pub. L. No. 111-31, § 201, 123 Stat. 1776, 1845 (2009), and an order compelling the FDA to expedite a final graphic warnings rule. Complaint [#1]; see also Pls.' Mot. Summ. J.

2 [#27]. On the parties' cross-motions for summary judgment, the court found that the FDA has both "unlawfully withheld" and "unreasonably delayed" agency action, and that pursuant to the Administrative Procedure Act, 5 U.S.C. § 706(1), the court must compel agency action. Mem. & Order, 2, 15 [#50].

The court sought further input from the parties as to the proper time frame for the agency to act. Id. at 15. Having reviewed Defendant's Statement Regarding Proposed Expedited Rulemaking Schedule ("Def. Proposed Schedule") [#53], and Plaintiffs' Response to FDA's Proposed Schedule and Request for Urgent Action ("Pl. Response") [#54] and Renewed Request for Urgent Action [#55], and taking judicial notice of the Agency publicized rule-making activities, the court compels the Agency to act in accordance with the schedule set forth below.

I. Background

The background to this dispute is set forth in detail in the Memorandum and Order [#50], which the court incorporates herein. In brief, Congress directed the FDA that the new graphic warning rule mandated by the Tobacco Control Act was to be promulgated within two years of the statute's enactment, or by June 22, 2011. Tobacco Control Act Pub. L. No. 111-31, 101(b), 123 Stat. 1776, 1845 (2009), § 201, codified in 15 U.S.C. § 1333(d) (2012). The FDA initially met the deadline for promulgation of the rule, but the United States District Court for the District of Columbia enjoined the rule before its effective date, R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 823 F.Supp.2d 36 (D.D.C. 2012), and subsequently granted summary judgment to the tobacco company challenging the rule. R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 845 F.Supp.2d 266 (D.D.C. 2012). On appeal, the United States Court of Appeals for the District Columbia Circuit found that the FDA "failed to present any data – much less the substantial evidence required under the Administrative Procedure Act ('APA') – showing that enacting their

proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates." R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1222 (D.C. Cir. 2012), overruled in part by Am. Meat Inst. v. U.S Dep't of Agric., 760 F. 3d 18, 26 (D.C. Cir. 2014) (en banc). The D.C. Circuit vacated both the rule and the permanent injunction issued by the district court, and remanded to the FDA. Id. On March 15, 2013, the Attorney General reported to Congress that the FDA intended to undertake research to support a new graphic warnings rule. Pls.' App. Ex. 2, 3 [#30-1]. It is the FDA's subsequent action (or lack of action) that prompted this litigation.

Prior to the court's issuance of its Memorandum & Order, the FDA estimated that a final rule mandating color graphic warnings as required by the Tobacco Control Act would be submitted to the Office of the Federal Register in November 2021, First Suppl. Def.'s L.R. 56.1 Statement of Undisputed Material Facts ("Def.'s 1st Suppl.") 2 [#42], a date more than eight and a half years after the Attorney General's March 15, 2013, report to Congress. Plaintiffs argued that the FDA has violated the Administrative Procedures Act by "unlawfully withholding" agency action by failing to promulgate the new graphic warnings, or in the alternative, has "unreasonably delayed" the final rule. Pls.' Mem. in Supp. of Mot. Summ. J. ("Pls.' Mem.") 2 [#28], citing 5 U.S.C. § 706(1).

Under the "unlawfully withheld" analysis, the court concluded that the D.C. Circuit's vacatur and remand back to the agency did not free the FDA from Congressional mandates and allow the FDA to promulgate this rule at whatever pace it chooses. Instead, "[w]hile the vacatur may reset the two-year clock, it does not negate the FDA's continuing obligation to comply with Congress' deadlines." Mem. & Order [#50] at 10. The court also found that in light of the timeline originally set forth by Congress, the FDA's proposed timeline (and work completed thus

far), the human health and welfare at stake, and the lack of competing priorities enumerated in the FDA's brief, the FDA has failed the factors set forth in Telecommunications Research and Action Center, et. al. v. Federal Communications Commission, 750 F.2d 70 (D.C. Cir. 1984) ("TRAC"), that the FDA asked the court to apply. Mem. & Order, 15 [#50].

The court concluded that because the FDA has both "unlawfully withheld" and "unreasonably delayed" agency action, the court must compel agency action pursuant to 5 U.S.C. § 706(1). Id. The court nonetheless provided the FDA a final opportunity to utilize its expertise to offer an expedited schedule that would respond sufficiently to the urgency expressed by the court. Id.

II. The Schedule Going Forward

Despite this court's admonition that Congress's two-year deadline had restarted when the matter was remanded to the agency in 2013, and the court's directive that the FDA propose an expedited schedule, in an October 2018 response, the FDA proposed publication of a final rule in the Federal Register in May 2021, more than two and a half years from the date of the proposal, more than four and a half years after the Plaintiffs brought this litigation, and more than eight years after advising Congress that it was undertaking research to support a new rule. The court rejects FDA's proposed schedule.

(1) The Final Qualitative Study of Nine Graphic Warnings and Analysis shall be completed by April 15, 2019

On September 26, 2018, the FDA published a Federal Register notice pursuant to the Paperwork Reduction Act ("PRA"). Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings, 83 Fed. Reg. 48,624, 68,626 (Sept. 26, 2018). According to the government website, the initial comment period closed on November 26, 2018, the request was submitted to the Office of Management and Budget

Review on December 18, 2018, and a second comment period closed on January 22, 2019. Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Cigarette Warnings, https://www.regulations.gov/document?D=FDA-2018-N-3552-0015. (last visited Mar. 5, 2019). The only comment received was from Plaintiffs here. Id. The court finds no reason for further delay.

As Defendant has previously conceded, the PRA requires OMB to respond to an agency's request within 60 days. [#48], citing 44 U.S.C. § 3507(c)(2), (c)(3). Where OMB has failed to timely respond, the FDA "may request, and OMB shall assign without further delay, an OMB control number . . . ." Id., citing 5 C.F.R. § 1320.10(c). Defendant also has acknowledged that the anticipated data collection will take place over 15 days. Def. Proposed Schedule, 5 [#53]. Defendant has provided no reason why review of that data should take an extensive period of time. Accordingly, Defendant shall take all steps necessary to obtain an OMB control number without further delay, and shall complete the study and analysis by April 15, 2019.

(2) The Proposed Rule Shall Be Submitted for Publication in the Federal Register by August 15, 2019

Defendant proposes a nine months period from completion of the final study to submission of a proposed rule for publication. [#53]. This proposed post-study timeline for drafting and reviewing the rule cannot be squared with the Congressional mandate of a total two year period for promulgation of a rule. Moreover, as Plaintiffs point out, in light of all the work the Agency has already completed, an additional eleven month period for this stage of review is not warranted, and further delays based on OMB review can and must be avoided in light of Congress's directive and this court's order.

(3) The Final Rule Shall Be Submitted for Publication in the Federal Register by March 15, 2020

Defendant proposes a thirteen months period from publication of the proposed rule to publication of the final rule. [#53]. Again, this timeline ignores the Congressional mandate of a total two year period for promulgation of a rule and the tools that are available to speed up OMB review.

Accordingly, for the reasons set forth herein and in the Memorandum and Order [#50], the Plaintiffs' Request for Urgent Action [#54] and Renewed Request for Urgent Action [#55] are ALLOWED. Defendant FDA shall:

1. take all steps necessary to obtain an OMB control number immediately, and complete the final qualitative study of nine graphic warnings and analysis of that study by April 15, 2019;
2. submit the proposed rule mandating color graphic warnings on cigarette packs and in cigarette advertisements as required by Tobacco Control Act for publication in the Federal Register by August 15, 2019; and
3. submit the Final Rule mandating color graphic warnings on cigarette packs and in cigarette advertisements as required by Tobacco Control Act for publication in the Federal Register by March 15, 2020.

IT IS SO ORDERED.

Date: March 5, 2019

/s/ Indira Talwani
United States District Judge